INTERNATIONAL STANDARD

ISO 21366

First edition
2019-05

Traditional Chinese medicine — General requirements for smokeless moxibustion devices

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

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

Reference number
ISO 21366:2019(E)

© ISO 2019

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

© ISO 2019 – All rights reserved

Contents

Page

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

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.

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

 © ISO 2019 – All rights reserved

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.

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

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/

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

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]

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

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.

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

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 (NO_2)

For the determination of NO_2, 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

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.

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

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		
	PM_{10}[8] ($\mu g/m^3$)	**$PM_{2.5}$**[8] ($\mu g/m^3$)	**Benzene**[7] a	**Styrene**[9] ($\mu g/m^3$)	**Toluene**[9] (mg/m^3)	**Formaldehyde**[7] (mg/m^3)	**CO**[7] (mg/m^3)	**NO_2**[7][8] ($\mu g/m^3$)
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 PM_{10}

The annual mean concentration of PM_{10} shall not be over 20 $\mu g/m^3$.

The 24-h concentration of PM_{10} shall not be over 50 $\mu g/m^3$.

A.2.2 $PM_{2.5}$

The annual mean concentration of $PM_{2.5}$ shall not be over 10 $\mu g/m^3$.

The 24-h concentration of $PM_{2.5}$ shall not be over 25 $\mu g/m^3$.

A.3 Volatile organic compounds (VOCs)

A.3.1 Benzene

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

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

A.3.2 Styrene

The concentration of formaldehyde shall not be over 70 µg/m^3 in a 30 min average.

A.3.3 Toluene

The concentration of toluene shall be below 0,26 mg/m^3 in a 7 days average.

The concentration of toluene shall be below 1 mg/m^3 in a 30 min average.

A.4 Formaldehyde

The concentration of formaldehyde shall not be over 0,1 mg/m^3 in a 30 min average.

A.5 Carbon monoxide (CO)

The average concentration of CO shall not be over 7 mg/m^3 in 24 h, 10 mg/m^3 in 8 h, 35 mg/m^3 in 1 h and 100 mg/m^3 in 15 min.

A.6 Nitrogen dioxides (NO_2)

The annual mean concentration of NO_2 shall not be over 40 µg/m^3.

The 1-h concentration of NO_2 shall not be over 200 µg/m^3.

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

Annex B
(normative)

Test method for moxibustion smoke density measurement

B.1 General

This annex describes a test method for moxibustion smoke density, including the measuring apparatus, test conditions and formulae for calculating smoke density.

For other test methods for moxibustion smoke density, refer to ASTM E662-15a:2015 and ISO 5659-2:2017.

Test methods may be modified in accordance with the shape or size of each product and any other method that proves to be equally suitable.

B.2 Measuring apparatus for smoke density

B.2.1 General

The measuring apparatus for moxibustion smoke density shall be constructed with a chamber and a photometric system.

