
**Traditional Chinese medicine —
Electric heating moxibustion
equipment**

*Médecine traditionnelle chinoise — Équipements de moxibustion par
chauffage électrique*



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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*.

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 — Electric heating moxibustion equipment

1 Scope

This document specifies general requirements for electrical heating moxibustion equipment.

It is not applicable to infrared moxibustion equipment covered by ISO 20493 and smokeless moxibustion devices covered by ISO 21366.

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

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

IEC 60601-1, *Medical electric equipment — Part 1: General requirements for basic safety and essential performance*

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

electric heating moxibustion equipment

device that delivers the heat which is applied to the skin or acupoints

3.2

heating unit

part that delivers heat energy to the skin or acupoints through a touching pad

Note 1 to entry: This device is used to heat the moxibustion substance.

3.3

moxibustion pad

replaceable component which can be placed in a heating unit

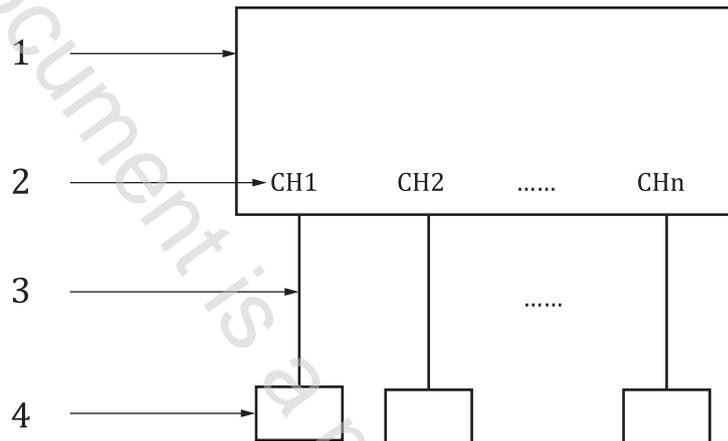
Note 1 to entry: In some cases, a moxibustion pad is not required. When required, the moxibustion pad is intended to be in direct contact with the body areas where the treatment is applied.

4 Components

The device consists of a control unit (including mains part) and the output components as shown in [Figure 1](#).

The output component includes the output line and a heating unit, which is placed on the skin or acupoint. If the device has a moxibustion pad, it shall be placed in the moxibustion heating unit during use. One end of the moxibustion pad is attached to the body.

The equipment may have one or more output components. For the wireless type, the equipment might not have an output line.



Key

- 1 control unit (including mains part)
- 2 independent channels
- 3 output line
- 4 heating unit with moxibustion pad inside

Figure 1 — Electric heating moxibustion equipment

5 Requirements and test methods

5.1 Preparation

Prepare the test according to the requirement of IEC 60601-1. Before testing, maintain the equipment in a stable position at the test site with the power off for at least 24 h. Prior to commencing testing, preheat and run the equipment according to the instructions for use.

5.2 Heating unit temperature

The test method of the heating unit temperature of this equipment shall conform with ISO 18666.

If the equipment has more than one heating unit, the temperature for each unit shall be adjusted independently. The set temperature range of the heating unit is specified by the manufacturer and the error shall be no more than ± 2 °C. The upper limit of temperature shall be no more than 60 °C.

If the equipment has a temperature indicator, the error of the displayed temperature displayed shall be no more than ± 2 °C.

Check conformity as follows: