
**Traditional Chinese medicine —
Therapeutic fumigation devices**

*Médecine traditionnelle chinoise — Dispositifs de fumigation
thérapeutique*

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Published in Switzerland

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of 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 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.

Traditional Chinese medicine — Therapeutic fumigation devices

1 Scope

This document specifies the requirements and test methods for therapeutic fumigation devices, hereafter referred to as the device.

This document does not apply to decoction pieces.

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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*

IEC 60601-2-52, *Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

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 <http://www.electropedia.org/>

3.1

therapeutic fumigation device

device that heats liquid decoction pieces to form steam

Note 1 to entry: The steam is used therapeutically.

3.2

closed therapeutic fumigation device

therapeutic fumigation device which uses an enclosed capsule for treatment

Note 1 to entry: During treatment, the steam and areas of the patient's body undergoing therapeutic fumigation are predominantly isolated from the surrounding environment.

3.3

open therapeutic fumigation device

therapeutic fumigation device which does not use an enclosed capsule for treatment

Note 1 to entry: During treatment, both the steam and areas of the patient's body undergoing therapeutic fumigation are exposed to the surrounding environment.

4 Classification and components

4.1 Classification

The device is classified according to the body area being treated and the fumigation method being applied.

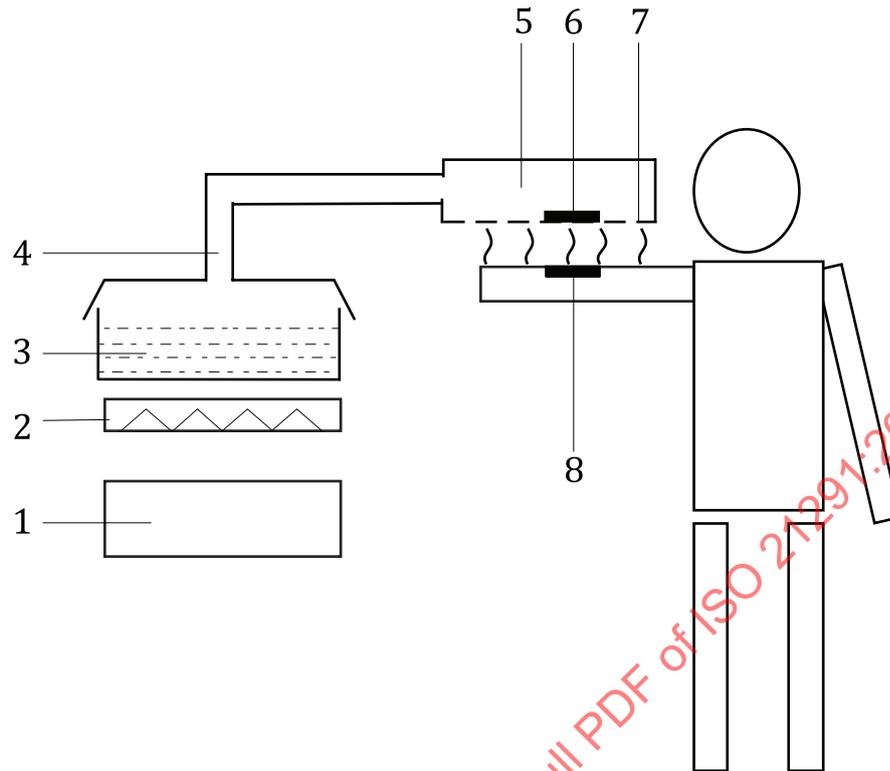
- a) Local type and full-body type can be classified by body area being treated (see [Figure 1](#) and [Figure 3](#)).
- b) Open therapeutic fumigation devices and closed therapeutic fumigation devices, hereinafter referred to as open devices and closed devices, can be classified by the exposure to the environment (see [Figure 1](#) and [Figure 2](#)).

4.2 Components

The device consists of a heating unit, decoction container, steam outlet temperature-sensing unit, control unit, steam pathway and output unit with steam outlet.

For open devices, a skin temperature-sensing unit is also included.

