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

YY 0830-2011

Ultrasonic therapy equipment for superficial tissue

浅表组织超声治疗设备

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. This standard was proposed by the State Food and Drug Administration. This standard by the medical ultrasound equipment Standardization Technical Committee of the National Standardization Technical Committee centralized medical appliances. This standard was drafted. Chongqing into the sea of Ultrasound in Medicine Engineering Research Center Co., Ltd., Hubei State Food and Drug Administration medical devices Mechanical Quality Supervision and Inspection Center, Mianyang Sonic Electronics Co., Ltd. The main drafters of this standard. Yefang Wei, Wang Zhijian Chen Temple Song, Jiang Shilin, Regulus Kai, Li Tao, Su Qiang Hua. Superficial tissue ultrasound treatment device

1 Scope

YY 0830 is the mandatory Chinese standard for therapeutic ultrasound equipment used on superficial tissue, the physiotherapy units applied to muscle, tendon and joint. It sets the requirements such equipment has to meet and the test methods that verify them, covering the acoustic output power and intensity and their accuracy, the effective radiating area of the transducer, the beam non-uniformity ratio that reveals hot spots within the beam, the duty cycle and the timer. The measurements matter because the operator cannot see or feel the acoustic field: a transducer with a degraded crystal delivers a fraction of the indicated intensity, and one with a hot spot burns periosteum. These units are used in enormous numbers in Chinese rehabilitation departments. Compliance is compulsory.

This standard specifies the terms and definitions superficial tissue ultrasound treatment equipment, requirements, composition and basic parameters, test methods, inspection rules.

3.1 This standard applies to the definition of superficial tissue ultrasound treatment device (hereinafter referred to as "equipment"). This standard does not apply to ultrasound physiotherapy equipment YY 1090 involved. This standard does not apply to high-intensity focused ultrasound YY 0592 involved (HIFU) therapy system. This standard does not apply to the ultrasonic surgical system YY/T 0644 involved.

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 Medical Electrical Equipment Part 1. General requirements for safety

GB/T 7966-2009 of acoustic radiation force balance power measurement methods and performance requirements

GB/T 14710 Medical electrical equipment environmental requirements and test methods Characterization of ultrasonic fields in the

GB/T 16540-1996 Acoustics 0.5 ~ 15MHz frequency range and its measurement method hydrophone Measurement

GB/T 19890-2005 Acoustics High Intensity Focused Ultrasound (HIFU) acoustic power field characteristics

GB 9706.15 Medical electrical equipment - Part 1-1. General requirements for safety Collateral standard. Safety requirements for medical electrical systems

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Using Piezoelectric ultrasonic transducer as a sound source, emitting ultrasonic energy to the target tissue superficial to achieve tissue degeneration and (or) Necrosis treatment characteristics, and does not belong YY 1090, YY 0592 ultrasound treatment devices within and YY/T 0644 range.

3.2 Treatment head treatmenthead The ultrasonic transducer and the ultrasound assembly in a patient associated member constituted.

Note. The first treatment is also known as application head.

3.3 Focal Plane focalsurface Focused ultrasound transducer sound field, perpendicular to the acoustic axis and including a sound pressure maximum point of the plane.

3.4 Focal plane distance focalsurfacelength Treatment of head end face of the ultrasonic transmission from the window, and the treatment of head and focal plane. Symbol. d Unit. mm, mm.