
**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.

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The committee responsible for this document is ISO/TC 249, *Traditional Chinese medicine*.

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Introduction

This International Standard 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 growing patients' expectations and concerns 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 International Standard is to ensure 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.

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Traditional Chinese medicine — General requirements of moxibustion devices

1 Scope

This International Standard 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 uses 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 International Standard 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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* <https://standards.iteh.ai/catalog/standards/sist/a1be3f1-c550-4dac-b99e-6c59625bf5e4/iso-10993-1-2016>

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

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

3 Terms and definitions

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

3.1

moxibustion device

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

EXAMPLE Moxibustion with tube is a type of moxibustion device, 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 device includes 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 during treatment 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, medicinal moxa stick (with additives) or 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

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4.1 Structure

4.1.1 Size and shape

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The sizes and shapes of moxibustion devices can be different to perform moxibustion at a single point or over 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 could 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, be well ventilated to facilitate combustion and it should also contain the following:
 - 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 human body. The dimensions of the moxibustion device shall be expressed in centimetres and specified as length × breadth × height for a rectangular shaped device, or diameter × height for a circular shaped device.

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

EXAMPLE 2 For a circular shaped device, \varnothing 4 cm \times 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 from occurring in moxibustion. The materials of the component of the moxibustion device that comes in 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 is 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 meet the following requirements:

- a) to have a similar burning rate as moxa floss;
- b) not to 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.