
**Traditional Chinese medicine —
General requirements for smokeless
moxibustion devices**

*Médecine traditionnelle chinoise — Exigences générales relatives à la
moxibustion sans fumée*

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Foreword

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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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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 one of the major traditional medical therapies. Smokeless moxibustion is an emerging form of moxibustion therapy. However, smokeless moxibustion devices have different forms or are composed of the materials used in conventional moxibustion without additional materials or processing needed for their safe use.

The standardization of smokeless moxibustion devices will enhance the efficacy and improve the quality and safety of moxibustion treatments using smokeless moxibustion devices, especially in regard to biocompatibility with the human body and indoor air quality.

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Traditional Chinese medicine — General requirements for smokeless moxibustion devices

1 Scope

This document specifies general requirements to ensure the performance and safety of smokeless moxibustion devices. It covers smoke density, moxibustion temperature, noxious gas and test methods for smokeless moxibustion devices.

This document is applicable to any combustion-type device that claims to provide smokeless moxibustion.

This document does not apply to devices that imitate moxibustion, such as electro moxibustion and infrared moxibustion devices.

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 2248, *Packaging — Complete, filled transport packages — Vertical impact test by dropping*

ISO 5659-2:2017, *Plastics — Smoke generation — Part 2: Determination of optical density by a single-chamber test*

ISO 7240-2, *Fire detection and alarm systems — Part 2: Fire detection control and indicating equipment*

ISO 7240-7:2018, *Fire detection and alarm systems — Part 7: Point-type smoke detectors using scattered light, transmitted light or ionization*

ISO/TS 7240-9, *Fire detection and alarm systems — Part 9: Test fires for fire detectors*

ISO 15011-2, *Health and safety in welding and allied processes — Laboratory method for sampling fume and gases — Part 2: Determination of the emission rates of carbon monoxide (CO), carbon dioxide (CO₂), nitrogen monoxide (NO) and nitrogen dioxide (NO₂) during arc welding, cutting and gouging*

ISO 16000-4, *Indoor air — Part 4: Determination of formaldehyde — Diffusive sampling method*

ISO 16000-6, *Indoor air — Part 6: Determination of volatile organic compounds in indoor and test chamber air by active sampling on Tenax TA sorbent, thermal desorption and gas chromatography using MS or MS-FID*

ISO 18666:2015, *Traditional Chinese medicine — General requirements of moxibustion devices*

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 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.

[SOURCE: ISO 18666:2015, 3.1]

**3.2
smokeless moxibustion device**

moxibustion device (3.1) intended to reduce the smoke and bad odour caused by combustion

Note 1 to entry: Carbonized moxa floss, carbonized mugwort leaves or other carbonized materials may be used as the main combustion material.

**3.3
smoke density
aerosol density**

number of particulates per volume as described operationally by one of two parameters:

- m , an absorbance index, used in the testing of smoke detectors using scattered or transmitted light;
- y , a dimensionless variable, used in the testing of smoke detectors using ionization

Note 1 to entry: These parameters are not concentrations, strictly speaking, but represent values that are proportional to the concentration and have been shown to function in lieu of a true concentration value for the purposes of these tests.

[SOURCE: ISO 7240-1:2014, 2.1.5, modified — The order of the terms has been switched so that "smoke density" is the preferred term.]

**3.4
carbon monoxide
CO**

gas formed by the combination of one atom of carbon and one atom of oxygen

Note 1 to entry: In its chemical formula, C stands for carbon and O for oxygen. For the purposes of this document, the CO level is always expressed in terms of mass fraction of CO in air.

[SOURCE: ISO 12133:2011, 3.1]

**3.5
volatile organic compound
VOC**

organic compound where the boiling point is in the range from (50 to 100) °C to (240 to 260) °C

[SOURCE: ISO 12219-2:2012, 3.4]

3.6 total volatile organic compound tVOC

sum of *volatile organic compounds* (3.5) sampled on Tenax TA^{®1)} and eluting between and including *n*-hexane and *n*-hexadecane, detected with a flame ionization detector (tVOC_{FID}) or mass spectrometric detector (tVOC_{MS}), and quantified by converting the total area of the chromatogram in that analytical window to toluene equivalents

[SOURCE: ISO 12219-2:2012, 3.5, modified — Note 1 to entry has been removed.]

3.7 moxibustion smoke

visible suspension of solid and/or liquid particles in gases, which is generated by the use of a *moxibustion device* (3.1)

3.8 aldehyde

organic compounds containing formyl families

Note 1 to entry: Formaldehyde, acetaldehyde and vanillin are members of aldehyde families.

