YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.60

C 41

YY/T 1090-2018

Replacing YY 1090-2009

Ultrasonic Physiotherapy Equipment

超声理疗设备

Issued on: December 20, 2018 **Implemented on: January 1, 2020**

Issued by: National Medical Products Administration

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Ultrasonic Physiotherapy Equipment

1 Scope

This Standard specifies the requirements, test methods and inspection rules of ultrasonic physiotherapy equipment.

This Standard is applicable to ultrasonic physiotherapy equipment, which generates continuous wave or quasi-continuous wave ultrasonic energy through planar circular ultrasonic transducer within the frequency range of 0.5 MHz ~ 5 MHz (hereinafter referred to as equipment). This Standard is not applicable to equipment whose effective sound intensity is more than 3 W/cm^2, or equipment which adopts focused ultrasound.

2 Normative References

The following documents are indispensable to the application of this Standard. In terms of references with a specified date, only versions with a specified date are applicable to this Standard. In terms of references without a specified date, the latest version (including all the modifications) of is applicable to this Standard.

GB 9706.1 Medical Electrical Equipment - Part 1: General Requirements for Safety

GB 9706.7 Medical Electrical Equipment - Part 2-5: Particular Requirements for the Safety of Ultrasonic Physiotherapy Equipment

GB/T 14710 Environmental Requirement and Test Methods for Medical Electrical Equipment

YY/T 0750-2018 Ultrasonic - Physiotherapy Systems - Field Specifications and Methods of Measurement in the Frequency Range 0.5 MHz to 5 MHz

YY/T 0865.1-2011 Ultrasonic - Hydrophone - Part 1: Measurement and Characterization of Medical Ultrasonic Fields up to 40 MHz

3 Terms and Definitions

Terms and definitions defined in GB 9706.7 and YY/T 0750 are applicable to this Standard.

5 Test Methods

5.1 Accuracy of Ultrasonic Output Power

Ultrasonic output power shall comply with the test methods stipulated in 7.2 and 7.3 in YY/T 0750-2018.

The measurement of the rated ultrasonic output power and the rated ultrasonic time maximum output power shall respectively be conducted under the condition of 90%, 100% and 110% rated power supply voltage. During the measurement, manual adjustment of the equipment is no longer allowed. Take the most unfavorable value to examine whether the measurement result complies with the requirements.

Respectively measure at 1/3 and 2/3 point (or nearby, or gear) of the ultrasonic output power and the rated ultrasonic time maximum output power, so as to verify the deviation between the indicated power and the actually measured value.

5.2 Effective Radiation Area

Comply with the test methods stipulated in 7.4 in YY/T 0750-2018. The deviation shall be calculated in accordance with Formula (1).

$$\text{Deviation} = \frac{\text{Measured Value} - \text{Indicated Value}}{\text{Indicated Value}} \quad \cdots\cdots (1)$$

5.3 Effective Sound Intensity

In accordance with the measured value of output power and effective radiation area, calculate effective sound intensity.

5.4 Acoustic Operating Frequency

Comply with the test methods stipulated in 7.3 in YY/T 0865.1-2011 and YY/T 0750-2018. The deviation shall be calculated in accordance with Formula (1).

5.5 Beam Non-uniformity Ratio

Comply with the test methods stipulated in 7.4 in YY/T 0750-2018.

5.6 Appearance and Structure

Conduct visual inspection on appearance and structure. It shall comply with the requirements in 4.7.

5.7 Random Files

Examine random files. It shall comply with the requirements in 4.8.

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