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Traditional Chinese medicine — Laser acupoint devices

Médecine traditionnelle chinoise — Dispositifs laser pour traitement par acuponcture

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Foreword

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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 — Laser acupoint devices

1 Scope

This document specifies requirements and test methods for laser acupoint devices. This document is not applicable to carbon-dioxide-type lasers. In the case of combined devices, it is applicable only to the laser features.

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 11145, *Optics and photonics — Lasers and laser-related equipment — Vocabulary and symbols*

ISO 11146-1, *Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams*

ISO 11554, *Optics and photonics — Lasers and laser-related equipment — Test methods for laser beam power, energy and temporal characteristics*

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

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

IEC 60601-2-22, *Medical electrical equipment — Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11145 and IEC 60601-2-22 and the following 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
laser acupoint device
device used for non-invasive stimulation of traditional acupuncture points with low-intensity, non-thermal laser irradiation

3.2
radiation probe
emission part of the laser acupoint device

3.3
pulse repetition rate
f_p
number of laser pulses per second of a repetitively pulsed laser

[SOURCE: ISO 13695:2004, 3.16]

3.4
accessible emission limit
AEL
maximum accessible emission permitted within a particular class

[SOURCE: IEC 60825-1:2014, 3.3]

3.5
Class 3R and Class 3B laser products
any laser product which during operation permits human access to laser radiation in excess of the accessible emission limit of Class 1 and Class 2, as applicable, but which does not permit human access to laser radiation in excess of the accessible emission limit of Classes 3R and 3B (respectively) for any emission duration and wavelength

[SOURCE: IEC 60825-1:2014, 3.23]

4 Configuration and classification

4.1 Configuration

The laser acupoint device usually consists of two parts: the mainframe and the laser radiation probe. For some devices, the laser radiation probe is integrated into the mainframe. The configuration can be found in Figure 1.

4.2 Classification

4.2.1 General

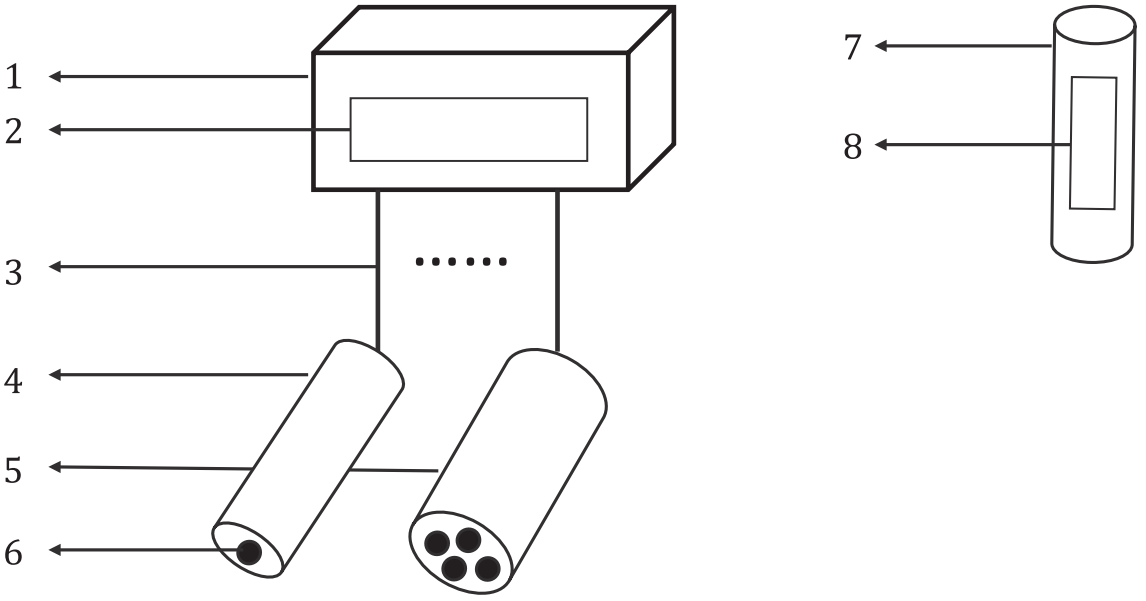
The device includes two categories according to the number of laser beams and the number of laser radiation probes.

4.2.2 According to the number of laser beams on an individual laser radiation probe

The radiation probe can be classified as a single beam or a cluster beam radiation probe, see Figure 1 a).

