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Traditional Chinese medicine — Acupoint magnetotherapy plasters for single use

Médecine traditionnelle chinoise — Bande pour magnétothérapie sur les points d'acupuncture à usage unique

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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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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.

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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 and acupoint magnetic bead therapy.

The use of natural magnets for the treatment of diseases has long been recorded in China. *Shen Nong's Materia Medica*[1] prescribed the use of magnets as medicine. According to this book, magnetism (ci) stone is pungent and cold and magnets are used to treat arthralgia, rheumatism and pain in the limbs, as well as fever and deafness. The Ming Dynasty pharmacist Li Shizhen's *Compendium of Materia Medica*[2] also claims that magnetite placed on specific acupoints can be used to treat swelling, rectal prolapse and other diseases. This indicates that magnetic therapy was associated with meridians and acupoints during the Ming Dynasty. There are also records of the use of magnets to treat diseases in the most recent edition of modern prescriptions, such as *Medical Philosophy*.[3]

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Traditional Chinese medicine — Acupoint magnetotherapy plasters for single use

1 Scope

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

For devices containing other medicine ingredients, this document only applies to the magnetotherapy functions 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 purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
plaster
tape with adhesive substance applied on one side which can fix a *permanent magnet* (3.2) and attach to the surface of 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 — Term and definition revised.]

3.3
acupoint magnetotherapy plaster
plaster (3.1) containing a *permanent magnet* (3.2) which is attached to an acupoint of the skin

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3.4
magnetic field strength
vector quantity obtained at a given point by subtracting the magnetization from the *magnetic flux density* (3.5) 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 is sometimes called "magnetic field", risking confusion with the *magnetic field strength* (3.4) (H).

3.6
magnetic field leakage
critical *magnetic field strength* (3.4) not acting in the direction of the human body

4 Requirements

4.1 Material

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

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4.2 Appearance

The permanent magnet shall be without sharp edges or burrs.

4.3 Magnetic strength

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4.3.1 Magnetic field strength

The range that can be set as the target value of maximum magnetic field strength for magnetotherapy plasters 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 strength exceeds 60 mT at a distance of 5 mm from the surface of the magnetotherapy plaster, the fact shall be stated by the manufacturer on the package and/or in the instructions of use.

4.4 Adhesion strength

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

4.5 Geometric

4.5.1 Geometric dimensions of a plaster

The geometric dimensions of a plaster shall be more than double that of a permanent magnet.

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4.5.2 Geometric dimensions of a permanent magnet

The minimum diameter of a permanent magnet shall not be less than 1 mm. If the permanent magnet has a special shape, its minimum cross-sectional area shall not be less than 1 mm^2.

4.6 Biological evaluation

The biocompatibility of a contact part which is intended to attach to the skin shall be assessed and documented in accordance with ISO 10993-1.

5 Test methods

5.1 Material

The material used for a permanent magnet shall be stated by the manufacturer in accordance with IEC 60404-8-1.

5.2 Appearance

The exterior of the permanent magnet shall be checked by visual inspection to ensure it is free of burrs, cracks or buttons.

5.3 Magnetic strength

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5.3.1 Magnetic field strength

According to the intended use of the product, magnetic field strength shall be measured using a gauss meter at the position and direction that shows the strongest value among the target magnetic pole positions. 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 requirements specified in 4.3.1.

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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 5 mm. The magnetic field strength shall be measured using a gauss meter at six 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 six points shall be found.

5.4 Adhesion strength

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

The adhesion strength between plaster and permanent magnet shall be tested by putting 10 identical permanent magnets under the plaster.

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5.5 Geometry

5.5.1 Geometric dimensions of a plaster

The geometric dimensions of a plaster shall be checked by measuring both of the geometric dimensions of the plaster and the permanent magnet to ensure that the requirement specified in 4.5.1 is satisfied. If the shape of the permanent magnet is irregular, choose the maximum projected area.

5.5.2 Geometric dimensions of a permanent magnet

The geometric dimensions of a permanent magnet shall be checked by inspecting measuring points specified by the manufacturer.

6 Packaging and labelling

6.1 Packaging

a) The packaging of acupoint magnetotherapy plasters shall be sealed to prevent opening due to pressure, light shock or mishandling.

b) Packaging shall, once opened, be impossible to seal again.

c) Packaging shall ensure adequate protection of the contents during normal handling, transit and storage.

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6.2 Labelling

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

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a) the name, trademark or logo of the manufacturer and supplier (if any);

b) a description of the contents;

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

d) expiry date for magnetotherapy plaster supplied as sterile and with enough adhesiveness;

e) the words “For single use” or “Do not reuse” or a symbol;

f) the polarity information based on the product shape.

For opaque products where the permanent magnet is in an interlayer of the plaster, or if the permanent magnet cannot be seen directly, the position of the permanent magnet shall be marked on the plaster.

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. those with heart disease or 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;

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