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Liquid Nitrogen Cryosurgical Equipment

液氮冷冻外科治疗设备

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Liquid Nitrogen Cryosurgical Equipment

1 Scope

This Standard specifies the scope, terms and definitions, requirements, test methods, inspection rules, marking, labelling and packaging of liquid nitrogen cryosurgical equipment.

This Standard is applicable to cryosurgical treatment equipment which uses liquid nitrogen as the refrigerant and utilizes the latent heat of vaporization phase change for refrigeration, and with the capacity of liquid nitrogen storage greater than 1 L (hereinafter referred to as cryosurgical equipment). The cryosurgical equipment mainly generates low temperature to the target tissue, which is used for cryo-necrosis, cryo-block, inflammatory reaction and cryo-adhesion.

2 Normative References

Through the reference in this Standard, clauses of the following documents become clauses of this Standard. In terms of references with a specific date, all the subsequent modification sheets (excluding the corrected content) or the revised editions are not applicable to this Standard. However, all parties that reach an agreement in accordance with this Standard are encouraged to explore the possibility of adopting the latest version of these documents. In terms of references without a specific date, the latest version is applicable to this Standard.

GB 9706.1 *Medical Electrical Equipment - Part 1: General Requirements for Safety* (GB 9706.1-2007, IEC 60601-1:1988, IDT)

GB/T 14710-1993 *The Environmental Requirements and Test Methods for Medical Electrical Equipment*

GB/T 16886.1 *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing* (GB/T 16886.1-2001, idt ISO 10993-1:1997)

YY 0466-2003 *Medical Devices - Symbols to be Used with Medical Device Labels Labelling and Information to be Supplied* (YY 0466-2003, ISO 15223:2000, IDT)

YY 0678 *Standard Performance and Safety Specification for Cryosurgical Medical Instruments*

Regulations on Administration of Instructions, Packaging Marks and Labels for Medical Devices - China Food and Drug Administration - No. 10 Order

Ambient temperature: -5 °C ~ 40 °C;

Atmospheric pressure: 86 kPa ~ 106 kPa;

Working voltage: AC 220 V, 50 Hz.

4.2 Composition of Cryosurgical Equipment

The cryosurgical equipment is mainly composed of liquid nitrogen storage, liquid nitrogen pipe, cryo-tip, pressure gauge, cryo-valve and temperature control equipment.

4.3 Appearance of Cryosurgical Equipment

4.3.1 The outer surface of liquid nitrogen storage of cryosurgical equipment shall be smoot and clean, and with uniform solder joints; there shall be no defects like trimmings.

4.3.2 The surface of cryo-tip shall be smooth; there shall be no burrs, trimmings or agnails.

4.3.3 The control panel of cryosurgical equipment shall be smooth; the reading shall be clear.

4.3.4 The surface of liquid nitrogen pipe shall be smooth.

4.4 Airtight Performance of Cryosurgical Equipment (applicable to self-pressurized liquid nitrogen storage)

4.4.1 After the liquid nitrogen storage of the main unit of the cryosurgical equipment is closed, when the working pressure is greater than the standard atmospheric pressure, the air leakage rate of the cryosurgical equipment within 1 h shall not exceed 5%.

4.4.2 There shall be no leakage at the connection of each connection pipeline of the cryosurgical equipment.

4.5 Working Performance Indexes

4.5.1 Working pressure of liquid nitrogen storage (applicable to self-pressurized liquid nitrogen storage)

Within 10 min after starting up, the working pressure indicated by the liquid nitrogen storage shall be reached.

4.5.2 Working temperature regulation range

The temperature indicating regulator of the cryosurgical equipment has an indication range of -200 °C ~ 40 °C, which can instantly display the working temperature of the freezing zone of the cryo-tip. In addition, within this temperature range, there shall be the functions of temperature setting and regulation.

4.6.2 Pressure alarm (using pressure control method)

When the equipment is normally working, and the pressure in the liquid nitrogen storage exceeds the normal working pressure range, the alarm device shall give an alarm.

4.6.3 Liquid level alarm

When the equipment is normally working, and the liquid level in the liquid nitrogen storage is lower than the normal working range, the alarm device shall give an alarm.

4.7 Electrical Safety Performance of Cryosurgical Equipment

The electrical safety performance of cryosurgical equipment shall comply with the requirements of GB 9706.1 and YY 0678.

