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Lens Ultrasonic Removal and Vitrectomy Device for Ophthalmic Surgery

眼科晶状体超声摘除和玻璃体切除设备

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Foreword

This Standard's entire technical contents are mandatory.

This Standard was proposed by State Food and Drug Administration.

This Standard shall be under the jurisdiction of Subcommittee for Medical Ultrasonic Device Standardization of National Technical Committee for Standardization of Medical Apparatus (SAC/TC10/SC2).

Drafting organizations of this Standard: Hubei Center of Medical Device Quality, Supervision and Testing of State Food and Drug Administration, Alcon (China) Ophthalmic Product Co., Ltd., and Tianjin Maida Medical Science And Technology Co., Ltd..

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Lens Ultrasonic Removal and Vitrectomy Device for Ophthalmic Surgery

1 Scope

This Standard specifies the terms and definitions, product classification, requirements and test methods of lens ultrasonic removal and vitrectomy device for ophthalmic surgery.

This Standard is applicable to the lens ultrasonic removal device for ophthalmic surgery (hereinafter refers to device), which also possesses the vitrectomy function.

NOTE: Phacofragmentation of lens indicates, in the earliest period, the surgery to use ultrasonic energy to crush (or emulsify) cataract lens, and extract lens tissues through small incision; currently, ultrasound is still the most important means for the lens removal and vitrectomy device for ophthalmic surgery; recently, there are the device using other energy and extracting cataract lens through small incision (such as laser and liquefaction); for which this Standard can be referred to.

2 Normative References

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB 9706.1 Medical Electrical Equipment - Part 1: General Requirements for Safety (IEC 60601-1:1988, IDT)

GB 9706.15 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems (IEC 60601-1-1:2000, IDT)

YY/T 0644-2008 Ultrasonic-Surgical Systems - Measurement and Declaration of the Basic Output Characteristics (IEC 61847:1998, IDT)

ISO 15752:2000 Ophthalmic Instruments - Endoilluminators - Fundamental Requirements and Test Methods for Optical Radiation Safety

In the surgery, the height of the patient eye against the device.

3.9 Phacofragmentation

The surgical method to use ultrasonic energy to crush the lens into small pieces.

3.10 Prime (Priming)

The preparation procedure prior to the test, fill the tubing device (liquid channel) with ophthalmic irrigation solution.

3.11 Solution support pole

The hanger suspending the gravity irrigation container and the height of which can be adjusted.

NOTE: The electrically controllable height f solution support pole is generally called IV pole.

3.12 Tip

The hollow needle-shaped parts mounted on the handpiece.

NOTE: it is clinically known as needle.

3.13 Tubing set

Catheter assembly for fluid flow during ocular irrigation and aspiration.

NOTE: it is clinically known as tubing package.

3.14 Vitrectomy

The surgical procedures to remove the vitreous body, membrane, blood, lens and other tissues, which involve the irrigation, aspiration and vitrectomy.

NOTE: Such procedure may also involve illumination, coagulation, liquid/gas exchange, and injection of viscoelastic agent.

3.15 Vitrectomy device

The medical electrical instruments or systems sued for the vitrectomy.

NOTE: such device can also be sued for other ophthalmic surgeries.

4 Product Classification

The devices are divided into the following ones as per their intended use:

5.4 Vitrectomy

The device with vitrectomy function shall conform to the following requirements:

5.4.1 Accuracy of vitrectomy tip speed

For all types of tips listed in the instruction manual, the deviation between actual cutting speed and the set cutting speed shall not exceed ± 20%.

5.4.2 Minimum vitrectomy tip speed

In case the setting is lowest, the speed of vitrectomy tip in water shall be no less than 10 times/min (except for single-cut mode).

5.5 Coagulation

If the device is equipped with coagulation function, it shall conform to the following requirements:

5.5.1 Frequency of coagulation

The deviation between coagulation output frequency and the nominal frequency shall not exceed ± 20%; while the frequency range shall be between 0.01 MHz and 15 MHz.

5.5.2 Power of coagulation

The total coagulation power for lens removal and vitrectomy shall not exceed 40 W.

5.6 Illumination

IF the device is equipped with illumination function against the eye during the surgery period, it shall conform to the following requirements:

5.6.1 Accuracy of illumination output

If illumination output provides the setting function between the maximum value and 20% or other lower value (take the larger one between the two); the deviation between actual illumination output and the device displayed illumination value or the setting value shall not exceed ± 25%.

5.6.2 Limit of illumination output intensity

When testing at a distance of 5 mm from the optical fiber outlet, the illumination light intensity shall conform to the following requirements in 4.2 of ISO 15752:2000:

a) Light intensity with wavelength range of 305 nm ~ 400 nm shall not exceed 0.05 mW/cm^2; the illumination intensity on such wavelength shall be as small as

eye level; gravity irrigation device shall regulate the height range of irrigation solution container;

i) Warning shall be given to the operator that ensure sufficient irrigation solution capacity during the surgery period, and monitor the irrigation solution level;

j) If applicable, warning shall be given to the operation that the maximum volume of the drainage vessel shall not be exceeded, otherwise, it may result in the risk of the patient.

