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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0649-2016

Replacing YY 0649-2008

Electrical potential therapy equipment

电位治疗设备

Issued on: April 25, 2008 **Implemented on: June 1, 2018**

Issued by: National Medical Products Administration

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Foreword

The technical content of this standard is mandatory. This standard is drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces YY 0649-2008 "high potential treatment equipment", compared with YY 0649-2008, in addition to editorial modification of the main skills The changes are as follows: - modified terms and definitions. potential treatment equipment, application sections and overcurrent protection devices (see 3.1,

3.2 and 3.9); - Added terms and definitions. treatment mats, treatment blankets and therapeutic mattresses (see 3.3,

3.4 and 3.5); - increase the stability of the output voltage time (see 4.5.2), the safe range of the electric field space (see 4.8), the safe range of the magnetic field 4.9), treatment mats, treatment blankets and treatment mattress durability (see 4.10), working noise (see 4.11), biocompatibility (see 4.12) and Timer (see 4.13.5) requirements; - modified on the output voltage stability (see 4.5.1), output overcurrent protection (see 4.7), function (see 4.13.3), external marking (4.14.2.2), the instruction manual (see 4.14.2.3), the technical specification (see 4.14.2.4), the continuous leakage current and the patient auxiliary current (See 4.14.2.6), abnormal operation and fault conditions (see 4.14.2.10), components and components (see 4.14.2.11) and electromagnetic and Tolerance (see 4.15) requirements;

--- Added Appendix B. Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. This standard is proposed by the State Food and Drug Administration. This standard by the National Medical Electrical Apparatus Standardization Technical Committee of physical therapy equipment standardization sub-technical committee (SAC/TC10/SC4) Go back. The standard drafting unit. Tianjin Medical Device Quality Supervision and Inspection Center, Shanghai Guanrui Medical Electronics Co., Ltd., Shenzhen City, Elman Medical Electronic Instrument Co., Ltd. The main drafters of this standard. Zhang Haiming, Liu Bo, Gao Shan, Jiang Guoqiang, Jia Yuechao, Zhang Huibing, Qi Liming, Zhang Yun, Qian Xuebo, This standard replaced the previous version of the standard release.

--- YY 0649-2008. Potential treatment equipment

1 Scope

YY 0649 is the mandatory Chinese standard for electrical potential therapy equipment, the devices that place a patient in a high-voltage low-current electric field for therapeutic purposes. They are widely sold in China for home and clinic use, which is precisely why a mandatory standard exists: the field strengths involved are high, the users are unsupervised, and the electrical safety case has to be made regardless of what one believes about the therapeutic claim. This document sets the requirements such equipment has to meet and the test methods that verify them, covering the output voltage and its control, the insulation and leakage current, the treatment timing and the protections against electric shock. It replaces YY 0649-2008 and carries Amendment 1 of 2023.

This standard specifies the terms and definitions of potential therapy equipment, requirements, test methods, inspection rules and signs, labels, instructions, Packaging, transportation and storage. This standard applies to the potential treatment equipment specified in 3.1 (hereinafter referred to as equipment). Combination therapy with potential therapy function, this standard The same applies. This standard does not apply to the following equipment.

--- electrostatic paste;

--- wearable equipment.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the latest edition (including all modifications) applies to this document.

GB/T 191-2008 Packaging and storage icon (ISO 780..1997, MOD)

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety (IEC 60601-1. 1988, IDT)

GB 9706.15-2008 Medical electrical equipment - Part 1-1. General requirements for safety - Side standard. Medical electrical system safety (

IEC 60601-1-1..2000, IDT) Environmental requirements and test methods for medical appliances GB/T 14710-2009

GB/T 16886.1-2011 Biological evaluation of medical devices - Part 1. Evaluation and testing in risk management (

ISO 10993-1..2009, IDT) Medical devices - Symbols for labeling, marking and providing information on medical devices - Part 1. Generic requirements for medical devices YY/T 0466.1-2009 (ISO 15223-1..2007, IDT)

YY 0505-2012 Medical electrical equipment - Part 1-2. General requirements for safety - Parallel standards. Electromagnetic compatibility requirements and tests (

IEC 60601-1-2..2004, IDT)

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 An apparatus for treating an electric field generated by a voltage having an effective value of not more than 30 kV and a frequency not higher than 100 kHz. Including the use of cross Electric field and DC electric field equipment.

3.2 Apply part of appliedpart Components that are in contact with or in contact with the patient during treatment, including topical treatment head, treatment pad, treatment blanket for systemic treatment, treatment mattress, A chair, a foot pedal, and the like, and an output cable that may be in contact with the patient.