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Traditional Chinese medicine — General requirements of moxibustion devices

Médecine traditionnelle chinoise — Exigences générales concernant les dispositifs de moxibustion

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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 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*.

This second edition cancels and replaces the first edition (ISO 18666:2015), of which it constitutes a minor revision. The changes to the previous edition are as follows:

— Introduction: the term 'International Standard' changed to 'document' in the first and third paragraphs; improvement of English expression to 'increasing expectations and concerns by patients' and the term 'ensure' changed to 'guide' in the second and third paragraphs;

— Scope: the term 'International Standard' changed to 'document' in the first and third paragraphs; minor editorial change of the term 'uses' to 'use' in the second paragraph;

— Clause 3: addition of the introductory text according to ISO/IEC Directives, Part 2;

— 3.4: deletion of the phrase 'during treatment';

— 4.1.1: improvement of English expression for clarity;

— minor editorial changes.

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

This document specifies the general requirements for safety and quality of moxibustion devices, including the moxibustion materials used in such devices. The safety and quality of both moxibustion devices and materials are closely related to moxibustion safety and quality.

There is a wide variety of moxibustion devices and materials currently available commercially, but there are no standards guiding their manufacture and finishing. Increased interest and use of moxibustion, as well as increasing expectations and concerns by patients regarding moxibustion safety and quality, have given rise to the need to improve safety and quality of moxibustion through implementation of an International Standard.

The primary aim of this document is to guide the safety and quality of moxibustion devices and materials.

Annex A gives guidance on the methods that can be used to determine the moxibustion temperature at the human body surface during treatment using the moxibustion device.

Annex B gives guidance on the method of artificial drying of mugwort leaves by heat.

Traditional Chinese medicine — General requirements of moxibustion devices

1 Scope

This document specifies the general requirements for configuration, materials, performance and safety requirements of moxibustion devices. It also specifies the minimum requirements for moxibustion materials used in moxibustion devices.

It is applicable across a wide range of moxibustion devices that use moxa floss as the main combustion material and can remain on or over the body throughout the moxibustion process. It is applicable to moxibustion devices for both single and repeated usage.

This document does not apply to devices that imitate moxibustion, such as electro-moxibustion and infrared moxibustion devices that do not involve the use of moxa floss. It also does not apply to moxa floss used in direct moxibustion.

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*

ISO/TS 10993-19, *Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

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
moxibustion device
apparatus that uses moxa floss as the main combustion material and is intended for single or repeated usage

EXAMPLE Moxibustion with tube, such as a short moxa roll with a cardboard base and a moxa tube (made of cardboard) that is single-use and developed as an alternative to direct moxibustion.

Note 1 to entry: Moxibustion devices include those accessories as defined by the manufacturers that are necessary to enable the normal use of the moxibustion device.

3.2
moxibustion material
combustible material comprising mainly moxa floss and used in moxibustion

3.3
body of moxibustion device
part of the moxibustion device that is used to hold moxibustion materials and remains on or over the human body throughout the moxibustion process

3.4
moxibustion temperature
temperature at the human body surface when using the moxibustion device

3.5
moxa floss
cotton-like material for moxibustion made from mugwort leaves

3.6
moxa stick
round long stick made of moxa floss, also called moxa roll

Note 1 to entry: Moxa sticks can be in the form of a pure moxa stick, a medicinal moxa stick (with additives) or a smokeless moxa stick.

3.7
medicinal moxa stick
moxibustion with the moxa roll made of moxa and various substances

3.8
fineness of moxa floss
weight of the starting material (mugwort leaves) to the weight of the final product (moxa floss) presented in the form of a ratio

4 Configuration

4.1 Structure

4.1.1 Size and shape

The size and shape of moxibustion devices can vary according to the intended use, such as on a specific point or an area of the human body surface.

4.1.2 Visual inspection

When inspected by normal or corrected-to-normal vision:

a) the surface of the moxibustion device shall not have any obvious defects such as breakages, protrusions, dents or rust that can cause accidental cuts or injuries to the user;

b) moxibustion devices for repeated use shall have a temperature-adjusting mechanism or other appropriate arrangement to maintain moxibustion at an appropriate temperature;

c) except for moxibustion with tube, the body of the moxibustion device shall ensure that the removal of ash is easy and shall be well ventilated to facilitate combustion; it should also contain:

   1) a mounting base or support that can hold the stick (s) firmly;

   2) a barrier or other safety arrangement to prevent ash or ember from falling onto the surface of the human body.

4.2 Expression of dimensions

The moxibustion device shall be easy to manipulate in size and applicable to various parts of the human body. The dimensions of the moxibustion device shall be expressed in centimetres and specified as length × breadth × height for a rectangular device, or diameter × height for a circular device.

EXAMPLE 1 For a rectangular device, 15 cm × 10 cm × 8 cm.

EXAMPLE 2 For a circular device, 4 cm × 6 cm.

5 Materials

5.1 General

The materials of the moxibustion device in contact with the human body surface shall be assessed for their biological safety and physico-chemical, morphological and topographical (PMT) characteristics in accordance with ISO 10993-1 and ISO/TS 10993-19.

