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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.60
C 37

YY 0678-2008

Standard Performance and Safety Specification for Cryosurgical Medical Instruments

医用冷冻外科治疗设备性能和安全

(ASTM F 882-84[Reapproved 2002], MOD)

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Issued on: October 17, 2008 **Implemented on: June 1, 2010**

Issued by: China Food and Drug Administration

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Foreword

This Standard modifies and adopts ASTM F 882-84 (Reapproved 2002) “Performance and Safety Cryosurgical Medical Instruments”.

The differences between this Standard and ASTM F 882-84 (Reapproved 2002) are as follows: Delete the contents such as continuous leakage current, protection against combustibility anesthesia gas mixture ignition danger, and determining temperature monitor (cryotip and tissue) accurateness.

This Standard was proposed by and shall be under the jurisdiction of Hangzhou Medical Appliance Quality Supervision Testing Center of China State Food and Drug Administration.

Drafting organization of this Standard: Hangzhou Medical Appliance Quality Supervision Testing Center of China State Food and Drug Administration

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Standard Performance and Safety Specification for Cryosurgical Medical Instruments

1 Scope

This Standard specifies the basic requirements that cryosurgical medical instrument in refrigeration system shall meet in the performance, reproducibility, publication, labelling, documentation, and safety aspects.

The cryosurgical medical instrument referred in this Standard adopts the principle of Latent Heat of Vaporization or the Joule-Thompson Effect, produces low temperature in cryotip rod or directly to the target tissue, so as to produce cryonecrosis, inflammatory response or cryoadhesion.

If, during the application, cryosurgical medical instrument utilizes displayable cryotip or accessories at cryogen area temperature to monitor the treatment process, the requirements of this Standard are applicable to these accessories.

2 Normative References

The following normative documents contain provisions which, through reference in this text, constitute the provisions of this Standard. For dated references, subsequent amendments (excluding corrigendum) or revisions of these publications do not apply. However, all parties who enter into an agreement according to this Standard are encouraged to study whether the latest editions of these documents are applicable. For undated references, the latest editions of the normative documents referred to applies.

GB/T 1226-2001 General Pressure Gauge

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

GB 15382-1994 General Technique Specifications for Cylinder Valves

Safety Inspection Regulations for Gas Cylinders, AQSIQ Decree No. 46

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3 Terms and Definitions

For the purpose of this Standard, the following terms and definitions apply.

3.1 closed cryotip

a hollow, closed end usually shaped to fit a particular anatomical site where the cryogen cools the external surface which is applied to the target tissue.

3.2 open cryotip

a device specifically designed to apply the cryogen directly to the target tissue.

3.3 cryoprobe

the instrument used to deliver the cryogen to the cryotip or open tip. For a cryotip, a cryoprobe also directs the cryogen away from the target tissue.

3.4 cryosystem

all parts of a system excluding the cryogen and its container, unless supplied by the manufacturer, that is designed to apply or use a cryogen.

3.5 compressed gas cylinder

a container that is specifically designed to store a gas or liquid under elevated pressure conditions.

3.6 compressed gas cylinder connector

a device specifically designed to attach to a cylinder for proper and safe removal of its contents.

3.7 Withdrawal device

connected device specially designed to make the cryogen in the container be released as required.

3.8 cryogen

a substance used to obtain reduced temperatures.

Note: Cryogens are usually classed by their boiling points. The most common cryogens and their respective boiling points are as follows:

Cryogen	Boiling Point at S.T.P.,°C
Freon 22	−49.8
Carbon Dioxide (CO_2)	−78.6

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water in a standard 1000 mL beaker. The water shall be maintained at 30°C±2°C by a constant temperature bath. The water in the beaker shall not be circulated artificially during the actual test.

- Fast thermal thermocouple sensor.
- Temperature indicator or chart recorder.
- Other components, to make the cryosystem functional in accordance with the manufacturer's operational instructions.

b) Sampling:

- For limited production or a unique cryosystem, perform and record a series of three freeze modes.
- For cryosystems of the same model, test and record three individual systems.

c) Procedure:

- Attach the thermocouple sensor to the therapeutic surface of the cryotip as determined by the manufacturer.
- Immerse the closed cryotip into the simulated tissue model in a way which stimulates the intended application as determined by the manufacturer.
- Follow all parameters as described in the manufacturer's operational instructions to make cryosystem functional.
- Allow the cryotip to defrost between cycles.
- Include disposable devices.
- A pre-cycle for the cryosystems to normalize operating conditions is permitted.
- Calculate the reference temperature and limits of deviation from the recorded data.

d) Conformance:

Conformance with the requirements shall be checked by comparison of the deviation between the closed cryotip reference temperature and Table 1.

4.3 Tractive Force of Closed Cryotip

All the Cryosystem specially designed for cryoadhesion shall be able to lift weight of 60g at least in adhesion for at least 45 minutes.

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manufacturer may label his product as conforming to this Standard only if the product fulfills the requirements of this specification.

5.2 Disclosure

A manufacturer shall disclose each specification listed, where applicable.

5.2.1 A manufacturer of a cryosystem shall provide a warning statement to inform the user where contact with the cryosystem may cause user/patient harm. This statement shall appear in the instrument's instruction manual and, if possible, on sections of the instrument that become 0°C or colder.

5.2.2 A cryosystem designed to spray a cryogen onto a target tissue must have a disclosure statement warning the user to provide adequate protection to himself and the patient due to excess or residual cryogen droplets or mist.