4 Test methods for smokeless moxibustion devices

4.1 General

A device that makes moxibustion smoke under the density levels described in [Annexes B](#) and [C](#) may be labelled as a smokeless moxibustion device.

Testing for smokeless moxibustion devices shall conform to a suitable test method, e.g. the test methods outlined in [Annexes B](#) and [C](#). Test methods may be modified in accordance with the shape or size of each product.

4.2 Smoke density test

Follow the smoke density test in accordance with [Annex B](#).

4.3 Smoke generation test

Follow the smoke generation test in accordance with [Annex C](#).

5 Safety requirements

5.1 Noxious gas

5.1.1 General

Smokeless moxibustion devices shall emit the following materials within the range described in World Health Organization (WHO) guidelines.

The analysis of chemical concentration shall be performed in accordance with the following test methods or by any other method that proves to be equally suitable. The chamber and sampling methods may be modified in accordance with the various shapes or sizes of smokeless moxibustion devices.

NOTE A summary of the recommended values is given in [Annex A](#).

1) Tenax TA[®] is the trade name of a product supplied by Buchem. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

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5.1.2 Carbon monoxide (CO)

For the determination of CO, test methods shall be in accordance with ISO 15011-2.

5.1.3 Nitrogen dioxide (NO₂)

For the determination of NO₂, test methods shall be in accordance with ISO 15011-2.

5.1.4 Total volatile organic compounds (tVOCs)

For the determination of tVOCs, test methods shall be in accordance with ISO 16000-6.

5.1.5 Aldehyde

For the determination of aldehyde, test methods shall be in accordance with ISO 16000-4.

5.2 Moxibustion temperature

Test methods and requirements for the moxibustion temperature of smokeless moxibustion devices shall be in accordance with ISO 18666:2015, 6.1, 6.2 and 6.3.

5.3 Device materials

Materials of the smokeless moxibustion device that could come into contact with the human body shall be in accordance with ISO 18666:2015, Clause 7.

6 Packaging and labelling

6.1 General

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The requirements of packaging and labelling shall be in accordance with ISO 18666. However, the use of the statement "smokeless" shall follow [6.2](#).

6.2 Smokeless statement

Products conforming to the requirements of this document (see [Clause 4](#)) may only use the statement "smokeless" on the primary or secondary package.

6.3 Protection of products

Packaging shall be designed to protect the smokeless moxibustion device from being crushed. A protective device shall keep more than 90 % of products safe in accordance with the impact test given in ISO 2248.

NOTE The test method can be replaced with the test methods given in ISO 2244 or ISO 7965-1.

Annex A (informative)

WHO guidelines for indoor air quality

A.1 General

Various chemicals are contained in the smoke produced during moxibustion. Although smokeless moxibustion devices are designed to reduce noxious chemical compounds, the concentration of noxious chemicals should be controlled. A summary of the WHO guidelines for indoor air quality from References [7], [8] and [9] is provided in Table A.1.

Table A.1 — Summary of WHO guidelines

	Particulate matter		VOCs			Aldehydes	CO[7] (mg/m ³)	NO ₂ [7][8] (µg/m ³)
	PM ₁₀ [8] (µg/m ³)	PM _{2.5} [8] (µg/m ³)	Benzene ^a [7]	Styrene[9] (µg/m ³)	Toluene[9] (mg/m ³)	Formaldehyde[7] (mg/m ³)		
15 min	—	—	—	—	—	—	100	—
30 min	—	—	—	70	1	0,1	—	—
1 h	—	—	—	—	—	—	35	200
8 h	—	—	—	—	—	—	10	—
24 h	50	25	—	—	—	—	7	—
7 d	—	—	—	260	0,26	—	—	—
1 year	20	10	—	—	—	—	—	40

^a Benzene is carcinogenic to humans and no safe level of exposure can be recommended.

A.2 Particulate matter (PM)

A.2.1 PM₁₀

The annual mean concentration of PM₁₀ shall not be over 20 µg/m³.

The 24-h concentration of PM₁₀ shall not be over 50 µg/m³.

A.2.2 PM_{2.5}

The annual mean concentration of PM_{2.5} shall not be over 10 µg/m³.

The 24-h concentration of PM_{2.5} shall not be over 25 µg/m³.

A.3 Volatile organic compounds (VOCs)

A.3.1 Benzene

Benzene is carcinogenic to humans and no safe level of exposure can be recommended.