4.8 Environmental Test of Cryosurgical Equipment

The grouping and item requirements of environmental test of cryosurgical equipment shall be specifically provided by the manufacturer in accordance with GB/T 14710-1993.

4.9 Biological Performance of Cryosurgical Equipment Probe

Conduct the biological assessment in accordance with the stipulations of GB/T 16886.1.

5 Test Methods

5.1 Appearance

Handle and visual inspection. It shall comply with the requirements of 4.3.

5.2 Airtightness Test

5.2.1 Airtightness test of liquid nitrogen storage

Conduct the test at 25 °C ± 2 °C.

Correctly connect the equipment and put it in a standby state. Properly connect the pressure device and ensure its airtightness. Remove the overpressure relief device or inactivate it. The switch that controls the output of liquid nitrogen shall be adjusted to the turned-off state.

Turn on the pressure device, until the pressure gauge shows that the pressure in the liquid nitrogen storage reaches 2 times of the maximum working pressure of the equipment. Then, turn off the pressure device and record the reading of the pressure

5.3.5 Cryo-tip temperature control test

After the debugging of the equipment is completed, fill it up with nitrogen and put it in a standby state. Its cryo-tip shall be fixedly supported and exposed to the air; there shall be no significant air flow or heat source around.

Tightly attach and fix the temperature sensor of the temperature measuring equipment to the freezing zone of the cryo-tip. The shape of the sensor of the temperature measuring equipment shall ensure close contact with the temperature measuring point and relatively small heat capacity.

Set the working temperature of the equipment to half of the full scale T_1; turn on the equipment and put it in the working state.

Wait till the reading displayed by the temperature measuring equipment is basically stable, observe the temperature measuring equipment's reading T_2 and record it. Compare T_1 with T_2. It shall comply with the requirements of 4.5.5.

Set the working temperature of the equipment to the lowest working temperature; repeat the above-mentioned process.

Insert the cryo-tip into gelatin gel and fixedly support it. The gelatin gel is prepared by heating 4% gelatin solution to 42 °C and cooling it.

Successively set the working temperature of the equipment to half of the full scale and the lowest working temperature. Wait till the temperature becomes stable, then, record the reading. It shall comply with the requirements of 4.5.5.

5.3.6 Thermometer accuracy test

Turn on the equipment; confirm that its thermometer is in the normal working state.

Immerse the part of the equipment equipped with a temperature sensor in a container filled with liquid nitrogen. Wait till the liquid level is basically stable, record the temperature displayed by the equipment as T_1. After respectively replacing the liquid with ice-water mixture and boiling water, repeat the above process.

Compare the temperatures of the liquid nitrogen, the ice-water mixture and the boiling water. It shall comply with the requirements of 4.5.6.

5.3.7 Cryo-valve performance test

Fill the equipment with liquid nitrogen of 2/3 storage capacity and pressurize it. Wait till the liquid nitrogen storage reaches the working pressure, then, open and close the solenoid valve for 3 times, with an interval of 5 min each time. There shall be no phenomenon of freezing or jamming. It shall comply with the requirements of 4.5.7.

5.7 Cryo-tip Biological Performance Test

In accordance with the stipulations of GB/T 16886.1, conduct biological assessment on the biological performance of the cryosurgical equipment's cryo-tip. It shall comply with the requirements of 4.9.

6 Inspection Rules

6.1 General Rules

Cryosurgical equipment must pass the inspection conducted by the manufacturer's quality inspection department before being submitted for acceptance inspection.

6.2 Classification

The inspection is divided into exit-factory inspection and periodic inspection (type inspection).

6.3 Exit-factory Inspection

6.3.1 When exiting factory, cryosurgical equipment must be inspected one by one.

6.3.2 The exit-factory inspection items are 4.3, 4.4, 4.5.1, 4.5.2, 4.5.4, 4.5.6, 4.5.7, 4.5.8, 4.5.9, 4.6.2, 4.6.3, 4.7 and 4.9 of this Standard.

6.3.3 Each inspection item shall comply with the requirements of this Standard. The cryosurgical equipment is only allowed to exit factory after all inspection items are qualified.

6.4 Periodic Inspection

6.4.1 Timing of periodic inspection

Under the following circumstances, periodic inspection shall be conducted:

a) Before new products are put into production (including the transferring of old products to a new company for production);

b) When the products are put into production after an interval of more than one year;

c) When there are significant changes in the design process that might affect product performance (for example, when there are changes of the source of raw materials or technical conditions);

d) When the national quality supervision department conducts supervision and random inspection of the products.

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