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Traditional Chinese medicine — Electric heating moxibustion equipment

Médecine traditionnelle chinoise — Équipements de moxibustion par chauffage électrique

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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.

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

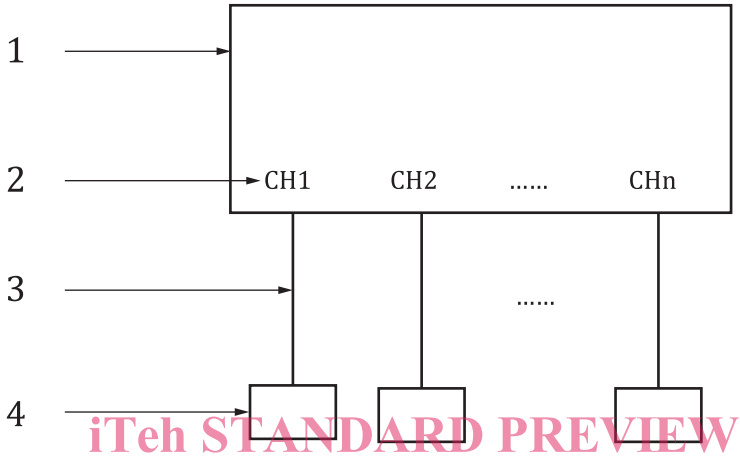
Note 1 to entry: In some cases, a moxibustion pad is not required. When required, the moxibustion pad is intended to be in direct contact with the body areas where the treatment is applied.

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:

The temperature of the heating unit shall be set in accordance with the manufacturer's instructions. Maximum, middle and minimum temperatures shall be set and tested separately. Once the stabilization time specified by the manufacturer has passed, measure the temperature at the centre of the heating unit's surface with a reference thermometer and then compare it with set values. Either the displayed value or the set value shall meet the value.

5.3 Timing function

The equipment shall be provided with a timing device. The range shall be 1 min to 60 min and the difference of timing shall be no more than ± 5 %.

Check conformity as follows:

Adjust the timer of the equipment to the maximum set value. Using a stopwatch to test the real-time value, start the equipment and the stopwatch at the same time. When the pre-set timer stops, stop the stopwatch synchronization and record the real-time value of the stopwatch.

5.4 Safety requirements

The equipment shall include the following functions:

a) a manual stop function;

b) a temperature indication function in the heating unit. When the heating unit's temperature exceeds 60 °C, an audio and/or visual signal shall be produced;

c) an over-temperature protection device which is independent of the heating unit temperature control system and which can automatically turn off the heating unit. This equipment cannot be automatically reset. The value of the over-temperature protection shall be specified by the manufacturer.

Check conformity as follows:

For a) and b), operation of the equipment is performed according to the instructions for use and checked by visual inspection.

For c), simulate the single fault conditions of the heating unit temperature control system. Increase the temperature of the heating unit to check the function of over-temperature protection equipment.

5.5 Biocompatibility

Conformity shall be confirmed if records provided by the manufacturer establish that the biocompatibility of the materials selected has been demonstrated. The biocompatibility of parts intended to come into contact with patients shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Check conformity using the methods and procedures in ISO 10993-1.

5.6 Instructions for use

The instructions for use shall meet the requirements of IEC 60601-1 and include, but not be limited to, the following information:

a) a warning about the risk of burns to the patient's skin if the upper limit of heating unit temperature exceeds 60 °C;

b) the geometric requirements of the moxibustion pad, such as shape, configuration and dimensions appropriate for the equipment;

c) instructions indicating how to connect the heating unit and moxibustion pad;

d) a warning that the equipment must be used with caution on patients with low heat sensitivity;

e) a warning that the device must not be used on patients with skin ulceration;

f) instructions that the equipment must be used under the supervision of medical or other healthcare personnel at all times;

g) the recommended heating unit temperature and treatment duration;

h) if there is not a real-time temperature indicator on the heating unit, the corresponding heating unit temperature from the value dialled/set on the machine;

i) the preparation and preheating time of equipment.

Conformity is achieved by inspecting the documents from the manufacturer.

6 Package

6.1 Primary packaging

6.1.1 Electrical heating moxibustion equipment shall be sealed in a primary package.

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

6.2 Secondary packaging

6.2.1 One or more primary packages shall be packaged in a secondary package for the electrical moxibustion equipment.

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

7 Labelling

7.1 General

The symbols to be used on the package shall conform with ISO 15223-1.

7.2 Primary and secondary packages

The primary and secondary packages shall be marked with at least the following information:

a) the name, trademark or logo of the manufacturer and/or supplier, if applicable;

b) a description of the contents;

c) the lot number, prefixed by the word “LOT”, and/or date of manufacture;

d) the expiry date.

Bibliography

[1] ISO 20493, *Traditional Chinese medicine — Infrared moxibustion-like instrument*

[2] ISO 21366, *Traditional Chinese medicine — General requirements for smokeless moxibustion devices*