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温控红外灸疗垫

Thermo-controlled Infrared Moxibustion-like Pad

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Preface

Attention is drawn to the possibility that some of the elements of this standard may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights.

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The drafting procedures of this standard were consistent with *SCM 0001-2009 Working Regulation for Formulation and Publication of Standard* and document of *2011 (No. 20) Implementation of Technical Standards of the Specialized Committee* released by World Federation of Chinese Medicine Societies (WFCMS).

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Thermo-controlled infrared moxibustion-like pad

1 Scope

This standard specifies the terms and definitions, specifications and models, technical requirements, inspection methods and rules, and signs, packaging, transportation and storage of thermo-controlled infrared moxibustion-like pad.

This standard is applicable to the non-washed thermo-controlled infrared moxibustion-like pad.

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 20493:2018 *Infrared moxibustion-like instruments*

IEC 60601-1-2:2014 *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances-Requirements and tests*

IEC 60601-1-11:2015 *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

ISO 780:2015 *Packaging-Distribution packaging-Graphical symbols for handling and storage of packages*

ISO/IEC Guide 37:2012 *Instructions for use of products by consumers*

GB 4343.2-2009 *Electromagnetic compatibility requirements for household appliances, power tools and similar appliances Part 2: immunity from disturbance*

GB 4706.1-2005 *Safety of electrical appliances and similar apparatus Part 1: General requirements*

GB 4706.8-2008 *Safety of electrical appliances and similar apparatus Special requirements for electric blankets, electric pads and similar flexible heating apparatus.*

GB/T 4654-2008 *General specification for non-metallic matrix infrared radiation heaters*

GB/T 7287-2008 *Test method for infrared radiation heater*

3 Terms and definitions

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

3.1 Regular work

A state that inputting AC voltage 220 V, pad is tiling, no folding, and with a certain covering (quilt or human body) put on it.

3.2 Heating element

An element composed of silica gel electric heating wire, non-magnetic boundary electric heating wire, shielded electric heating wire, etc.

3.3 Flexible component

An apparatus or detachable enclosure made of heating elements and all other auxiliary materials.

3.4 Thermo-controlled infrared moxibustion-like pad

A kind of pad that can produce infrared radiation wavelength in the range of 1~10 μm by heating to a certain extent with the similar effect of moxibustion therapy.

Note: Thermo-controlled infrared moxibustion-like pads include cervical spine pad, lumbar pad, and mattress.

4 Specifications and models nomenclature

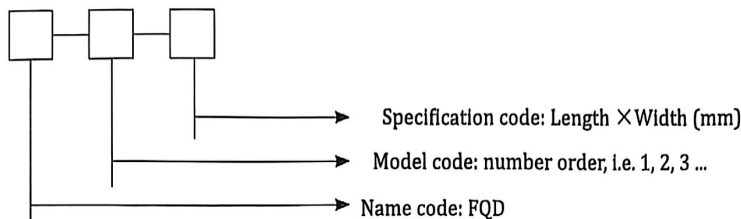
4.1 Specifications

The specifications of thermo-controlled infrared moxibustion-like pads shall comply with the provisions of Table 1.

Table 1. Product specifications

Types	Size (mm)		
	Length	Width	Thickness
Single-bed mattress	1900, 2000, 2030, 1500	1000, 1200, 550	Thickness \geq 50
Twin-bed mattress	1900, 2000, 2030	1350, 1500, 1530	
		2000	1800
Cervical spine pad	450, 420, 410, 400, 390, 350	330, 300, 210, 190, 140	
Lumbar pad	1280, 900, 700, 550	550, 460, 450, 350	
Tolerance	± 5		

4.2 Models nomenclature



Example:FQD-1 (1900mm×1500mm) is for the thermo-controlled infrared moxibustion-like pad of the type of FQD-1, with the size of 1900mm×1500mm.

5 Technical requirements

5.1 Appearance

The surface shall be flat without any damage.

5.2 Temperature control

5.2.1 The temperature rise is no less than 17K and the maximum average temperature of the product surface is no more than 45°C, under specified test conditions.

5.2.2 The error in temperature control shall be no more than ±5°C.

5.2.3 The adjustable temperature of the product is 20~60°C and it has 12-hour automatic power-off function.

5.3 Shield against radio and television signal interference

The products have the function of shielding harmful electromagnetic waves and shall comply with GB 4343.2-2009.

5.4 Electrical safeties

General requirements for electrical safeties shall comply with IEC 60601-1-11:2015.