5.8 Instruction Manual

a) It shall include the description of system function inspection before use on the current day;

b) If applicable, it shall instruct the loading, priming, changing and re-loading of the tubing set, and the varying intervals of it; so that maintain its conformable performance;

c) If applicable, it shall give the use instructions for the clamp of the tubing set, and how to avoid the free flowing of the ophthalmic irrigation solution; as well as the procedures that shall be conformed to when changing the source of ophthalmic irrigation solution;

d) It shall include the instructions of fixed connection plug, handpiece cable, and Luer joint or other joint;

e) It shall include the methods that is recommended to the operator or relevant organizations about regularly checking all handpiece cables and other cables, as well as the measures that shall be taken in case of the damages (e.g. wire exposure, insulator fracture, deformation and etc.);

f) It shall publish the nominal vibration speed for all types of phacoemulsification tips, as well as the nominal speed of all types of vitrectomy tips.

NOTE: If the nominal frequency and vibration excursion of the phacoemulsification tip are published at the same time, which can be regarded as publishing the vibration speed.

6 Test Methods

6.1 Static irrigation pressure

6.1.1 Test method of gravity irrigation device

The following test method shall be taken:

a) The ambient test temperature shall be at 25°C ± 5°C;

b) According to the manufacturer's instruction manual, install the tubing assembly, and priming the device;

c) Set the readings of the pressure gauge to be zero; connect the pressure gauge to the end of the irrigation tube, and fix within the ± 2.5 cm height range of simulation patient's eye level; then see Figure 2;

d) Conduct the liquid diversion according the requirements of the manufacturer's instruction manual;

e) Set the test irrigation pressure to be 0 kPa (0 mmHg) or at the lowest position; stand for 5s and then record the readings of the pressure gauge;

f) Improve the pressure by 2.7 kPa (20 mmHg); stand for 5s and then record the readings of the pressure gauge;

g) Repeat the procedure of f), increase pressure of 2.7 kPa (20 mmHg) each time; stand for 5s at each point, record the reading of pressure gauge till the maximum pressure is reached;

h) Once the maximum pressure is reached, record the readings of pressure gauge, which shall conform to the requirements of 5.1.1;

i) Reduce the height of gravity irrigation vessel to each point in Procedure g) to e), stand for 5s at each point, and record the readings of the pressure gauge;

NOTE: If necessary, the irrigation tube can be re-connected during the reverse measurement period.

j) Calculate the deviation between static irrigation pressure and device's setting value at each point, which shall conform to the requirements of 5.1.2.

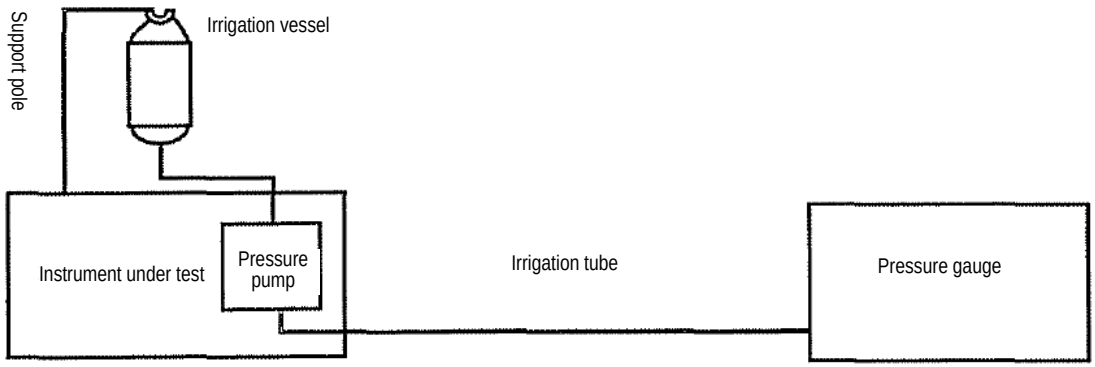

Figure 2 Test Method of Pressure Irrigation Device

6.2 Aspiration vacuum degree

NOTE: If feasible, it is a easy way to wrap the insulated fine wire around the handpiece for several laps to obtain the ultrasonic driving signal, see 6.3.1 of YY/T 0644-2008.

The vibration speed of tip ultrasound shall be calculated by multiplying the tip vibration offset, vibration frequency and **π**, which shall conform to the requirements of 5.3.1 and 5.3.2.

6.4 Vitrectomy tip speed

6.4.1 Accuracy of vitrectomy tip speed

Method I: Use stroboscopic instrument to measure

a) Connect the vitrectomy tip with the handpiece, and place them under the microscope, so that the tip can be observed visibly;

b) Set the frequency of stroboscopic instrument to be the cutting speed of tested instrument (the deviation shall be within ± 10%);

c) Activate the vitrectomy tip and the stroboscopic instrument;

d) Adjust the flash rate of stroboscopic instrument, and make the tip figure static;

e) Read the frequency of stroboscopic instrument, so that determine the cutting speed.

Method II: use oscilloscope or frequency meter to measure.

Open the chassis, use oscilloscope or frequency meter to measure the vitrectomy control signal.

Calculate the deviation between the device displaying cutting speed and the actually measured speed, which shall conform to the requirements of 5.4.1.

Method I is the arbitration law.

6.4.2 Lowest speed of vitrectomy tip

In addition to the single-cutting mode, any cutting speed under any setting background measured by the above method shall conform to the requirements of 5.4.2.

6.5 Coagulation function

6.5.1 Coagulation frequency

Use oscilloscope or frequency meter, test by the probe with 100 times of ultrasonic frequency and 100 MΩ high impedance in the two loading ends, which shall conform

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