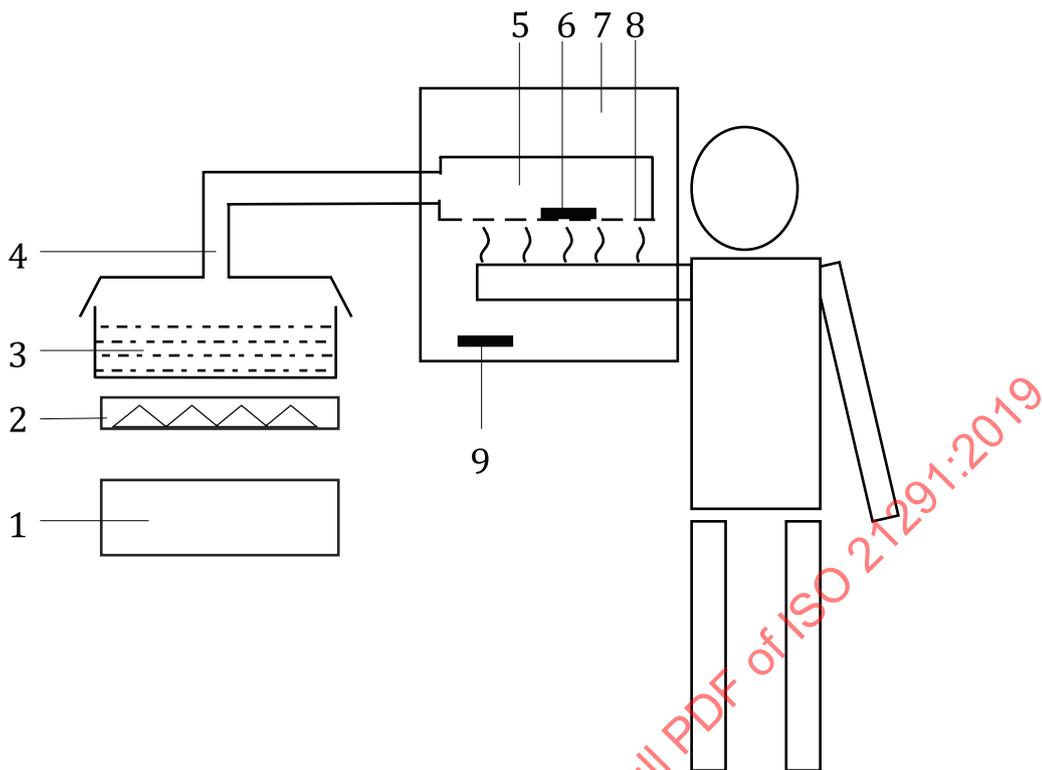
For closed devices, a treatment capsule and a capsule steam temperature-sensing unit are also included. For closed devices involving therapeutic fumigation of the whole body, a support system for the treatment capsule is also included (see [Figures 1](#) to [3](#)).



Key

- 1 control unit
- 2 heating unit
- 3 decoction container
- 4 steam pathway
- 5 steam output unit
- 6 steam outlet temperature-sensing element
- 7 steam outlet
- 8 skin temperature-sensing element

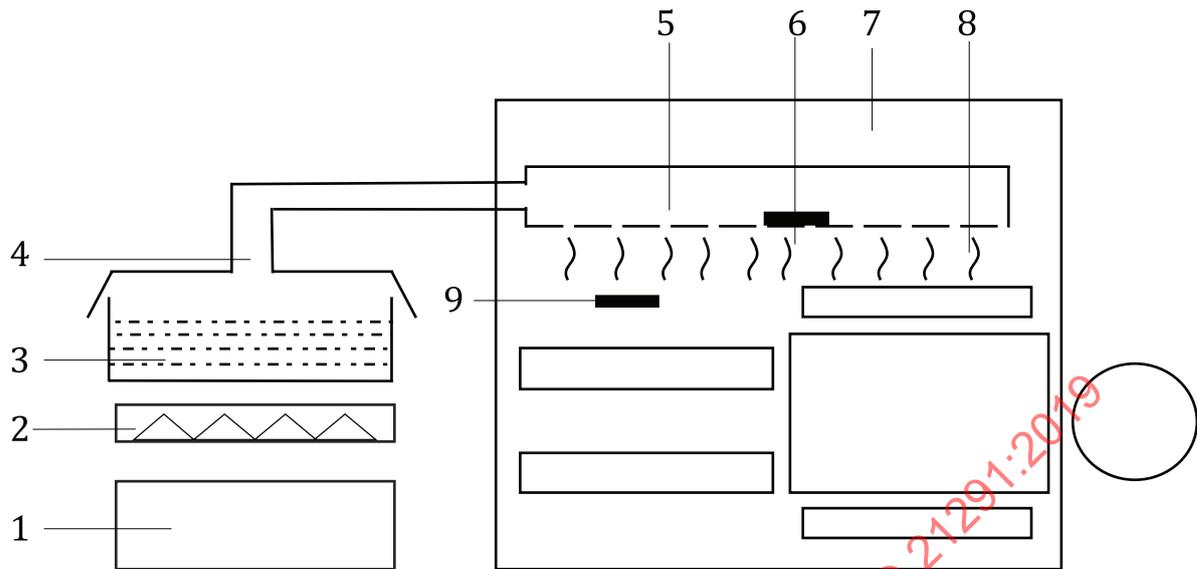
Figure 1 — Open devices



Key

- 1 control unit
- 2 heating unit
- 3 decoction container
- 4 steam pathway
- 5 steam output unit
- 6 steam output temperature-sensing element
- 7 treatment capsule
- 8 steam outlet
- 9 capsule steam temperature-sensing element

Figure 2 — Closed devices for body area fumigation

**Key**

- 1 control unit
- 2 heating unit
- 3 decoction container
- 4 steam pathway
- 5 steam output unit
- 6 steam output temperature-sensing element
- 7 treatment capsule
- 8 steam outlet
- 9 capsule steam temperature-sensing element

Figure 3 — Closed devices for whole body fumigation

5 Technological requirements and test methods

5.1 Temperature protection

5.1.1 Temperature protection at steam outlet

The device shall have an over-temperature protection function at the steam outlet. When the temperature exceeds that specified by the manufacturer, heating of the decoction shall automatically stop and a corresponding auditory alarm signal and/or visual alarm signal shall be produced as specified in IEC 60601-1-8.