5.5 Remote infrared emissivity

Remote infrared emissivity shall be no less than 0.83.

5.6 Range of infrared radiation wavelength (μm)

The product can form a heating area with remote infrared ray with a wavelength of 1μm to 10μm when heated.

6 Test methods

6.1 Temperature rise

The test shall be in accordance with the requirements in GB 4706.1-2005 and the test results shall meet the requirements of 5.2 in GB 4706.1-2005.

6.2 Shield of radio interference and television interference

The test shall be in accordance with the requirements in GB 4343.2-2009 and the test results shall meet the requirements of 5.3 in GB 4343.2-2009.

6.3 Electrical safeties

The test shall be in accordance with the requirements in IEC 60601-1-11:2015 and IEC 60601-1-2:2014 and the test results shall meet the corresponding requirements.

6.4 Rated power

Rated power shall be tested by electrical parameters tester.

6.5 Remote infrared emissivity

The test shall be in accordance with the requirements in GB/T 4654-2008 and GB/T 7287-2008 and the test results shall meet the corresponding requirements in 5.5.

6.6 Range of infrared radiation wavelength

The test shall be in accordance with the requirements in GB/T 4654-2008 and GB/T 7287-2008 and the test results shall meet the corresponding requirements in 5.6.

7 Verification norm

7.1 Classification

It is divided into outgoing quality control test and type test.

7.2 Outgoing quality control test

7.2.1 The products shall be inspected by the quality control department of the manufacturer and only with a certificate of conformity can the qualified products leave the factory.

7.2.2 The product shall be tested one by one during the outgoing quality control test and the manufacturer shall specify the test items in the corresponding standard of registered product. The results of the test includes two type, qualified and unqualified. The unqualified products shall retest after reparation.

7.3 Type test

7.3.1 Type test includes all the technical requirements of this standard.

7.3.2 The type test is normally conducted once a year under normal conditions. Type tests shall be carried out in any of the following cases:

- a) when trial production finalization for product produced in other factory;
- b) when the production is discontinued for over half a year;
- c) when there are major changes in design, process and materials;
- d) when there is a quality accident or a major quality fluctuation;
- e) When the quality supervision agency of the different nations requests type test.

7.3.3 Type test sample

The sample shall be randomly selected from the qualified products after outgoing quality control test.

7.3.4 Items in type test

If the product is qualified all items, then it is qualified in the type test. Mass production shall not be carried out if the type test fails.

8 Sign, label, instructions, packaging, transportation and storage

8.1 Sign

8.1.1 Sign shall be in accordance with the requirements in ISO 15223-1.

8.1.2 The products shall have at least the following signs:

- a) Manufacturer's name and trademark;
- b) Product name and model;
- c) Supply voltage;
- d) Power frequency;
- e) Input power;
- f) Product registration number.

8.1.3 The external package shall include at least the following signs:

- a) Manufacturer's name;
- b) Manufacturer's address;
- c) Product name and model;
- d) Gross and net weight;
- e) Size;
- f) Quantity;
- g) Manufacturing Date;
- h) Product registration number;
- i) Product standard number;

j) The words and signs on the box shall not be blurred during a period of time.

8.2 Label

The product qualification label shall include the following information:

- a) Manufacturer's name;
- b) Product name;
- c) Test date;
- d) Tester's code.

8.3 Instructions

Instructions shall include the following information:

- a) Main performance figures;
- b) Application scope;
- c) Storage and transportation conditions;
- d) Installing requirement;
- e) Usage and Precautions;
- f) Rules of safety use;
- g) Troubleshooting;
- h) Maintenance;
- i) Warnings;
- j) After-sales service commitment.

8.4 Packaging

8.4.1 Packaging shall have reliable moisture-proof and dust-proof measures to ensure the insulation and protection of the layer of products.

8.4.2 The outgoing products shall include complete products, instructions, product qualification label, warranty card, etc.

8.4.3 The packages shall include the manufacturer's full name, product name, product model, product specification, trademark, product quantity, name and address of the retailer, packing box shape and size, signs and labels including "Handle with care" or "abstaining from moistness", date of departure, etc.

8.5 Transportation

The transport mode is agreed upon by the manufacturer and the customer. Covering and necessary protection during transportation is to prevent heavy pressure in certain parts and rains.

8.6 Storage

The product shall be stored in a dry, well-ventilated warehouse, with the environment temperature of -10~40°C and the relative humidity of no more than 80%, and without corrosive gas.



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