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Traditional Chinese Medicine — Acupoint magnetotherapy plaster for single use

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 Material.....	2
4.2 Appearance.....	2
4.3 Magnetic strength.....	2
4.3.1 Magnetic field strength.....	2
4.3.2 Magnetic field leakage.....	2
4.4 Adhesion strength.....	2
4.5 Geometric.....	2
4.5.1 Geometric dimension of plaster.....	2
4.5.2 Geometric dimension of permanent magnet.....	2
4.6 Biological evaluation.....	3
5 Test methods	3
5.1 Material.....	3
5.2 Appearance.....	3
5.3 Magnetic strength.....	3
5.3.1 Magnetic field strength.....	3
5.3.2 Magnetic field leakage.....	3
5.4 Adhesion strength.....	3
5.5 Geometric.....	3
5.5.1 Geometric dimension of plaster.....	3
5.5.2 Geometric dimension of permanent magnet.....	3
6 Packing and Labelling	4
6.1 Packing.....	4
6.2 Labelling.....	4
7 Instructions for use	4
Biography	5

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.

Introduction

Acupoint magnetotherapy is a method of using a magnetic field to act on the acupuncture points of the human body. It is also called "magnetic acupoint therapy", "meridian magnetic field therapy", "acupoint magnetic bead therapy", etc.

The use of natural magnets for the treatment of diseases has long been recorded in ancient China. *Shen Nong's Materia Medica* has officially used magnets as medicine and pointed out: "The magnetism (ci) stone is pungent and cold, and it is responsible for arthralgia, rheumatism, and pain in the limbs, in addition to fever and deafness. *Compendium of Materia Medica* further expands the therapeutic effect of magnets, proposing "nourish kidneys, strengthen muscles and bones, nourish essence and eliminate troubles, improve joints, relieve dementia, rat fistula, cervical nucleus soreness, paediatric convulsions, condensate and drink water. It also makes people have a child".

There are also records of the use of magnets to treat diseases in the new editions of modern prescriptions, *Medical Philosophy, Chinese and Western Records* and other books. In 1962, a trial of ferrite magnets, which are many times stronger than natural magnets, was applied to the acupuncture points to treat diseases.

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Traditional Chinese Medicine — Acupoint magnetotherapy plaster for single use

1 Scope

This document specifies the requirements and test methods of the single-use acupoint magnetotherapy plaster.

For device containing other medicine ingredients, the document only applies to magnetotherapy function of the device.

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 8124-1, *Safety of toys — part 1: safety aspects related to mechanical and physical properties*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 29862, *Self adhesive tapes — Determination of peel adhesion properties*

IEC 60404-8-1, *Magnetic materials — Part 8-1: Specifications for individual materials — Magnetically hard materials*

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3 Terms and definitions

For the purpose 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

plaster

tape with adhesive substance applied on one side which can fix the permanent magnet and can attached on the surface of body skin

3.2

permanent magnet

magnet that retains its magnetism after being removed from an external magnetic field

[SOURCE: ISO 1069:1973, 1.1.2, modified]

3.3

acupoint magnetotherapy plaster

plaster containing permanent magnet, which is attached to acupoint of the body skin

3.4

magnetic field strength

vector quantity obtained at a given point by subtracting the magnetization from the magnetic flux density divided by the magnetic constant

3.5

magnetic flux density

vector field quantity (B) which exerts on any charged particle having velocity (v) a force (F) equal to the product of the vector product $v \times B$ and the electric charge (Q) of the particle

Note 1 to entry: The magnetic flux density (B) is sometimes called “magnetic field”, risking confusion with the magnetic field strength (H).

3.6

magnetic field leakage

critical magnetic field strength not acting on the direction of the human body

4 Requirements

4.1 Material

For the permanent magnet, the principal constituents in accordance with IEC 60404-8-1 shall be stated by the manufacturer.

4.2 Appearance

The permanent magnet shall be without sharp edges and burrs.

4.3 Magnetic strength

4.3.1 Magnetic field strength

The range that can be set as the target value of maximum magnetic field strength for magnetotherapy plaster is 35 mT to 400 mT. The error shall not exceed 5%. The manufacturer shall provide the information of the maximum magnetic field strength and flux shape on the package and/or in the instructions for use.

4.3.2 Magnetic field leakage

If the average maximum magnetic field exceeds 60 mT at a distance of 5 mm from the surface of the magnetotherapy plaster, this value shall be stated by the manufacturer.

