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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 14710-2009

Replacing GB/T 14710-1993

**The environmental requirement and test methods for medical
electrical equipment**

医用电器环境要求及试验方法

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1 Scope

GB/T 14710-2009 is the Chinese national standard on the environmental requirement and test methods for medical electrical equipment, in the field of health care technology. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 15 November 2009 by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardization Administration of China, and has been in force since 1 May 2010. Classification: ICS 11.040, CCS C30. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

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.

3 Environment grouping

3.1 Equipment grouping according to climatic environment Equipment is classified into three basic groups according to the service conditions.

3.2 Equipment grouping according to mechanical environment Equipment is classified into three basic groups according to the transportation and circulation conditions.

3.3 Environment test condition grouping Environment test condition grouping is detailed in Table 1.

4 Transportation test

Under normal exit-factory packaging conditions, the equipment shall be bundled at the back of motor truck according to the mark "This Side UP". In the test, load capacity of the truck shall be 1/3 of the rated load capacity.

5 Adaptability to power supply

5.1 For the equipment that is powered by grid power source, its test voltage is 110% or 90% of the rated value.

5.2 For the equipment that has special requirements to the power supply frequency and the power supply voltage, the operating frequency, voltage working-range, and test methods may be otherwise stated in the product standard.

6 Reference test conditions

Reference value or range and allowable tolerance under reference test conditions are detailed in Table 2.

7 Special circumstances

7.1 If the test condition of test group specified by the manufacturer are not quite consistent with those specified in Table 1, then it shall be conducted according to those specified by the manufacturer.

7.2 If individual influence quantity fails to be tested according to the reference test conditions specified in this Standard, then it shall conduct the test according to the 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);
- 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:

10.1 Requirements for the test chamber (room)

10.1.1 Requirements for the test chamber (room) for temperature test Requirements for the test chamber (room) for temperature test are as follows:

10.1.2 Requirements for the test chamber (room) for damp heat test Requirements for the test chamber (room) for damp heat test are as follows:

10.2 Requirements for the equipment Requirements for the equipment are as follows:

11.1 Rated operating low temperature test

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

11.1.2 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.

11.1.3 Test PLACE the equipment in the test chamber (room). 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. 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.

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

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

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.