
**Traditional Chinese medicine —
Infrared moxibustion-like instrument**

*Médecine traditionnelle chinoise — Instruments de moxibustion
infrarouge*

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Moxibustion is a traditional Chinese medicine external therapy that uses moxa floss made from dried mugwort. It plays an important role in traditional Chinese medicine. The heating effect and infrared spectrum produced during the burning of mugwort has therapeutic effects due to the irradiation of the channels and acupuncture points sites.

Based on traditional Chinese medicine, the infrared moxibustion-like instrument is a medical device that simulates the heating effect and infrared spectrum of burning mugwort to irradiate the acupuncture points and surrounding area of a human body for the treatment of a variety of diseases.

At present, the infrared moxibustion-like instrument is used in many nations and is well known for its therapeutic effect.

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Traditional Chinese medicine — Infrared moxibustion-like instrument

1 Scope

This document specifies the requirements for infrared moxibustion-like instrument as a medical device.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 37, *Instructions for use of products by consumers*

ISO 780, *Packaging — Distribution packaging — Graphical symbols for handling and storage of packages*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

infrared moxibustion-like spectrum

specific radiation spectrum generated by the radiator which simulates the burning of mugwort

Note 1 to entry: It is primarily distributed in the wavelength range of 1 μm to 10 μm .

3.2

infrared moxibustion-like instrument

non-contact traditional Chinese medical device that uses infrared moxibustion-like radiation effects for acupuncture point and local region treatment

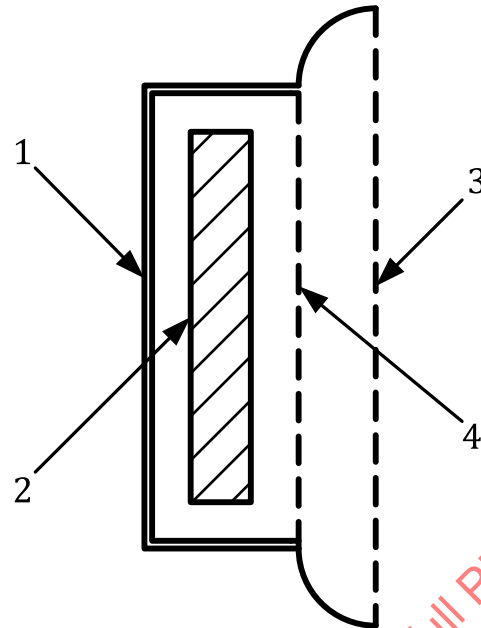
3.3

thermal response time

duration from the moment the device is energized, under indoor conditions to the moment it reaches the rated temperature with a level of stability

4 Structure and composition

The infrared moxibustion-like instrument shall have the structure as shown in [Figure 1](#) and be composed of the infrared heater, the back shield, the front shield, and the working shield.



Key

- 1 back shield
- 2 infrared heater
- 3 front shield
- 4 working shield

Figure 1 — Schematic diagram of infrared moxibustion-like instrument

5 Requirements

5.1 Wavelength range

The infrared moxibustion-like spectrum generated by the infrared heater shall be primarily distributed in the wavelength range of 1 μm to 10 μm .

5.2 Temperature control

5.2.1 The temperature of the infrared heater surface shall be maintained within $\pm 10\%$ of the value specified by the manufacturer (see [6.2.1](#)).

5.2.2 The unevenness of the infrared heater surface temperature shall not exceed 20 % (see [6.2.2](#)).

5.2.3 The maximum surface temperature of front, back and working shields shall not exceed 56 $^{\circ}\text{C}$ (see [6.2.3](#)).

5.3 Time control

5.3.1 Thermal response time shall not exceed 20 min.

5.3.2 The infrared moxibustion-like instrument shall be equipped with an adjustable timer. When reaching the set operating time, the infrared heater shall cease heating immediately, and give an indication through concurrent sound or light indicators. The timer accuracy error shall not exceed $\pm 10\%$ (see [6.3](#)).

5.4 Overheating protection

The infrared heater shall have a thermal protective device and the protective device shall operate reliably.

5.5 Protection against unwanted and excessive radiation hazards

The protection against unwanted and excessive radiation hazards shall be in accordance with the requirements of IEC 60601-1:2005+AMD1:2012, Clause 10.

5.6 Environmental testing requirements

The environmental testing requirements shall be in accordance with the requirements of IEC 60601-1:2005+AMD1:2012, Clause 5.

5.7 Electrical safety requirements

Electrical safety requirements shall be in accordance with the requirements of IEC 60601-1:2005+AMD1:2012, Clause 8.

5.8 Electromagnetic compatibility

The response to electromagnetic disturbances shall be in accordance with the provisions of IEC 60601-1-2.

6 Test methods

6.1 Wavelength range test

Use infrared spectrometer for testing. Test results shall meet the requirements of [5.1](#).

