GB

ICS 11.040
C 30

National Standard

of the People's Republic of China

GB/T 14710-2009

Replacing GB/T 14710-1993

Environmental Requirement and Test Methods for Medical Electrical Equipment

医用电器环境要求及试验方法

Issued on: November 15, 2009 **Implemented on: May 1, 2010**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China;

Standardization Administration of the People's Republic of China.

Table of Contents

Foreword

This Standard replaces GB/T 14710-1993 "The Environmental Requirements and Test Methods for Medical Electrical Equipment".

Compared with GB/T 14710-1993, major changes of this Standard are as follows:

— ADD requirements that the transportation test equipment can be used in the transportation test;

— MODIFY requirements for the reference test conditions;

— MODIFY requirements for relevant special circumstances;

— MODIFY requirements and test methods for adaptability to power supply;

— ADD Annex A “Test requirements and inspection items”.

Annex A of this Standard is informative.

This Standard was proposed by the State Food and Drug Administration.

This Standard shall be under the jurisdiction of the National Technical Committee 10 on Medical Electrical Equipment of Standardization Administration of China (SAC/TC 10).

Responsible drafting organization of this Standard: Shanghai Testing & Inspection Institute for Medical Devices.

Main drafters of this Standard: He Jun, and Shi Daifeng.

The previous edition of the standard replaced by this Standard is as follows:

— GB/T 14710-1993.

Environmental Requirement and Test Methods for Medical Electrical Equipment

1 Scope

This Standard specifies the medical electrical equipment's (hereinafter referred to as equipment) environment test purposes, environment grouping, transportation test, adaptability to power supply, reference test conditions, special circumstances, test procedures, test sequence, test requirements, test methods, and detailed-rules that need to be specified when quoting this Standard.

This Standard is applicable to all electrical equipment or electrical systems in conformity with the definitions of medical equipment.

Note: E.g. that medical electrical equipment as defined in GB 9706.1, the electrical equipment for laboratory as specified in GB 4793.1, and medical electrical system as defined in GB 9706.15.

This Standard aims at evaluating the adaptability of equipment to various service environment, and simulated storage and transportation environment.

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.

JTG B01-2003 Technical Standard of Highway Engineering

3 Environment grouping

3.1 Equipment grouping according to climatic environment

Equipment is classified into three basic groups according to the service conditions:

a) Group I

In good environment. Generally, Group I equipment refers to those used in

conditions specified by the manufacturer.

7.3 When the overall test is infeasible, the equipment may be tested partially (dozens of parts), and the manufacturer shall specify which critical component or part is to be tested.

7.4 When some environment test items (e.g. rated operating low temperature test, rated operating high temperature test, rated operating damp heat test) are not applicable to the equipment, the specific test requirements shall be provided by the manufacturer and stated in the product standard.

7.5 When other national or professional standards are applicable to the equipment and state the requirements of environment tests, environment tests shall be carried out according to the requirements of these standards.

8 Test procedures

Generally, each test includes the following procedures:

a) Preconditioning (if necessary);

b) Initial examination and measurement (if necessary);

c) Test;

d) Intermediate examination and measurement (if necessary);

e) Operation test (if necessary);

f) Recovery (if necessary);

g) Final examination and measurement.

9 Test sequence

When carrying out multiple tests for the same equipment successively, the test is generally carried out in the sequence as follows:

a) Rated operating low temperature test;

b) Low temperature storage test;

c) Rated operating high temperature test;

d) High temperature storage test;

e) Rated operating damp heat test;

test chamber (room) for monitoring test conditions;

— Temperature and humidity in the effective work space of test chamber (room) shall remain the corresponding specified values in Table 1, with a temperature difference no more than ± 2°C.

In order to keep required humidity, temperature fluctuation at control point shall be kept within the range of ± 0.5°C.

Note: ± 2°C allowable temperature tolerance shall include measuring absolute error as well as temperature uniformity and fluctuation in effective work space.

— Condensed water in test chamber (room) shall be discharged uninterruptedly. Before purification treatment, the discharged condensed water shall not be used as moisture source water;

— Water used for generating humidity shall have a resistivity not less than 500 Ω·m;

— The temperature in the effective work space inside the test chamber (room) shall remain uniform and approach the values at the control points as much as possible;

— Test equipment shall have such properties and electrical loads as generating no obvious effects to the conditions in the test chamber (room);

— Water condensing on the side or top of test chamber (room) shall not drip on the test sample;

— Test chamber (room) shall be equipped with observation window and lighting device.

10.2 Requirements for the equipment

Requirements for the equipment are as follows:

— The equipment accessories shall be tested together with the equipment, unless otherwise specified in the product standard;

— Equipment shall be put into the test chamber (room) at unpacking, ready-for-use conditions and the normal operating position;

— If the work space of test chamber (room) is not large enough to carry out overall test, if feasible to the equipment, partial machine may form a system with the complete machine for separate test. Test methods shall be specified in the product standard.

Note: this requirement is applicable to the equipment conducts rated operating low temperature

11.2.1 Preconditioning

PLACE the equipment under the reference test conditions to stabilize temperature.

11.2.2 Initial examination and measurement

After the equipment is at stable temperature, switch on the power of the equipment. After preheating, inspect the equipment according to the inspection items specified in the product standard.

11.2.3 Test

PLACE the equipment in the test chamber (room). DISCONNECT the power supply. REDUCE the temperature in the test chamber (room) to the corresponding values specified in Table 1 at an average speed of 0.3°C/min~1°C/min, and keep at the above values for 4 h.

