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

YY/T 0951-2015

Interferential current therapy instrument

干扰电治疗设备

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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. This revised standard adopts YY 0607-2007 "Medical electrical equipment - Part 2. nerve and muscle stimulators for the safety requirements" Provisions. The standards for electromagnetic compatibility in accordance with the requirements of YY 0505 "Medical electrical equipment - Part 1-2. General requirements for safety - Collateral standard. EMC requirements and tests "to run concurrently. 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. The main drafters of this standard. Juan Yang, Han desert, Wu Chi-wai, Liu Bo, Li Yanan. Interference therapy equipment

1 Scope

YY/T 0951 covers interferential current therapy equipment, the physiotherapy devices that cross two or more medium-frequency alternating currents inside the body so that a low-frequency modulated current is produced in the tissue itself. The point of the technique is that medium-frequency current passes the skin with far less resistance and discomfort than low-frequency current would, while the beat frequency generated at the crossing point delivers the therapeutic stimulation deep in the tissue. The standard specifies the terms and definitions, classification, requirements, test methods, inspection rules, marking, instructions for use, packaging, transport and storage. Its safety requirements implement GB 9706.1 in full and adopt the nerve and muscle stimulator provisions of YY 0607, with electromagnetic compatibility handled through YY 0505. It is the text a Chinese registration for such a device is assessed against.

This standard specifies the interference current therapy apparatus (hereinafter referred to as the device) terms and definitions, classification, requirements, test methods, inspection rules, marking Chi, instructions, packaging, transport and storage.

3.1 This standard applies to equipment regulations.

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/T 191-2008 Packaging - Pictorial signs

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 Biological evaluation of medical devices - Part 1. Evaluation of the risk management process and Test Symbols - Part 1

YY/T 0466.1-2009 medical equipment used with medical device labels, labeling and information. General Claim

YY 0505 Medical electrical equipment - Part 1-2. General requirements for safety Collateral standard. Electromagnetic compatibility requirements and tests

YY 0607-2007 Medical electrical equipment - Part 2. nerve and muscle stimulation requirements for the safety Used

YY 0868-2011 nerve and muscle stimulation electrodes

3 Terms and Definitions

GB 9706.1-2007 and YY 0607-2007 defined and the following terms and definitions apply to this document.

3.1 While more than two (including two) different IF frequencies (1000Hz ~ 100000Hz frequency within the range) AC current post Fork acts on the human body, in the low-frequency modulation current organization formed to an apparatus for treatment.

3.2 Difference frequency beatfrequency Difference in frequency between two carriers.

3.3 Carrier carrierwave A cyclical oscillating current. In the modulation wave, modulated frequency AC current.

3.4 Modulation modulation By modulating a carrier wave to change certain characteristics (e.g., amplitude, frequency or phase) of the process.