4.4 Adhesion strength

The adhesive force between the plaster and the permanent magnet shall be greater than 10 times the weight of the permanent magnet itself.

4.5 Geometric

4.5.1 Geometric dimension of plaster

The geometric dimension of plaster shall be more than double that of the permanent magnet.

4.5.2 Geometric dimension of permanent magnet

The minimum diameter of the permanent magnet shall not be less than 1 mm. If the permanent magnet has a special shape, its minimum cross-sectional area shall be no less than 1 mm².

4.6 Biological evaluation

The biocompatibility of contact part which is intended to attach to the body skin shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

5 Test methods

5.1 Material

The material used for permanent magnet shall be checked by IEC 60404-8-1 and the statement of the material shall be provided by the manufacturer.

5.2 Appearance

The exterior of the permanent magnet shall be checked by visual inspection.

5.3 Magnetic strength

5.3.1 Magnetic field strength

According to the intended use of the product, magnetic field strength at the position and direction that shows the strongest value among the target magnetic pole positions shall be measured using a Gauss meter. The position and direction of the product's maximum magnetic field strength shall be in accordance with the product description. The value shall meet the requirement specified in [4.3.1](#).

NOTE 1 (Tesla) = 10^4 (Gauss).

5.3.2 Magnetic field leakage

A magnetotherapy plaster shall be attached to the centre of a spherical case made of a hollow non-magnetic material. At this time, the distance from the surface of the permanent magnet in the magnetotherapy plaster to all surfaces of the spherical case shall be within 5mm. The magnetic field strength shall be measured using a Gauss meter at 6 points where three axes passing through the centre of the sphere and perpendicular to each other meet the surface of the sphere. The largest of the measured values at 6 points shall be found.

5.4 Adhesion strength

The adhesion strength between plaster and human skin shall be tested according to the procedures in ISO 29862.

The adhesion strength between plaster and permanent magnet shall be tested by putting ten identical permanent magnets under the plaster.

5.5 Geometric

5.5.1 Geometric dimension of plaster

The geometric dimension of the plaster shall be checked by measurement of geometric dimension of plaster and permanent magnet. If the shape of permanent magnet is irregular, choose the maximum projected area.

5.5.2 Geometric dimension of permanent magnet

The geometric dimension of the permanent magnet shall be checked by inspection of measuring points specified by the manufacturer.

6 Packing and Labelling

6.1 Packing

- a) packaging of acupoint magnetotherapy plaster shall be sealed so as to prevent opening due to pressure, light shock or mishandling;
- b) packaging shall, once opened, be unable to be sealed again;
- c) package shall be ensured with adequate protection of the contents during normal handling, transit and storage.

6.2 Labelling

The symbols to be used with device labels, labelling and information to be supplied on the package shall comply with ISO 15223-1. The package shall be marked with at least the following information:

- a) the name or trademark or logo of the manufacturer and/or supplier;
- b) a description of the contents;
- c) the lot number, prefixed by the word "LOT", and/or date of manufacture;
- d) expiry date;
- e) the words "For single use" or "Do not reuse" or symbol.
- f) the polarity information based on the product shape.

7 Instructions for use

The instructions for use shall include:

- a) advice for safe use of the acupoint magnetotherapy plaster:
 - 1) the need to give instructions for contraindicated patients (e.g., heart disease, high blood pressure, pregnant women or as directed by a doctor);
 - 2) that the product should be administered and used under the direction or supervision of a qualified practitioner;
 - 3) the precautions before use, for instance, indicate the device shall not be placed near the magnetic force and the device shall be stopped when checking for cracks on the sewn product;
 - 4) the precautions during use, for instance, the device cannot swallow, immediately stop using when abnormal feeling occurs, this safety information shall refer to ISO 8124-1;
- b) warnings about the possible side effects (dizziness and vomiting occur if sensitive to magnetic field) and suggested solutions (e.g. stopping treatment, reducing treatment dose or changing magnetotherapy method etc);
- c) if the equipment is used on the head, such as ear acupoint magnetotherapy plaster, warnings about the possible safety risks and possible injuries shall be given;
- d) instructions on the disposal of the product after use;
- e) information of the maximum magnetic field strength and flux shape; and
- f) for the opaque product that the permanent magnet is in the interlayer of the plaster, if the permanent magnet can not be seen directly, the position of the permanent magnet shall be marked on the plaster.