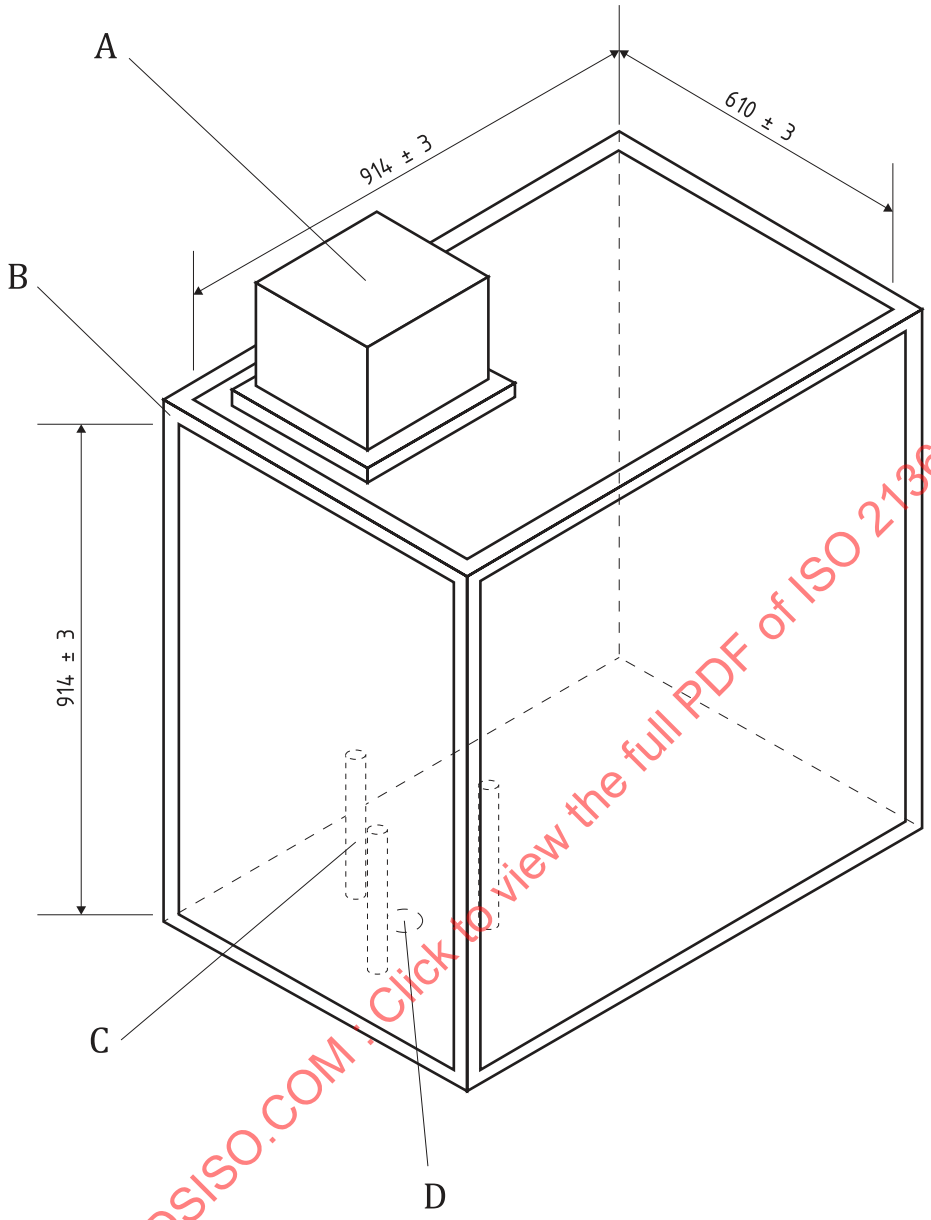
B.2.2 Smoke chamber

A smoke chamber with attached apparatus is modified from the chamber described in ASTM E662 -15a:2015 by the different shape of the specimen. The modified smoke chamber may not have furnace, burner and related apparatus. It shall contain a tray for the moxibustion device and it may combust manually (see Figure B.1).

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

Dimensions in millimetres



STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

Key

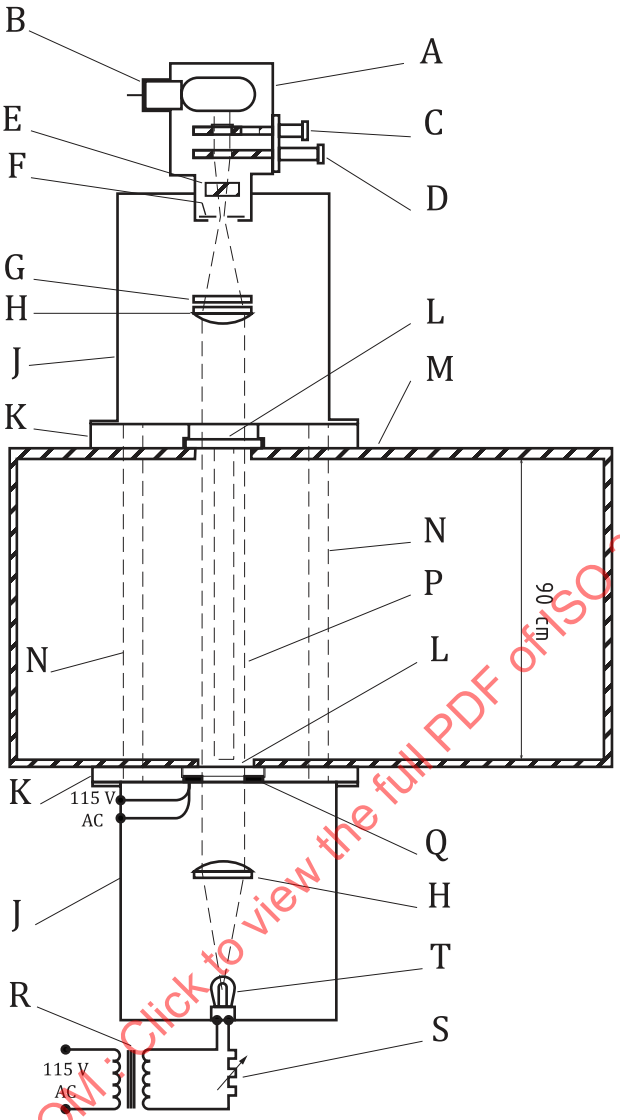
A photomultiplier tube housing
B chamber
C optical system rods
D optical system floor window

Figure B.1 — Smoke density chamber

B.2.3 Photometer

The photometer shall be attached to the smoke chamber to measure the smoke density optically (see Figure B.2).