5.2 Body of moxibustion devices

The frame of moxibustion devices can be made of materials such as wood, plastic, metal or cardboard. It shall have properties of low flammability and be fire-retardant to prevent fire hazards during moxibustion. The material of the component of the moxibustion device that comes into contact with the human body surface shall have low thermal conductivity and shall not cause skin sensitivity or irritation.

5.3 Moxibustion materials

5.3.1 Moxa floss

5.3.1.1 Moxa floss shall be processed from mugwort leaves of the *Artemisia* genus, including *Artemisia argyi*, *Artemisia princeps*, *Artemisia vulgaris* and other *Artemisia* species that have proven to be equally suitable.

5.3.1.2 Moxa leaves shall be stored under a dry and well-ventilated environment for at least 1 year or stored for 3 months and be artificially dried by heating before processing into moxa floss.

5.3.1.3 The minimum fineness of moxa floss should be in the ratio of 3:1, where 3 kg of mugwort leaves are processed into 1 kg of moxa floss.

5.3.1.4 Moxa floss shall not contain any foreign matter, such as metal shavings, which may contaminate the moxa floss during production and processing.

5.3.1.5 The quality and safety of moxa floss can be determined by visual or physical inspection and the use of other inspection equipment, such as a metal detector.

5.3.2 Moxa sticks

5.3.2.1 The external wrapping used for moxa sticks made using moxa floss shall be material manufactured from mulberry leaves or other combustible paper.

5.3.2.2 The external wrapping used for moxa sticks made using moxa floss shall:

a) have a similar burning rate to moxa floss;

b) not emit any harmful substances during combustion;

c) not be torn easily.

5.3.2.3 The adhesive material used in moxa sticks shall not be toxic or produce harmful substances during combustion.

6 Moxibustion temperature

6.1 General

The test methods to determine the moxibustion temperature are stated in Annex A.

6.2 Moxibustion with tube

The maximum temperature shall not exceed 60 °C.

6.3 Moxibustion devices other than moxibustion with tube

Except for moxibustion with tube, the moxibustion temperature of the moxibustion device shall be adjustable and the maximum temperature achievable during use of the device shall not exceed 51 °C.

6.4 Moxibustion devices for repeated use

For moxibustion devices for repeated use, there shall be a temperature-adjusting mechanism to maintain the temperature under the user's thermal pain threshold.

7 Safety requirements

7.1 General

7.1.1 Moxibustion devices for repeated use shall have a barrier or other safety arrangement to prevent any ash, ember or spark from falling onto the human body surface.

7.1.2 The body of the moxibustion device shall be able to remain on or over the human body surface in a stable manner throughout the moxibustion process to prevent the device from falling over or being dislodged.

7.1.3 The material of the part of the moxibustion device that comes into contact with the human body surface shall have poor thermal conductivity to ensure the temperature is within the acceptance limits of the moxibustion recipient.

7.1.4 Moxibustion devices that remain on the human body surface shall be either for single use or repeated use. For repeated use, they shall have a disposable bottom or protective lining on the areas that come into contact with the human body surface to prevent any form of direct-contact infection or transmission.

7.2 Environmental protection

Necessary measures that can protect the environment shall be identified and employed. Moxibustion devices can include a protective installation, use better quality moxa floss or have additives added to the moxa floss to reduce the amount of smoke.

8 Packaging

8.1 Primary packaging

8.1.1 The moxibustion device and moxibustion materials shall be sealed in a primary package.

8.1.2 The storage of the primary package shall be in dry, clean and adequately ventilated conditions.

8.2 Secondary packaging

8.2.1 One or more primary packages shall be packaged in a secondary package for the moxibustion device and moxibustion materials.

8.2.2 The secondary package shall be sufficiently robust to protect the contents during handling, transport and storage.

9 Labelling

9.1 Primary label

The labels, symbols and information on the package shall comply with ISO 15223-1. The primary package shall be marked with at least the following information:

a) the name, trademark or logo of the manufacturer and/or supplier of the moxibustion device;

b) a description of the contents of the moxibustion device, including the designated metric size in accordance with 4.2;

c) the lot number, prefixed by the word "LOT", and/or date of manufacture of the moxibustion device;

d) the country of origin of mugwort leaves, year of harvesting of mugwort leaves and fineness of moxa floss.

If the product is made by artificial drying by heating, replace the labelling of the year of harvesting of the mugwort leaves with "this product is artificially dried by heating".

If the country of origin of the mugwort leaves is different from where the moxa material is processed and the product is made from more than two materials, label all countries of origin of the mugwort leaves and label as "mixed product" instead of the year of harvesting.

9.2 Secondary label

The labels, symbols and information on the package shall comply with ISO 15223-1. The secondary package shall be marked with at least the following information:

a) the name, address and trademark of the manufacturer and/or supplier of moxibustion device;

b) a description of the contents of the moxibustion device, including the designated metric size in accordance with 4.2;

c) the lot number, prefixed by the word "LOT", and/or date of manufacture of moxibustion device;

d) the certified number of the moxibustion device;

e) information for handling, storage and transport;

f) warning to check the integrity of each primary package before use, such as "Do not use if package is damaged."

