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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 0592-2016

Replacing YY 0592-2005

High intensity focused ultrasound therapy system

高强度聚焦超声(HIFU)治疗系统

Issued on: January 26, 2016 **Implemented on: January 1, 2018**

Issued by: China Food and Drug Administration

Table of Contents

Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

Compared with YY 0592-2005, in addition to editorial modifications, the main technical changes in this Standard are as follows:

This Standard replaces YY 0592-2005 *High intensity focused ultrasound (HIFU) therapy system*.

- deleted the terms and definitions that overlap with other reference standards (3.2, 3.3, 3.4, 3.5, 3.6, 3.7 of Edition 2005);
- added requirements for longitudinal positioning accuracy (see 5.5.2 of this Edition);
- added relevant requirements for electromagnetic compatibility (see 5.11 of this Edition);
- deleted Annex A of Edition 2005.

This Standard was proposed by China Food and Drug Administration.

This Standard shall be under the jurisdiction of Subcommittee on Medical Ultrasound Equipment of National Technical Committee on Medical Appliances of Standardization Administration of China (SAC/TC10/SC2).

The drafting organizations of this Standard: China Food and Drug Administration Hubei Medical Device Quality Supervision and Inspection Center, Chongqing Haifu Medical Technology Co., Ltd., Wuxi Haiying Electronic Medical System Co., Ltd.

Main drafters of this Standard: Jiang Shilin, Ye Fangwei, Wang Guoying, Li Tao.

This Standard was issued on December 2005 for the first time.

High intensity focused ultrasound therapy system

1 Scope

This Standard specifies the terms and definitions, classification, requirements, test methods, inspection rules as well as marks, packaging, transport and storage for high intensity focused ultrasound therapy system.

This Standard applies to in-vitro focus high intensity focused ultrasound (HIFU) therapy system (hereinafter referred to as HIFU therapy system). The system is used for in-vitro high intensity focused ultrasound ablation therapy.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 191, *Packaging and storage marks*

GB/T 3947-1996, *Acoustical terminology*

GB 9706.1-2007, *Medical electrical equipment - Part 1: General requirements for safety*

GB/T 14710, *Environmental requirement and test methods for medical electrical equipment*

GB/T 19890-2005, *Acoustics - High intensity focused ultrasound (HIFU) measurements of acoustic power and field characteristics*

YY/T 0162.1-2009, *Medical ultrasound equipment class series - Part 1: B mode ultrasound diagnostic equipment*

YY 0505, *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standards：Electromagnetic compatibility - Requirements and tests*

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB/T

3947-1996 and GB/T 19890-2005 and the followings apply.

3.1 high intensity focused ultrasound therapy system

a therapy system that focused ultrasound source consisting of cell transducer or multivariate transducer array sends ultrasound; after the ultrasound gets through acoustic media, it penetrates patient's body surface in an acceptable sound intensity by human normal tissue and gathers energy on the target tissue to cause its coagulation necrosis (or instantaneous inactivation)

3.2 acoustic pressure focal region

focal domain

it includes the space body surrounded by the interfaces in which the acoustic pressure focus and its acoustic pressure value are 6 dB lower than acoustic pressure peak (0 dB)

3.3 acoustic pressure focal area

on the acoustic pressure focal plane, the area enclosed by the focal point of the acoustic pressure and its acoustic pressure level 6 dB lower than the acoustic pressure peak (0 dB)

unit: square millimeter, mm^2

3.4 transverse size of focal region

on an acoustic pressure focal plane, the distance between two points where the straight line passing through the peak of the acoustic pressure crosses the focal area interface

unit: millimeter, mm

NOTE: Focal domain horizontal size and vertical size of the focal field are called by a joint name as “-6dB focal domain size (FWHM)” in GB/T 19890-2005.

3.5 longitudinal size of focal region

distance between two points where the beam axis intersects the focal field interface

unit: millimeter, mm

3.6 major lobe (main lobe)

in acoustic pressure distribution of acoustic pressure in the focal plane, including the lobe of the maximum of pulse acoustic pressure square integral

5.9 Water treatment facility

For HIFU therapy system with medium temperature control, degassing device, the effects after therapy are required as follows:

a) water temperature control range and error shall comply with the manufacturer's requirements;

b) oxygen dissolved of degassing water is not more than 4 mg/L.

5.10 Electrical safety requirements

In accordance with relevant requirements of GB 9706.1-2007 and other applicable parallel or special safety standards.

5.11 Electromagnetic compatibility

In accordance with relevant requirements of YY 0505.

5.12 Environmental test requirements

The environmental test conditions for HIFU therapy system shall be in accordance with GB/T 14710. The manufacturer shall specify the appropriate test groups and test items in its corporate product standard. When the overall environmental test is not feasible, the climatic environmental test and the mechanical environmental test under the working conditions may not be carried out. It shall only carry out the storage test for key parts (such as ultrasonic power source, control part). Then check if the machine works properly after assembly.

6 Test methods

6.1 Test environment

6.1.1 Ambient temperature: +10°C ~ +40°C; relative humidity: 30% ~ 75%; atmospheric pressure range: 700hPa ~ 1060hPa; water cooling equipment inlet temperature not higher than 25°C.

