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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0994-2015

Magnetic stimulation equipment

磁刺激设备

Issued on: March 2, 2015 **Implemented on: January 1, 2016**

Issued by: National Medical Products Administration

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. The standard safety requirements for full implementation of the GB 9706.1-2007 "Medical Electrical Equipment Part 1. General requirements for safety," the content. Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents. This standard was proposed by the China Food and Drug Administration. This standard by the National Technical Committee of Standardization for medical electrical physical therapy equipment at the Technical Committee (SAC/TC10/SC4) centralized. This standard was drafted. Tianjin, the State Food and Drug Administration Medical Device Quality Supervision and Inspection Center, Chinese Academy of Medical Sciences Biological Institute of Biomedical Engineering. The main drafters of this standard. Wu Chi-wai, Chen Cheng, Jicai Yan, Wei Xu, Value of the Intensity Yin Tao. Magnetic stimulation device

1 Scope

YY/T 0994 covers magnetic stimulation equipment, the devices that induce current in nerve tissue with a rapidly changing magnetic field rather than through electrodes on the skin. Transcranial magnetic stimulation is used in China for depression, for motor pathway assessment and increasingly in rehabilitation, and peripheral magnetic stimulation for pain and muscle activation. This document sets the requirements such equipment has to meet and the test methods that verify them, covering the field the coil produces and its distribution, the pulse characteristics and repetition rate, the coil heating that limits a session, and the safety measures that address the seizure risk of high-frequency stimulation. The standard carries Amendment 1 of 2023. For a manufacturer, this is the product-specific text a Chinese registration is assessed against.

This standard specifies the magnetic stimulation device terms and definitions, requirements, test methods.

3.1 This standard applies to the terms defined in the magnetic stimulation device (hereinafter referred to as the device). This standard does not apply to the following

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devices.

--- Permanent magnet type of equipment;

--- Gyromagnetic class equipment;

--- Hot magnon therapy equipment.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety

GB/T 14710-2009 medical electrical environmental requirements and test methods

GB/T 16886.1-2011 Biological evaluation of medical devices - Part 1. Evaluation of the risk management process and Test

3 Terms and Definitions

GB 9706.1-2007 defined and the following terms and definitions apply to this document.

3.1 High-voltage energy storage capacitor utilizing the magnetic field coil spark device generating a pulse magnetic field cause irritation to the nervous system.

4 Requirements

4.1 Working conditions Unless the manufacturer otherwise specified, shall meet the requirements of Chapter 10 of GB 9706.1-2007.

4.2 magnetic induction Magnetic induction equipment shall meet the following requirements.

a) the maximum magnetic flux density of not less than 1T.

b) magnetic induction devices specified by the manufacturer, tolerance. ± 20%.

4.3 Output frequency The output frequency devices within 0Hz ~ 100Hz range, tolerance. ± 10%.

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