10 Transport and storage

10.1 The transportation requirements shall comply with the order contract.

10.2 The moxibustion devices shall be stored in a clean, dry and well-ventilated environment. Keep out of direct sunlight, avoid storing at high temperatures and in high humidity. The moxibustion devices should have sufficient protection from accidental damage.

11 Instructions for use

The following information shall be provided by the manufacturer for each moxibustion device:

a) instructions for safe performance of the moxibustion device, including storage and maintenance;

b) parts list defining all significant components and accessories;

c) advice for safe use of the moxibustion device:

   1) the maximum temperature that can be obtained during moxibustion;

   2) conditions that are not suitable for moxibustion, such as “people with sensory disturbances or allergies to smoke should avoid using or exercise caution when using the moxibustion device”;

   3) that moxibustion devices are not recommended to be used in an environment fitted with smoke alarms;

   4) the possibility that localized small blisters or skin irritation may appear even under routine or intended use of the moxibustion device and that medical attention should be obtained where appropriate;

   5) that the moxibustion device should be administered and used under the direction or supervision of a qualified practitioner.

Annex A
(informative)

Test methods to determine the moxibustion temperature

A.1 General

Moxibustion temperature refers to the temperature at the human body surface during treatment using the moxibustion device. A change in the temperature is a direct reflection of the thermal characteristics of moxibustion and the heat profile exhibits dynamic changes throughout the moxibustion process. The temperature during moxibustion should be maintained between the perception of the onset of warmth and thermal comfort. The temperature during moxibustion should not reach thermal pain threshold at any area across the body.

A.2 Test method

A.2.1 Contact temperature measurement

A.2.1.1 Principle

The contact measurement method is to place the temperature sensor on the bottom of the moxibustion device that is in contact with the human body surface, such that the temperature sensor and the human body surface are in their respective thermodynamic equilibrium states.

The purpose of this test is to determine the maximum moxibustion temperature achievable during intended use of the moxibustion device.

A.2.1.2 Apparatus and conditioning environment

The typical apparatus consists of a temperature sensor in the form of a digital thermometer or thermocouple. Temperature measurement should be conducted in a well-ventilated room at a temperature of (23 ± 2) °C and a relative humidity of (55 ± 5) % and shall be continuously monitored. The apparatus, test sample and test subject shall be conditioned in the same room at the aforementioned temperature conditions and relative humidity for a certain period of time, until the conditions stabilize prior to testing.

A.2.1.3 Procedure

The temperature sensor is placed on the bottom of the moxibustion device that is in contact with the human body surface. The temperature corresponding to a thermal perception is monitored and recorded. The heat profile during moxibustion is also observed concurrently.

A.2.1.4 Advantages

The contact measurement method has the following advantages:

a) high accuracy as the temperature sensor is in direct contact with the bottom of the moxibustion device, hence the reading is not affected by any medium;

b) the process is simple and convenient.

A.2.1.5 Disadvantages

The temperature sensor needs to reach the same thermodynamic state as the bottom of the moxibustion device, which requires time for thermal conduction to occur. This may result in a delay in temperature measurement.

A.2.2 Temperature measurement using the skin phantom model

A.2.2.1 Principle

Temperature measurement using the skin phantom model is made with various materials such as agarose, gelatin and acrylamidehydrogel. The temperature sensor is placed on the surface of the model or buried in the model during moulding. The moxibustion device is then placed on the sensor to measure the temperature.

The purpose of this test is to determine the maximum moxibustion temperature achievable during intended use of the moxibustion device.

A.2.2.2 Apparatus

The typical apparatus consists of a temperature sensor in the form of a digital thermometer or thermocouple that can be buried in the skin phantom model, automatic combustion device and sealed cage to minimize the effects from draft.

Temperature measurement shall be conducted in a well-ventilated room at a temperature of (23 ± 2) °C and a relative humidity of (55 ± 5) % and shall be continuously monitored. The apparatus, test sample and model shall be conditioned in the same room at the aforementioned temperature conditions and relative humidity for a certain period of time, until the conditions stabilize prior to testing. Care should be taken not to dry the skin phantom model during stabilizing.

A.2.2.3 Procedure

The tip of the temperature sensor is placed on the skin phantom model surface or buried in the model during moulding. The moxibustion device is then placed on the sensor. The temperature corresponding to a thermal perception is monitored and recorded. The heat profile during moxibustion is also observed concurrently.

The heat profile shall be calculated using Formula (A.1):

$$\max Ts = \Delta T\rho \times \frac{S\rho \times D\rho}{Ss \times Ds} + Ts \tag{A.1}$$

where

$\Delta T\rho$ is the thermal change of the phantom surface;

Ts is the normal temperature of the skin surface;

$\max Ts$ is the maximum temperature of the skin surface;

$S\rho$ is the specific heat of the phantom;

Ss is the specific heat of the skin = 3 500 J/(kg × °C);

$D\rho$ is the density of the phantom;

Ds is the density of the skin = 1,121 kg/m^3.