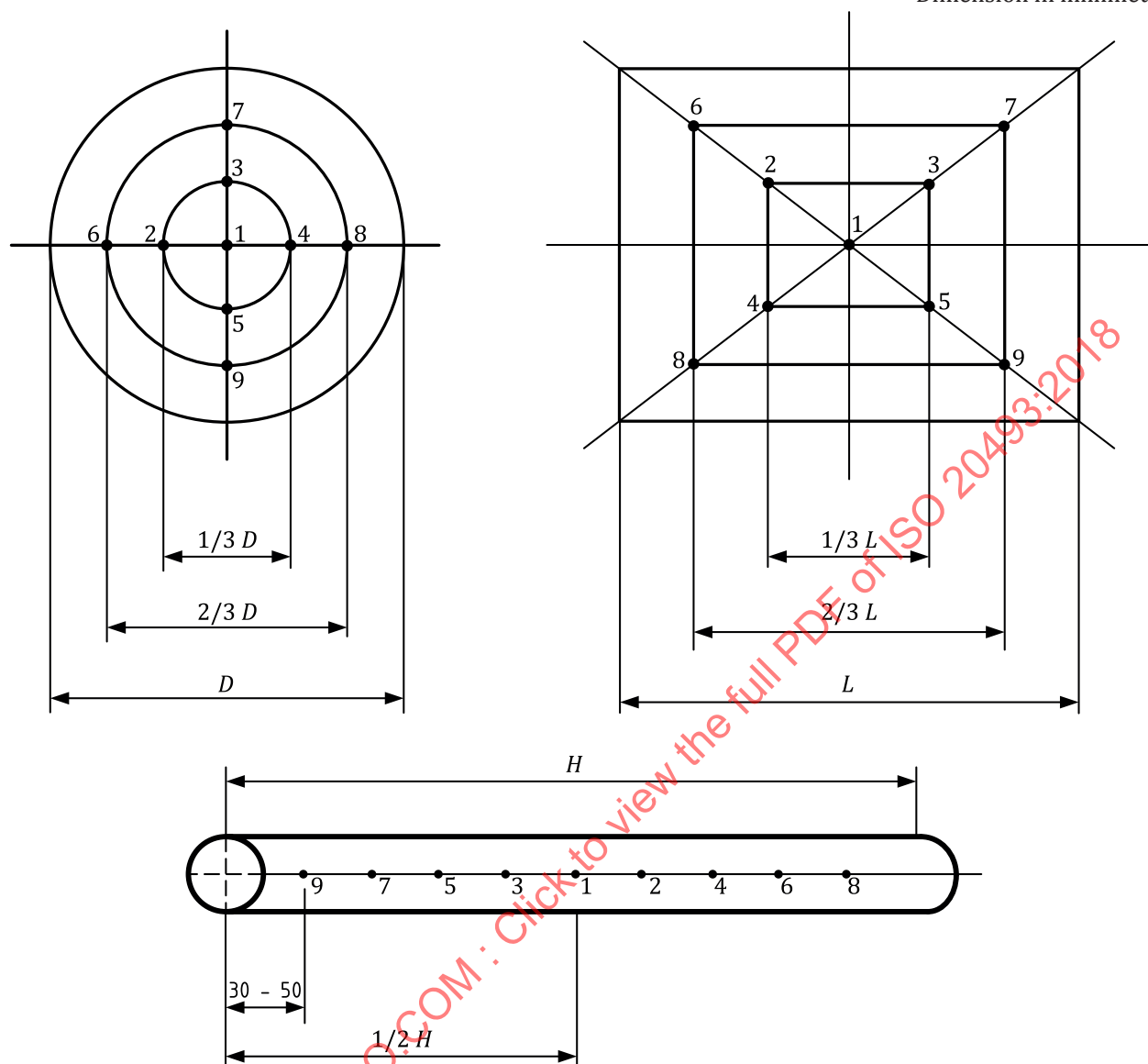
6.2 Temperature control test

6.2.1 Infrared heater surface temperature test

Energize the infrared moxibustion-like instrument for 20 min, then use a thermometer to measure the temperature of the infrared heater surface at nine evenly distributed points selected for testing. The testing points shall be at a distance from screws and holes, and the test points are selected as specified in [Figure 2](#).

Take the mean value of the nine test results. The mean value shall be consistent with the requirement of [5.2.1](#).

Dimension in millimetres

**Key**

- D diameter of the circular infrared heater
 L length of the rectangular infrared heater
 H height of the cylindrical infrared heater

Figure 2 — Test point distribution graph

6.2.2 Temperature unevenness test

Measure the temperature of each test point as specified in [Figure 2](#), and calculate the test results according to [Formula \(1\)](#). The results shall be consistent with the requirement of [5.2.2](#).

$$\xi = \frac{T_{\max} - T_{\min}}{\frac{1}{2}(T_{\max} + T_{\min})} \times 100 \% \quad (1)$$

where

ξ is the temperature unevenness;

$T_{\max}$ is the maximum temperature on the infrared heater surface;

$T_{\min}$ is the minimum temperature on the infrared heater surface.

6.2.3 Shield temperature test

Place the infrared moxibustion-like instrument in the normal position for use. Energize the infrared moxibustion-like instrument for 20 min, then measure the temperature of the front shield, the back shield and the working shield with a thermometer.