6.1.2 Test shall avoid external vibration, electromagnetic fields and other interference.

6.2 Measurement system requirements

In accordance with Clause 5 of GB/T 19890-2005.

NOTE: The stability of the electrical power of testing HIFU therapy system is changed from 10%/4h specified in GB/T 19890-2005 to 15%/4h.

the average acoustic intensity of special peak value according to equation (4):

$$I_{spta} = U_{rms,max}^{2} / \rho c M_L^{2} \quad \cdots\cdots (4)$$

where,

I_{spta} - the average acoustic intensity of special peak value, in Watts per square meter (W/m^2);

$U_{rms,max}^2$ - root mean square value of hydrophone output voltage at acoustic pressure focus within pulse duration, in volts (V);

ρ - water density, in kilograms per cubic meter (kg/m^3);

c - sound velocity in water, in meters per second (m/s);

M_L - load sensitivity of free field cable end at acoustic working frequency of hydrophone, in volts per pascal.

NOTE: In the actual measurements, the corresponding $U_{rms,max}^2$ can be calculated first by the I_{spta} nominated by HIFU therapy system. Stop the test after the test value reaches this value so as to protect the measuring hydrophone.

6.4.2 Measurement of spatial average value of time average acoustic intensity within -6 dB acoustic beam area

Carry out according to the method specified in GB/T 19890-2005.

For HIFU therapy system working by continuous wave, when the maximum acoustic pressure value of the calibrated hydrophone cannot meet the rated output value of HIFU therapy system, in order to ensure the safety and service life of the hydrophone, the testing system shall set a particular pulse measurement working state in which the pulse duration is less than or equal to 100 μs, pulse repetition frequency is less than 1 kHz (or working by manually triggering a single pulse).

If the HIFU therapy system working by continuous wave cannot set a particular pulse measurement working state, it shall measure the spatial average value of time average acoustic intensity within -6 dB acoustic beam area according to the following steps:

a) measure the maximum output acoustic power according to the method in GB/T 19890-2005;

b) use hydrophone to perform two-dimensional linear step-by-step scanning within focal plane of acoustic pressure (it may use the hydrophone with uncalibrated sensitivity but non-linear distortion is less

6.8 Positioning device

6.8.1 Measurements of movement scope and error

Set the maximum displacement of each axial movement and the maximum angle of each movement angle, respectively. Measure the actual displacement of each axial movement and the actual movement angle of each movement angle with a universal measuring tool. And calculate the error.

6.8.2 Measurement of XY plane positioning accuracy

It shall use the localization device, positioning device of testing equipment to measure. The steps are as follows:

a) make a mark on the center of a 3mm thick plexiglass plate, place or fix a reflector that can be detected by the positioning device at the marked point (the size of the reflector shall be as small as possible to avoid affecting the sound field), then fix the plexiglass plate to the acoustic pressure focal plane;

b) operate the positioning device, coincide the image of the reflector with the registration mark, and record the coordinate value at this moment. To avoid affecting the acoustic field distribution during the next ultrasonic launch, the reflector can now be removed;

c) operate the positioning device; translate the treatment head or treatment bed along a direction of X-axis. The moving distance shall choose an integer of millimeters;

d) set an appropriate ultrasonic power to launch (can be gradually increased), until the plexiglass plate has the smallest visible melting point;

e) move the treatment head or treatment bed at the opposite direction to the X-axis symmetry point. Perform ultrasound launch till visible melting point appears;

f) return to step b) and record the original point; perform ultrasound launch twice along with Y-axis direction according to the method mentioned above;

g) remove the plexiglass plate. Measure the distance between the center of four melting points and the marker center with a universal measuring tool. Take the maximum deviation according to requirements of 5.5.2.

6.8.3 Measurement of Z-axis positioning accuracy

temperature shall be measured by thermometer, oxygen dissolved by dissolved oxygen meter, in accordance with requirements of 5.9.

6.13 Safety performance

Carry out according to relevant method of GB 9706.1-2007 and other applicable parallel or particular safety standards.

6.14 Electromagnetic compatibility

Carry out in accordance with YY 0505.

6.15 Environmental test

Carry out according to the method and procedures specified in GB/T 14710.

7 Inspection rules

7.1 Exit-factory inspection

The number of sample, inspection items, determination rules of exit-factory inspection shall be stipulated by the manufacturer in the corporate product standard.

7.2 Type inspection

7.2.1 The type inspection shall be conducted in one of the following cases:

a) production of new product;

b) when production is resumed after the production has been discontinued for a long time;

c) when the design process, material have significant changes that may result in change of safety or technical performance;

d) when state quality supervision agencies require to carry out the type inspection.

7.2.2 The number for type inspection is one. The inspection sample shall be extracted from the qualified batches in exit-factory inspection.

7.2.3 The items of type inspection are all requirements specified in this Standard.

7.2.4 In type inspection, if there are more than two items in performance fail, this product shall be re-organized. After re-organization, carry out the inspection for the failed items. If they still fail, they shall be rejected.

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