11.2.4 Recovery

At the end of the test, keep the equipment in the test chamber (room), and raise the temperature of test chamber (room) to the reference test conditions. In order to ensure no water condensing in the equipment, it shall reduce the temperature recovery rate, or take other measures without prejudice to temperature test objective to stabilize the equipment temperature. Recovery time shall be specified in the product standard.

11.2.5 Final examination and measurement

After the equipment is recovered within specified time, switch on the power of the equipment. After preheating, inspect the equipment according to the inspection items specified in the product standard.

11.2.6 Details to be specified for quoting this Standard

Details to be specified for quoting this Standard are as follows:

a) Initial examination and measurement items and requirements;

b) Recovery time;

c) Final examination and measurement items and requirements.

11.3 Rated operating high temperature test

11.3.1 Preconditioning

PLACE the equipment under the reference test conditions to stabilize temperature.

11.3.2 Initial examination and measurement

After the equipment is at stable temperature, switch on the power of the equipment. After preheating, inspect the equipment according to the inspection items specified in the product standard.

11.3.3 Test

PLACE the equipment in the test chamber (room). RAISE the temperature in the test chamber (room) to the corresponding values specified in Table 1 at an average speed of 0.3°C/min~1°C/min. SWITCH on or load according to the requirements of the product standard. Test duration only needs to maintain the equipment to reach stable temperature, but shall not be lower than 1 h.

11.3.4 Intermediate examination and measurement

After test duration, immediately inspect the equipment at that temperature according to the inspection items specified in the product standard.

11.3.5 Operation test

KEEP the equipment in the test chamber (room). SWITCH on or load according to the requirements of the product standard. MAINTAIN test chamber (room) at the values specified in Table 1. Operation test duration shall be specified in the product standard but shall not be lower than 4 h.

11.3.6 Final examination and measurement

After operation test duration, immediately inspect the equipment at that temperature according to the inspection items specified in the product standard.

11.3.7 Details to be specified for quoting this Standard

Details to be specified for quoting this Standard are as follows:

a) Initial examination and measurement items and requirements;

b) Test duration;

c) Intermediate examination and measurement items and requirements;

d) Operation test duration;

e) Final examination and measurement items and requirements.

11.4 High temperature storage test

11.4.1 Preconditioning

PLACE the equipment under the reference test conditions to stabilize temperature.

At the end of the test, KEEP the equipment in the test chamber (room), RECOVER the test temperature in the test chamber (room) (at an average speed of 0.3°C/min~1°C/min) and relative humidity to the reference test conditions, and STABILIZE the equipment temperature and humidity. Recovery time shall be specified in the product standard.

11.6.5 Final examination and measurement

After the equipment is recovered within specified time, switch on the power of the equipment. After preheating, inspect the equipment according to the inspection items specified in the product standard.

11.6.6 Details to be specified for quoting this Standard

Details to be specified for quoting this Standard are as follows:

a) Initial examination and measurement items and requirements;

b) Recovery time;

c) Final examination and measurement items and requirements.

11.7 Vibration test

11.7.1 Initial examination and measurement

Before the test, inspect the equipment according to the inspection items specified in the product standard.

11.7.2 Equipment installation

Equipment installation shall meet the following requirements:

— Equipment test direction shall meet the requirements of the product standard;

— If the vibration equipment cannot satisfy tests of more than two axial that is specified in the product standard, it can realize the vibration test of more than two axial by virtue of position change method on the equipment with normal positions variable.

— Equipment installed with indicating head and glassware that cannot be vibrated, which can be removed in the impact test;

— When fixing the equipment under tested, the equipment is generally fastened to the vibrostand at its normal operating position, and its gravity center is located in the central zone of the vibrostand surface;

— It shall avoid fittings (bolt, platen, batten, etc.) for fastening the equipment under

test to generate resonance in the vibration test.

11.7.3 Test

Vibration tests shall be carried out on the vibrostand according to the groups specified in Table 1.

11.7.4 Final examination and measurement

After the test, inspect the equipment according to the inspection items specified in the product standard.

11.7.5 Details to be specified for quoting this Standard

Details to be specified for quoting this Standard are as follows:

a) Initial examination and measurement items and requirements;

b) Test direction;

c) Final examination and measurement items and requirements.

11.8 Impact test

11.8.1 Requirements for the test equipment

Test equipment shall meet the following requirements:

— Impact pulse shall be measured with the acceleration transducer installed at the inspection point. The inspection point shall approach the fixed point of the equipment under test nearest to the center of impact platform surface as much as possible. The acceleration sensor shall be connected to this fixed point through rigid coupling;

— At the inspection point, positive/negative acceleration value vertical to the impact direct shall not exceed 30% of the nominal pulse acceleration value at any time.

11.8.2 Initial examination and measurement

Before the test, inspect the equipment according to the inspection items specified in the product standard.

11.8.3 Equipment installation

Equipment installation shall meet the following requirements:

— FASTEN the equipment on the impact platform surface; equipment test direction shall meet the requirements of the product standard;

heat test								
Damp heat storage test	48	a	Switch-on after the test	b	c	—	c	d
Vibration test	—		Switch-on after the test	Reference test conditions	c	—	c	d
Impact test	—		Switch-on after the test	Reference test conditions	c	—	c	d
Transportation test	—		Switch-on after the test	Reference test conditions	c	—	c	d

[a] RECOVE according to the recovery time specified by the manufacturer.

[b] TEST according to the test conditions specified by the manufacturer.

[c] TEST according to the inspection items specified by the manufacturer.

[d] TEST according to the test voltage specified by the manufacturer.

_____ END _____

This is an excerpt of the PDF (Some pages are marked off intentionally)

------ The End ------