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PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

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Ultrasonic surgical equipment for osseous tissue

超声骨组织手术设备

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Ultrasonic surgical equipment for osseous tissue

1 Scope

This Standard specifies technical requirements, test methods, inspection rules, marks and user's manual for ultrasonic surgical equipment for osseous tissue (hereinafter referred to as the equipment).

This Standard is applicable to ultrasonic surgical equipment for osseous tissue.

This Standard is not applicable to ultrasonic tooth cleaning device for removing plaque and stones on teeth.

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

GB/T 9969-2008, *General Principles for Preparation of Instructions for Use of Industrial Products*

GB/T 14710-2009, *Environmental requirement and test methods for medical electrical equipment*

YY/T 0644-2008, *Ultrasonic - surgical systems - Measurement and declaration of the basic output characteristics*

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in YY/T 0644-2008 as well as the followings apply.

3.1 ultrasonic surgical equipment for osseous tissue

Surgical equipment powered by ultrasound, of which the frequency is generally

The output sound power of each type of tip of each ultrasonic hand-held component shall be within the range announced by the manufacturer.

4.8 Duty cycle

If the main amplitude of the tip is modulated, its duty cycle or range of duty cycle shall conform to the manufacturer's published value.

4.9 Static (no load) electrical power

The measured static (no-load) electrical power shall be less than the maximum value of the static (no-load) electrical power of each ultrasonic handheld component published by the manufacturer.

4.10 Maximum electric power

The measured maximum electric power shall be less than the maximum electric power value of each ultrasonic handheld component published by the manufacturer.

4.11 Power reserve index

The power reserve index shall conform to the value published by the manufacturer.

4.12 Main sound output area

If applicable, the output area of the main sound of each type of tip shall conform to the manufacturer's published value.

4.13 Output area of secondary transverse vibration sound

If applicable, the secondary transverse vibration sound output area of each type of tip shall conform to the manufacturer's published value.

4.14 Liquid flow

The manufacturer shall publish the adjustment range of liquid flow. The error of liquid flow relative to the nominal value shall not exceed $\pm 10\%$.

4.15 Noise

It shall not be greater than 90dB (A-weighted).

4.16 Features to be published in user's manual

- a) Main amplitude at the tip of the treatment head;
- b) Area of the main sound output of the treatment head;

5.5 Excitation frequency

Measure according to the method specified in 6.3.1 of YY/T 0644-2008. The result shall meet the requirements of 4.5.

5.6 Tip vibration frequency

Measure according to the method specified in 6.4 of YY/T 0644-2008. The result shall meet the requirements of 4.6.

5.7 Exported output sound power

Measure according to the method specified in 6.5.1 of YY/T 0644-2008. The result shall meet the requirements of 4.7.

5.8 Duty cycle

Measure according to the method specified in 6.8 of YY/T 0644-2008. The result shall meet the requirements of 4.8.

5.9 Static (no load) electrical power

Measure according to the method specified in 6.9 of YY/T 0644-2008. The result must not exceed the published value.

5.10 Maximum electric power

Measure according to the method specified in 6.10 of YY/T 0644-2008. The result must not exceed the published value.

NOTE: Simulated tip loads can use bone approximations, such as phenolic plastic and so on.

5.11 Power reserve index

According to the results of 5.9 and 5.10, calculate the power reserve index according to the method specified in 6.13 of YY/T 0644-2008.

5.12 Main sound output area

According to the definition of 3.9 in YY/T 0644-2008, calculate according to the method specified in 6.11 in YY/T 0644-2008.

5.13 Output area of secondary transverse vibration sound

According to the definition of 3.15 in YY/T 0644-2008, calculate according to the method specified in 6.12 in YY/T 0644-2008.

5.14 Liquid flow

- c) When requested by the national quality supervision department.

6.3.2 Type inspection items

All requirements specified in this Standard. The number of samples for type inspection is one.

6.3.3 Determination for conformity of type test

In the inspection items, if there are items that do not meet the requirements, it is allowed to repair the nonconforming items. After the adjustment and repair, for the items that may be related to the failure, the retest must all meet the requirements, otherwise it shall be determined as failure.

The inspection items and determination rules for quality supervision and inspection shall be separately stipulated by the quality supervision agency.

7 Marks and user's manual

7.1 Marks

7.1.1 The following marks shall be on the equipment:

- a) Manufacturer's name;
- b) Product named and model;
- c) Power used;
- d) Production date or exit-factory number;
- e) Other marks required by applicable standards and regulations.

7.1.2 The following marks shall be on the box:

- a) Manufacturer's name and address;
- b) Product name, model, quantity;
- c) Weight, volume (length × width × height);
- d) For "fragile items", "upward", "fear of rain" and other words or marks, the text and graphics shall comply with the relevant provisions of GB/T 191-2008;
- e) Other marks required by applicable standards and regulations.

7.2 Accompanying documents

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