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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1621-2018

**Medical carbon dioxide incubator
(English Translation)**

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Table of Contents

Foreword...	3
1 Scope...	4
2 Normative references...	4
3 Terms and definitions...	4
4 Requirements...	5
5 Test methods...	8
6 Labels, packaging identification, instructions for use...	10
7 Packaging, transportation, storage...	12
Appendix A (Normative) Test method for temperature control performance...	13

1 Scope

This standard specifies the terms and definitions, requirements, test methods, labels, packaging identification and instructions for use, packaging, transportation, storage of medical carbon dioxide incubators (hereinafter referred to as incubators).

This standard is applicable to medical carbon dioxide incubators, for culturing biological cells, tissues, bacteria and other human-derived samples, in clinical tests. The upper limit of the incubation temperature of the incubator, to which this standard applies, is 55 °C; the lower limit of the temperature is 3 °C ~ 5 °C higher than the ambient temperature; the control range of carbon dioxide concentration is 0% ~ 20%; the internal volume is 100 L ~ 300 L.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB 4793.1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1.General requirements

GB 4793.6 Safety requirements for electrical for measurement control and laboratory use - Part 6.Particular requirements for laboratory equipment for the heating of materials

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

GB/T 18268.1 Electrical equipment for measurement, control and laboratory use -

EMC requirements - Part 1.General requirements

YY/T 0466.1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1.General requirements

3 Terms and definitions

The following terms and definitions apply to this document.

4.2.3 The incubator shall have a gas sampling port, to facilitate the measurement of gas concentration.

4.2.4 The incubator shall be able to be placed stably; it shall be equipped with a level-adjusting device.

4.3 Temperature display and control performance

4.3.1

The manufacturer shall specify the temperature control range of the incubator.

4.3.2

The temperature display resolution of the incubator shall be 0.1 °C or better.

4.3.3

The temperature display error of the incubator shall be within ± 0.2 °C. When the temperature is set to 37.0 °C, the display error shall be within ± 0.1 °C.

4.3.4

The temperature control error of the incubator shall be within ± 0.5 °C. When the temperature is set to 37.0 °C, the control error shall be within ± 0.3 °C.

4.3.5

The temperature fluctuation of the incubator shall be within ± 0.5 °C. When the temperature is set to 37.0 °C, the temperature fluctuation shall be within ± 0.3 °C.

4.3.6

The temperature uniformity of the incubator shall be within ± 1.0 °C. When the temperature is set to 37.0 °C, the temperature uniformity shall be within ± 0.5 °C.

4.4 Carbon dioxide concentration display and control performance

4.4.1

The manufacturer shall specify the carbon dioxide's concentration control range for the incubator.

4.4.2

The display resolution of carbon dioxide's concentration of the incubator shall be 0.1% or better.

4.4.3

The display error of carbon dioxide's concentration in the incubator shall be within $\pm 0.2\%$.

4.4.4

The carbon dioxide's concentration control error of the incubator shall be within $\pm 1.0\%$. When the carbon dioxide's concentration is set to 5.0%, the carbon dioxide's concentration control error shall be within $\pm 0.5\%$.

4.5 Relative humidity control performance

If applicable, the relative humidity, inside the incubator, shall not fall below the limit, which is specified by the manufacturer after stabilization.

4.6 Noise

When the incubator is working normally, the noise shall be ≤ 65 dB(A).

4.7 Alarm

The incubator shall be able to set the temperature and carbon dioxide concentration. It shall have the following alarm functions.

- a) The alarm for the temperature exceeding the upper limit;
- b) The alarm for the temperature exceeding the lower limit;
- c) The alarm for carbon dioxide concentration exceeding the upper limit;
- d) The alarm for carbon dioxide concentration exceeding the lower limit;
- e) The alarm for the door opening time exceeding the limit.

4.8.1 Temperature recovery time

The temperature recovery time of the incubator shall be ≤ 10 min.

4.8.2 Carbon dioxide's concentration recovery time

The recovery time of carbon dioxide concentration in the incubator shall be ≤ 10 min.

4.9 Thermal insulation performance

The incubator shall have good thermal insulation performance. The secondary temperature difference shall be $\leq 8.0\text{ }^{\circ}\text{C}$.

4.10 Prevention of condensation

The incubator shall control the generation of condensed water. There shall be no condensed water, on the inside of the inner door, the top, side walls and upper half of the rear wall of the working room.

Note: The inner door generally refers to the sealed glass door of the incubator.

4.11 Over-temperature protection

In order to prevent the damage to the cultured samples, which are caused by excessive temperature, the incubator shall have an over-temperature protection function. When the temperature control device fails, it shall be able to ensure that the temperature of the incubator does not exceed the set temperature by $1.5\text{ }^{\circ}\text{C}$.

4.12 Safety

4.12.1

The general requirements for electrical safety of the incubator shall comply with the provisions of GB 4793.1.

At 1 m from the front, rear, left, right directions of the incubator, use the sound pressure level A-level weighting network to make measurement; take the maximum value of 4 points, which shall meet the requirements of 4.6.

5.6 Alarm

Carry out inspection of the actual operation, according to the instruction for use, which is provided by the manufacturer; it shall meet the requirements of 4.7.

5.7.1 Temperature recovery time

According to the test conditions specified in A.1, in the normal working mode of the incubator, the temperature is set to $37.0\text{ }^{\circ}\text{C}$; the carbon dioxide's concentration is set to 0.0%.

After the device shows that the temperature reaches the set temperature, wait for 2 hours.

Quickly open all the doors of the incubator; the door opening angle is at least 90° ; the door opening time is 30 s. Start timekeeping, immediately close the door. When the incubator's temperature recovers to $36.3\text{ }^{\circ}\text{C}$, stop timekeeping. The time interval meets the