The maximal temperature shall be consistent with the requirement of [5.2.3](#).

6.3 Thermal response time test

Use contact temperature measurement method as shown in [Figure 3](#). Measuring points are distributed on the surface of the central portion of the radiator, and its thermal response curve is shown in [Figure 4](#). The results shall be in accordance with the requirements of [5.3.1](#).

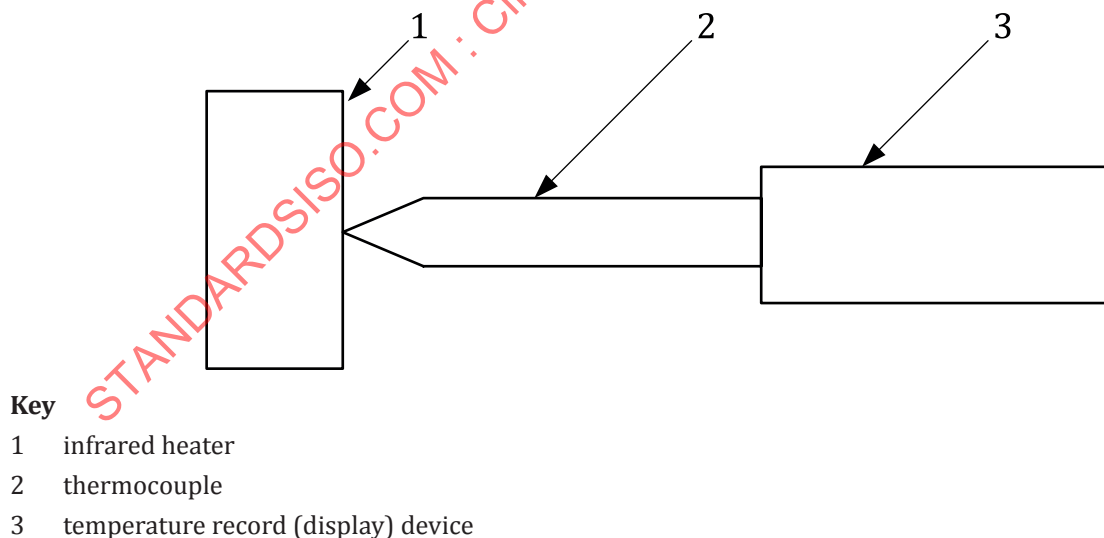
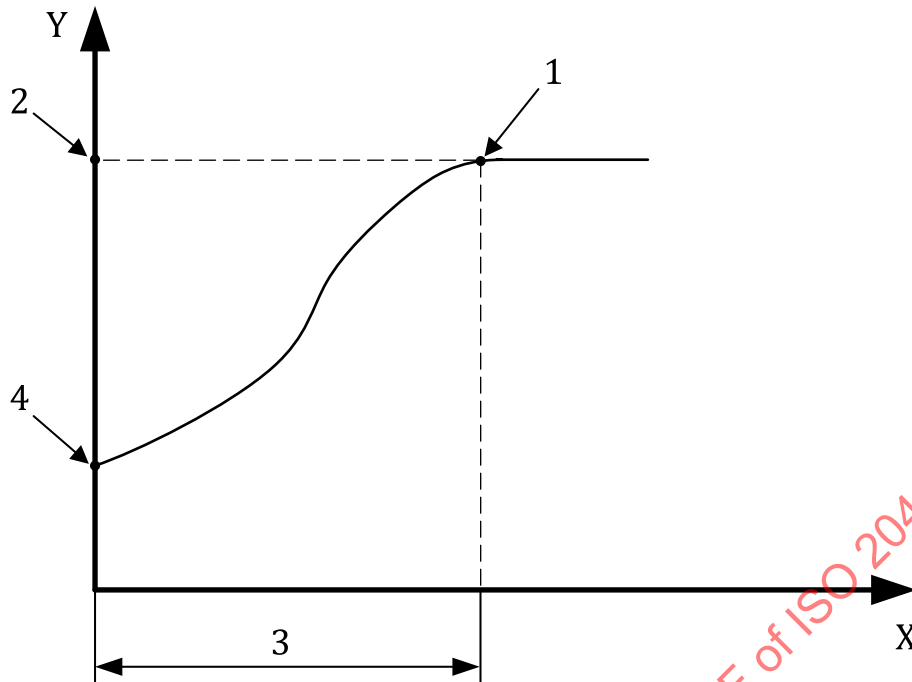


Figure 3 — Sketch map of thermal response test



Key

- X time
- Y temperature
- 1 start point of stabilization
- 2 rated temperature
- 3 thermal response time
- 4 indoor temperature

Figure 4 — Thermal response time curve

7 Labels, instruction, packaging, transportation and storage

7.1 Labels

7.1.1 The symbols to be used with device labels, labelling, and information to be supplied on the package shall comply with ISO 15223-1.

7.1.2 An indelible label shall be attached to the apparatus in an obvious position and shall contain the following information:

- a) production unit;
- b) product name and model;
- c) power connection and the input power;
- d) product serial number;
- e) date of production;
- f) product registration number and product standards.