Conformity is checked by the following test:

Place a thermometer and the temperature-sensing element of the steam outlet temperature-sensing unit into a constant-temperature water tank, and steadily increase the temperature in the tank until the over-temperature ($\pm 5\%$ of the manufacturer's specified maximum value) protection function is triggered. Record the thermometer's temperature and compare it with the value of over-temperature specified by the manufacturer.

5.1.2 Temperature protection for fumigated body areas

5.1.2.1 Open devices

When the steam temperature at the site undergoing treatment exceeds 45 °C, the device shall automatically stop heating the decoction and a corresponding auditory alarm signal and/or visual alarm signal shall be produced as specified in IEC 60601-1-8.

Conformity is checked by the following test:

Place a thermometer and the temperature-sensing element of the skin temperature-sensing unit into a constant-temperature tank, and steadily increase the temperature until the over-temperature ($\pm 5\%$ of the manufacturer's specified maximum value) protection is triggered.

5.1.2.2 Closed devices

When the temperature in the treatment capsule exceeds 45 °C, heating of the decoction shall be automatically stopped and a corresponding auditory alarm signal and/or visual alarm signal shall be produced as specified in IEC 60601-1-8.

Conformity is checked by the following test:

Place a thermometer and the temperature-sensing element of the capsule temperature-sensing unit into a constant-temperature water tank, and steadily increase the temperature until the corresponding over-temperature ($\pm 5\%$ of the manufacturer's specified maximum value) protection is triggered.

5.2 Temperature set function

The device shall have a set function for steam temperature. The error between the set temperature value and the actual temperature value shall be no more than ± 2 °C.

Conformity is checked by the following test:

Use a thermometer to detect the actual steam temperature at testing points specified by the manufacturer. The error between the detected temperature value and the set temperature value shall meet the requirements.

5.3 Temperature display function

5.3.1 Open devices — skin temperature-sensing unit

The real-time temperature of the areas undergoing therapeutic fumigation shall be displayed. The error between the displayed real-time temperature value and the actual temperature value shall be no more than ± 1 °C.

Conformity is checked by the following test:

Put the skin temperature-sensing unit into a constant-temperature water tank and steadily increase the temperature from the minimum to the maximum temperature as specified by the manufacturer. Throughout the heating process, the error between the real-time displayed temperature value and the actual temperature value of the constant-temperature water tank shall conform with the requirements.

5.3.2 Closed devices — capsule temperature-sensing unit

Real-time temperature in the treatment capsule shall be displayed. The error between the displayed real-time temperature and the actual temperature value shall be no more than ± 1 °C.

Conformity is checked by the following test:

Put the capsule temperature-sensing unit into a constant-temperature water tank and steadily increase the temperature from the minimum to the maximum temperature specified by the manufacturer. Throughout the heating process, the error between displayed temperature value of the device and the actual temperature value of the constant-temperature water tank shall conform with the requirements.

5.4 Temperature consistency in steam capsule

For closed devices, the error of temperature consistency in the treatment capsule shall be no more than ± 3 °C.

Conformity is checked by the following test:

Temperature shall be set in accordance with the manufacturer's instructions. Maximum, middle and minimum temperatures shall be set and tested separately. For each test, select five testing points that are evenly distributed within the treatment capsule. Once the stabilization time specified by the manufacturer has passed, 20 min to 30 min of continuous testing is performed. The temperature at each testing point during the all-time period shall meet the requirements.

5.5 Treatment timing

The error of treatment timing shall be no more than ± 30 s of that specified by the manufacturer. Steam output shall automatically stop and the corresponding information signal(s) shall be produced as specified in IEC 60601-1-8 when the treatment time has finished.

Conformity is checked by simulation of actual use.

5.6 Emergency stop function

The device should have an emergency stop function which can turn off the heating unit and steam output unit in accordance with IEC 60601-1:2005/AMD1:2012. This function cannot be automatically restored. The actuator for the emergency stop function shall be installed in a position that is easily visible and accessible to the user and the operator. The actuator for the emergency stop function shall be coloured red.

Conformity is checked by visual inspection.

5.7 Heating prevention against empty decoction container

When the decoction container is empty, the heating unit shall automatically stop and the corresponding information signal(s) shall be produced.

Conformity is checked by simulation test of the least favourable condition.

5.8 Mechanical strength of patient support system

The support system for the patient shall withstand mass loading of not less than 135 kg in accordance with IEC 60601-2-52.

If the manufacturer specifies that the device is only applicable for use with children, mass loading may be less than 135 kg in accordance with the manufacturer's instructions.

Conformity is checked by the following test:

The support system is placed in the least favourable position as specified in the instructions for use. A mass equal to two times 135 kg or two times the mass loading if specified by the manufacturer is