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NATIONAL STANDARD OF  
THE PEOPLE'S REPUBLIC OF CHINA

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**YY/T 0291-2007**

**Replacing YY/T 0291-1997**

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**Environmental requirements and test methods for  
medical X-ray equipment**

**医用 X 射线设备环境要求及试验方法**

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## Foreword

This Standard replaces YY/T 0291-1997 *Environmental requirements and test methods for medical x-ray equipment*.

Compared with YY/T 0291-1997, the main changes are as follows:

- rearranged clauses of Standard, according to requirements of GB/T 1.1-2000;
- modified certain clauses of GB/T 14710-1993 in Clause 1 and 4.2 of this Standard;
- added requirements for power supply in GB 9706.1 and GB 9706.3;
- modified requirements for “driving road”, “driving distance” and “driving speed”;
- modified requirements for high temperature storage test from 70°C to 55°C, according to GB/T 14710-1993;
- modified storage recovery time to not less than 4 h or determined by product standard, according to GB/T 14710-1993; modified recovery time in Table A.1 in Annex A;
- specified “this test” as “climatic environment test” in the 1<sup>st</sup> dash in 5.1; deleted examples; modified the 5<sup>th</sup> dash to “it shall perform according to provisions of product standard, if product standard has special requirements for environment test conditions”;
- modified the initial detection, middle or final detection items and requirements in the 1<sup>st</sup> dash in 5.3.1.7 to “specified by product standard”;
- split Figure 1 and Figure 2 into 4 figures, according to different requirements of Group I and Group II; moved text description of relevant test in figure to right above the test sequence segment; deleted electrifying test requirements when temperature changes;
- changed Annex A from informative to normative;
- added instructions on initial detection in Footnote c(1) in Table A.1 of Annex A.

Annex A of this Standard is normative.

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

This Standard shall be under the jurisdiction of National Technical Committee

# Environmental requirements and test methods for medical X-ray equipment

## 1 Scope

This Standard specifies the purpose of environment test, test items, environment group, transport test, adaptability to power supply, standard test conditions, special situations, test procedures, test sequence, test requirements and test methods of medical X-ray equipment.

This Standard is to evaluate the adaptability of equipment under various working environments and stimulation of storage and transport environment.

## 2 Normative references

The following standards contain the provisions which, through reference in this Standard, constitute the provisions of this Standard. For dated references, subsequent amendments (excluding corrections) or revisions do not apply to this Standard. However, the parties who enter into agreement based on this Standard are encouraged to investigate whether the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this Standard.

GB/T 9706.1-1995 *Medical electrical equipment - Part 1: General requirements for safety* (idt IEC 60601:1998)

GB/T 9706.3-2000 *Medical electrical equipment Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators* (idt IEC 60601-2-7:1998)

GB/T 14710-1993 *Environmental requirement and test methods for medical electrical equipment*

## 3 Environmental groups

### 3.1 Classify the equipment according to climatic environment and mechanical environment

Classify the equipment into Group I and Group II according to climatic environment and mechanical environment, as shown in 2.1, 2.2 of GB/T 14710-

During the test, power supply network shall meet requirements of 10.2.2 in GB 9706.1-1995 and 10.2.2a) in GB 9706.3-2000.

## **4.2 Adaptability to power supply**

For equipment of network power supply, the power supply frequency is 50 Hz  $\pm$  1 Hz (if necessary); voltage is 220 V  $\pm$  22  $\pm$  or 380 V  $\pm$  38 V.

For equipment which has special requirements for power supply frequency and power supply voltage, the working range of its frequency and voltage is specified in product standard.

## **4.3 Test requirements**

### **4.3.1 Climatic environment test requirements**

See climatic environment group requirements in Table 1.

### **4.3.2 Mechanical environment test requirements**

See mechanical environment group requirements in Table 1.

### **4.3.3 Transport test requirements**

The equipment shall be tied in the back of heavy-duty truck for transport test according to normal exit-factory packaging conditions.

After the test, carry out the detection to the equipment according to detection items specified in product standard.

## **5 Test methods**

### **5.1 Special situations**

The test shall consider the following special situations:

- climatic environment test is only applicable to those parts or components which might be affected by the stimulated climatic conditions;
- when test for the whole equipment is not feasible, it shall specify in product standard that which key parts or components are available to the test;
- if decomposition or re-assembly is essential to the test, the interval between treatment and test, or the interval between test and inspection shall be determined according to equipment transport, assembly and adjustment time;

- the components which can be opened without tools must be opened and tested together with main components;
- it shall specify in product standard if product standard has special requirements for environment test conditions.

## **5.2 Test specification**

### **5.2.1 Test procedure**

Every test usually contains the following programs:

- a) pre-treatment (when necessary);
- b) initial inspection (when necessary);
- c) test;
- d) middle inspection (when necessary);
- e) recovery (when necessary);
- f) final inspection.

### **5.2.2 Test sequence**

It shall perform according to the provisions in Clause 8 of GB/T 14710-1993.

### **5.2.3 Test requirements**

It shall perform according to the provisions in Clause 9 of GB/T 14710-1993.

## **5.3 Environment test methods**

### **5.3.1 Climatic environment test method**

See temperature test timing diagrams (Figure 1, Figure 2) and humidity test timing diagrams (Figure 3, Figure 4).

- Recovery time: the recovery time of storage test shall not be less than 4 h or specified by product standard.
- Thermal equilibrium: it shall make the equipment or parts reach to thermal equilibrium during inspection. The thermal equilibrium shall not be less than 1 h.

### **5.3.2 Mechanical environment test methods**

#### **5.3.2.1 Vibration test**

It shall perform according to the provisions of 10.7 in GB/T 4710-1993. The parts for test shall at least include the controller, the high voltage transformer assembly (excluding a component with an X-ray tube).

#### **5.3.2.2 Impact test**

It shall perform according to the provisions of 10.8 in GB/T 14710-1993. The parts for test shall at least include the controller, the high voltage transformer assembly (excluding a component with an X-ray tube). The test direction shall simulate the part easy to touch at normal working position.

#### **5.3.2.3 Transport test**

Under normal exit-factory packaging conditions, the equipment shall be tied in the back of heavy-duty truck according to "upward" sign. The load of truck during the test shall be about 1/3 of rated load.

Driving road: secondary road;

Driving distance: 600 km;

Driving speed: 60 km/h ~ 80 km/h.

After the test, detect the equipment according to the inspection items specified by the product standard.

## **6 Test results**

After the aforementioned test procedure is completed, in addition to the functional examination according to 5.3.1.7, it shall also carry out visual inspection on the equipment or parts. There shall be no corrosion, cracks, peeling or other damages to the coating layer. The texts and marks should be clear. Control mechanism should be flexible. There should be no tightening parts or overflowing perfusion.

## **Annex A**

### **(Normative)**

#### **Test requirements and inspection item**

Test requirements and inspection items are listed in the Annex for the modification of the product standard.