5.2.3 A disclosure statement shall be required that states the normal operating pressure at +20°C, the boiling point, and the type of cryogen for which the instrument is designed.

5.2.4 A disclosure statement that states exactly what items of the cryosystem and its accessories can be sterilized and the recommended sterilization procedures shall be included with each cryosystem.

5.2.5 A disclosure statement shall be included with each pre-sterilized cryosystem:

a) Sterile;

b) The expiration date of sterilization;

c) Notes of caution concerning means of shipping, storage and use of the instrument.

5.2.6 All ac powered cryosystems and accessories shall be prominently labeled "Danger-Explosion Hazard. Do Not Use in Presence of Flammable Anesthetics".

5.2.7 The following information shall be included in the disclosure statement for tissue temperature monitors.

a) Type of cryometer (analog, digital, recorder),

b) Temperature range: minimum to maximum,

c) Type of thermocouple (for example, Type "T"),

d) Temperature and humidity limits for storage, shipping and operation, and

e) Power requirements.

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c) Set up;

d) Use;

e) Dismantle;

f) Calibrations;

g) Intended Applications.

5.4.2.1 Specifications – Cryosystem and Cryogen:

a) Size;

b) Weight;

c) Type(s) of Cryogen(s) Used;

d) Minimum and Maximum Operation Pressure;

e) Power Requirements;

f) Temperature Control Description;

g) Cryosystem and Cryoprobe Performance Check

b) Defrost Features;

i) Temperature Sensor;

j) Serviceable Parts;

k) Manufacturer's Recommended Cryogen Containers;

l) Thermal Insulation;

m) Specifications – Cryogen Container.

5.4.2.2 Recommended Withdrawal Devices:

a) Type(s) of Cryogen Employed;

b) Size;

c) Weight;

d) Capacity;

e) Static Hold Time: Container Only;

f) Static Hold Time: Container and Withdrawal Device;

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g) Optimum and Maximum Operating Pressure;

h) Rating on Pressure Limiting Device;

i) Filling Directions;

j) Serviceable Parts.

5.4.3 Servicing Instructions:

a) Trouble-Shooting Chart;

b) Cryogen Flow Chart;

c) Electrical Schematics;

d) User Serviceable Parts List;

e) Preventive Maintenance Recommendations;

f) Warranty Information.

5.4.4 Electrical and Cryogen Safety Instructions:

a) User Related;

b) Patient Related.

5.4.5 Available Accessories.

6 Cryosystem Safety Requirements

6.1 General

These cryosystem safety requirements are intended to protect the user and patient from harm during the use and storage of the cryosystem.

6.2 Mechanical Integrity

6.2.1 The purpose of this requirement is to ensure the user that the cryosystem is capable of withstanding the pressure and temperatures normally encountered during operation.

6.2.2 All related assemblies of new or repaired cryosystems must be able to withstand static overpressure of at least two times the normal operating pressure that the assembly shall encounter. The pressure normally encountered shall be calculated based on the following conditions:

6.2.2.1 A cryosystem that uses a cryogen regulated Compressed Gas Association

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All cryosystems are required to vent the exhausted cryogen in such a manner that the user or patient cannot come into contact with cryogen droplets or mist, or both under operating conditions.

Exception: This requirement does not apply to those cryosystems that spray the cryogen directly onto the target tissue.

6.3.2 Ambient Concentrations of Nitrous Oxide

Ambient concentrations of nitrous oxide shall not exceed 25 μg/mL.

All nitrous oxide cryosystems shall be equipped with a gas collection system that can be conveniently routed for safe disposal. To minimize nitrous oxide exposure, the disposition of the gas collected and exhausted from the system is the responsibility of the user.

Check whether they meet the requirements through the following test:

a) Apparatus:

- Standard Test Room is shown in Figure 2.
- Test Room Volume, 27 m^3 maximum, rated 3 m×3 m.
- Ceiling height, 2m minimum.
- Fan Flowrate, 14 m^3/min~17 m^3/min, fixed position household fan style to circulate air is required.
- Infrared Spectrophotometer.

b) Sampling

- For a cryosystem of a similar design, test one cryosystem. This cryosystem shall be a representative sample of a currently marketed production system.

c) Preparation of Apparatus:

- Locate fan 0.3m from two walls and floor to the center of the fan. Make sure the flow is parallel to the wall and floor.
- The room is to be leak-tight with essentially zero room air changes.
- Place the entire cryosystem including nitrous oxide cylinders in geometric center of room and confine about center as close as is practical.
- Rout the scavenging hose out of the test room. Locate the sampling point at any point on a 1-meter radius from geometric center, one-meter above floor level.

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and the patient due to contact with the cold sections of a cryosystem.

6.4.2 Where feasible, the manufacturer is responsible for adequate insulation designed into the cryosystem to prevent accidental injury. See disclosure requirement in 5.2.1.

6.5 Sterilization

6.5.1 The purpose of this requirement is to inform the user of sterilizing methods suitable for the cryosystem(s).

6.5.2 See disclosure requirement in 5.2.4.

6.6 Cryogen Cylinder Connector(s)

They shall meet the requirements of GB 15382 -1994, and Safety Inspection Regulations for Gas Cylinders - AQSIQ Decree NO. 46.

6.7 Safe Current Limits

They shall meet the requirements of GB 9706.1.

_____ END _____