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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.250-2021

Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

医用电气设备 第2-50部分：婴儿光治疗设备的基本安全和基本性能专用要求

Issued on: March 9, 2021 **Implemented on: May 1, 2023**

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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 C40.

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;

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---Part 2: Special requirements. This part is part 2-50. This section was drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0669-2008 "Medical Electrical Equipment Part 2: Special Requirements for the Safety of Infant Phototherapy Equipment", and Compared with YY 0669-2008, the main technical changes except for editorial changes are as follows.

--- Added the term and definition "baby" (see.201.3.202);

--- Deleted the term and definition of irradiance parameter" (see 2.12.101 of YY 0669-2008);

--- Deleted the term and definition "uniformity of total bilirubin irradiance" (see 2.12.103 of YY 0669-2008);

---Modified the "measurement location" (see.201.5.4.102, 4.6.102 of YY 0669-2008);

---Modified the "spatial layout" (see.201.5.4.104, 4.6.104 of YY 0669-2008);

---Modified "Infant light therapy equipment placed under the patient" (see.201.6.3.101, 5.3.101 of YY 0669-2008);

--- Added "Safety Marks for Patient Eye Masks" (see.201.7.2.101);

--- Modified "Warning and Safety Instructions" (see 6.8.2 of.201.7.9.2.2, YY 0669-2008);

--- Added "Accessories, additional equipment, materials used" (see.201.7.9.2.14);

--- Added "Accessory bracket and mounting frame" (see.201.9.8.101);

--- Added "ME equipment power supply/power supply network interruption" (see.201.11.8);

--- Modified "Bilirubin total irradiance after pre-aging" (see.201.12.1.105, 50.104 of YY 0669-2008);

--- Added "weight scale" (see.201.12.1.107);

---Modified the "Immunity Test Level" (see 202.8.9, 36.202 of YY 0669-2008);

---Modified the "UV radiation exposure limit and spectral weighting function" (see Table AA.1, YY 0669-2008 Table AA.1). This part uses the redrafting law to amend and adopt IEC 60601-2-50.2009 A1.2016 "Medical Electrical Equipment Part 2-50. Special requirements for basic safety and basic performance of infant phototherapy equipment. Compared with IEC 60601-2-50.2009 A1.2016, this part has technical differences. The vertical single line (|) of the outer margin position is marked. This part is technically poor with IEC 60601-2-50.2009 A1.2016 The differences and their 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 the "201.2 Normative Reference Documents", and the specific adjustments are as follows. * Replace IEC 60601-1 with GB 9706.1 which is

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modified to adopt international standards; * Replace IEC 60601-1-2 with YY 9706.102 which is modified to adopt international standards;

---Modified the safety mark of the patient's eyewear (see.201.7.2.11) to make the requirements more clear;

--- Modified.201.11.1.2.2 (see Appendix AA), corresponding to.201.11.1.2.2. This section has made the following editorial changes.

---Deleted part of the notes in IEC 60601-2-50.2009 A1.2016. 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 organized by the National Optical and Photonics Standardization Technical Committee Medical Optics and Instrument Sub-Technical Committee (SAC/TC103/SC 1) Centralized. Drafting organizations of this section. Zhejiang Medical Device Inspection and Research Institute, Ningbo Dawei Medical Devices Co., Ltd. The main drafters of this section. Ye Yueshun, Du Kun, Guo Yongbing, Fang Chunzi, Lin Dingyu, Wu Yi. The previous releases of the standards replaced by this part are as follows.

---YY 0669-2008.

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Introduction

This section deals with the safety of infant light therapy equipment. This part is a revision and supplement to GB 9706.1 (hereinafter referred to as the general standard) Charge. The requirements of this section take precedence over the requirements of general standards. The guidelines and basic principles required by this section are contained in Appendix AA. Understanding the reasons for the preparation of these requirements not only helps to apply this standard correctly, but also accelerates the changes due to clinical practice in a timely manner. Or the process of revising the standard as a result of technological development. Nevertheless, this appendix is not an integral part of the requirements of this section. Chapters and articles marked with an asterisk (*) provide explanatory notes in Appendix AA "Guidelines and Basic Principles for Specific Provisions" of this part. Medical Electrical Equipment Part 2-50. Basic safety and safety of infant light therapy equipment Special requirements for basic performance 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 section specifies the safety requirements for infant phototherapy equipment. However, if the manufacturer has indicated in its risk management Compared with the benefits of preparation treatment, the related hazards and risks can be maintained within an acceptable range, and the replacement that meets specific provisions and has the same safety Substitution method will not be regarded as a violation of relevant regulations. This section applies to the basic safety and basic performance of infant light therapy equipment, also known as ME equipment. If a clause or sub-clause is specifically applicable to ME equipment or ME system, the title and content of the clause or sub-clause will be clearly

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stated. Make it clear. If not clearly stated, this clause or sub-clause applies to the relevant ME equipment and ME system. Except for 7.2.13 and 8.4.1 in the general standards, the special requirements of this part do not include ME equipment or ME systems within the scope of this part The inherent hazards of expected physiological functions. Note. See 4.2 in the general standard. This section does not apply to.

--- Devices that provide heat through blankets, pads or mattresses in medical use, see YY 9706.235 for information;

---Infant incubator, see YY 0455 for information;

---Infant transfer incubator, see YY 9706.220 for information;

---Infant radiant warmer, see GB 11243 for information. 201.1.2 Purpose replace. The goal of this part is to formulate special requirements for the basic safety and basic performance of infant phototherapy equipment, so as to reduce such equipment as much as possible. Prepare the safety hazards to patients and operators, and specify tests to confirm compliance with these requirements. 201.1.3 Parallel standards supplement. These applicable parallel standards involved in this section have been listed in Chapter 2 of the General Standard and Chapter 2 of this Part. According to the modification described in 202, YY 9706.102 applies. GB 9706.103 and YY/T 9706.1101) are not applicable. According to the issued For information, all other published parallel standards in the GB 9706.1 series apply. 1) YY/T 9706.110 "Medical Electrical Equipment Part 1-10: General Requirements for Basic Safety and Basic Performance. Parallel Standard. Physiological Closed Loop Controller Development requirements 201.1.4 Specific standards replace.

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1 Scope

YY 9706.250 is the mandatory Chinese standard for infant phototherapy equipment, the blue light units used to treat neonatal jaundice. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the irradiance delivered at the infant's skin and its uniformity across the treated area, the spectral band that actually breaks down bilirubin, the thermal effect on a newborn with limited temperature regulation, and the eye protection. Under-dosing prolongs jaundice towards exchange transfusion and kernicterus; over-heating harms a baby who cannot move away. Phototherapy units run in every Chinese maternity unit. Being a YY standard without the /T suffix, compliance is compulsory. It took effect in May 2023.

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