© ISO 2019 – All rights reserved



Key

A	photomultiplier housing	K	optical system platforms (2)
B	photomultiplier tube and socket	L	optical windows (2)
C	upper shutter blade, with ND2 filter over one aperture	M	chamber
		N	alignment rods (3)
D	lower shutter blade, with single aperture	P	parallel light beam, 37,5 mm diameter
E	opal diffuser filter	Q	optical window heater, silicone fibreglass 50 W/115 V
F	aperture disk	R	regulated light source transformer, 115/125 V-6 V
G	neutral density compensating filter (from a set of 9)	S	adjustable resistor, light source, adjusted for 4 V
H	lens, 7 dioptre (2)	T	light source
J	system housing (2)		

Figure B.2 — Structure of photometer

B.3 Test conditions

The test conditions shall follow ISO 5659-2:2017.

NOTE In this document, the test time is limited to 10 min.

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

B.4 Formulae for calculating smoke density

B.4.1 General

The smoke density shall be calculated in accordance with Formulae (B.1) to (B.4).

B.4.2 Smoke density

$$D_s = 132 \log_{10} \frac{100}{T} \tag{B.1}$$

where

T is transmissivity of light;

D_S is the smoke density;

132 is the constant value induced from the condition of the combustion chamber (see ISO 5659-2).

B.4.3 Maximum smoke density

$$D_m = 132 \log_{10} \frac{100}{T_r} \tag{B.2}$$

where T_r is transmissivity of light (maximum range).

B.4.4 Correction factor of smoke density

$$D_c = 132 \log_{10} \frac{100}{T_c} \tag{B.3}$$

where T_c is transmissivity of light (clear beam).

B.4.5 Correction value of smoke density

$$D_s = D_m - D_c \tag{B.4}$$

B.4.6 Data selection

The maximum density of moxibustion smoke shall be measured more than three times. The median value shall be used out of measured values.

B.5 Limit values of moxibustion smoke density

B.5.1 General

For the limit value in this annex, refer to ISO 5659-2:2017, Annex B.

B.5.2 Limit value

As a result of the test, the smokeless moxibustion device shall not produce smoke with an optical density over 150 ± 10.

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved

Annex C
(normative)

Test method for moxibustion smoke generation

C.1 General

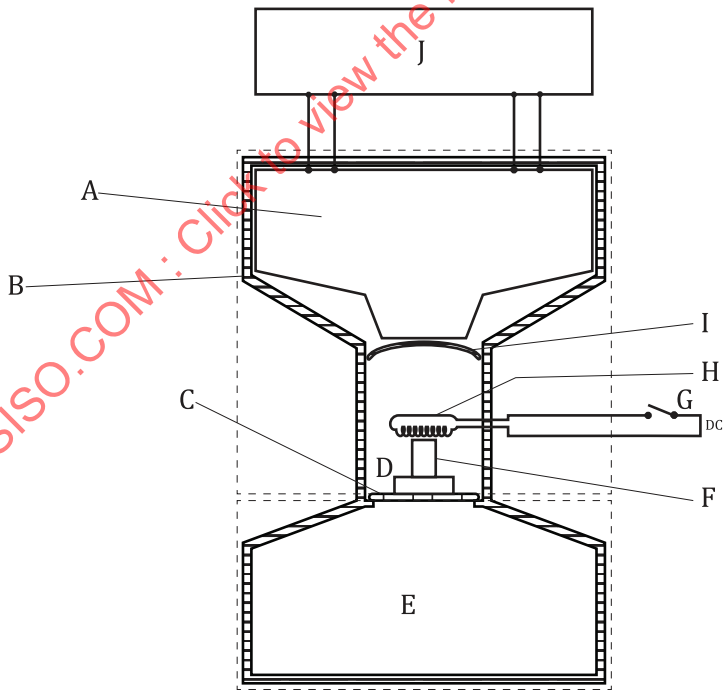
This annex describes a test method for moxibustion smoke generation, including the measuring apparatus, test conditions and formulae for calculating smoke generation.

Test methods may be modified in accordance with the shape or size of each product and any other method that proves to be equally suitable.

C.2 Measuring apparatus for smoke generation

C.2.1 General

The measuring apparatus for moxibustion smoke density shall be constructed with a chamber and a fire alarm system. The fire alarm system may be included in the chamber (see Figure C.1).



Key

A	smoke detector (light/ionization)	E	CO_2 area	I	heat protection shell
B	chamber housing	F	sample	J	fire alarm system
C	mesh board	G	switch		
D	smoke area	H	electric combustion apparatus		

Figure C.1 — Smoke generation chamber

STANDARDSISO.COM : Click to view the full PDF of ISO 21366:2019

© ISO 2019 – All rights reserved