4.2.3 According to the number of laser radiation probes

The device can be classified as a multi-probe laser acupoint device or a single-probe laser acupoint device, see Figure 1 a) and b).



a) multi-probe laser acupoint device b) single-probe laser acupoint device

Key

1 mainframe
2 control unit
3 channel
4 single beam radiation probe
5 cluster beam radiation probe
6 laser beam
7 integrated laser radiation probe
8 control unit

Figure 1 — Configuration of the laser acupoint device

5 Requirements and test methods

5.1 Wavelength

The peak wavelength of the device shall be in the range of 400 nm to 1 400 nm.

Conformity shall be checked by the spectrometer to measure the laser wavelength.

5.2 Spot size

The maximum spot size should be specified by the manufacturer and the maximum error shall be no more than ± 10 %. If the device has several spots, each spot size error shall not exceed ± 10 %.

Conformity shall be checked in accordance with the method in ISO 11146-1, and the result shall meet the requirements.

5.3 Pulse repetition rate

For pulsed laser, the pulse repetition rate of the laser output shall be specified by the manufacturer and the tolerance shall be within ± 10 %.

Conformity shall be checked by a frequency counter to measure the pulse repetition rate from the detector output signal. Alternatively, a measurement of the time between two successive pulses from the detector output will yield the pulse repetition period (T).

The pulse repetition rate is shown in Formula (1).

$$f_{\mathrm{p}} = \frac{1}{T} \tag{1}$$

where

f_{p} is the repetition rate;

T is the pulse repetition period.

5.4 Output power

For a single beam spot, the maximum accumulated output power shall not exceed 200 mW.

Conformity shall be checked in accordance with the method in ISO 11554 for both continuous wave laser and pulsed laser. The result shall meet the requirements.

5.5 Energy density

At the maximum spot size specified by the manufacturer, the cumulative maximum energy density during the treatment time for each laser beam shall be no more than 10 J/cm^2, see Formula (2).

$$D = w \times s \tag{2}$$

where

D is the energy density expressed in joules per square metre (J/m^2);

w is the numerical value of the power;

s is the numerical value of the duration, expressed in seconds (s).

NOTE The unit of power is milliwatts (mW).

Conformity shall be checked in accordance with the method in ISO 11554 for both continuous wave laser and pulsed laser. The result shall meet the requirements. For a cluster radiation probe, the whole energy density shall meet the requirements.

5.6 Output independency

For multi-probe laser acupoint devices, the output energy density for each radiation probe shall be independent.

Conformity shall be checked in accordance with the method in ISO 11554.

5.7 Laser emission indicators

The device shall be equipped with a visible or an audible indicator, which clearly indicates whether the device is operating.

For multi-probe laser acupoint devices, the indicators shall be individually displayed.

Conformity shall be checked by visual inspection.

5.8 Power stability of continuous wave laser

The tolerance of power stability for a continuous wave laser shall be no more than 10 %. For devices with adjustable output intensity, the power stability for each setting shall be no more than 10 %.

Conformity shall be checked in accordance with the method in ISO 11554.

5.9 Energy stability of pulsed laser

The tolerance of energy stability for a pulsed laser shall be no more than 10 %. For a device with adjustable output intensity, the power stability for each setting shall be no more than 10 %.

Conformity shall be checked in accordance with the method in ISO 11554.

5.10 Target-indicating function

For invisible infrared lasers and devices where the laser radiation probe does not directly contact the skin, the device shall have a target-indicating function to designate the position where the working beam will be applied.

The aiming beam and the working beam shall be concentric within the following tolerances:

a) At the working area, the maximum allowable lateral displacement between the centres of the two spots shall not exceed 50 % of the radius of the larger of the two spots.

b) For the aiming beam, the maximum spot diameter shall not exceed 1,5 times the working beam's spot diameter.

The indicating light shall be visible and the accessible emission limit (AEL) shall be less than 5 mW.

The target-indicating light shall be turned off or left on during treatment according to the user's need.

Conformity shall be checked by inspection and measurement.

5.11 Probe fixing unit

If the device is to be continuously applied to an acupoint for more than 2 mins, a radiation probe fixing unit shall be applied.

Conformity shall be checked by inspection.

5.12 Eye protection

The device shall have corresponding eye protection measures, such as protective face shield or a pair of glasses. The manufacturer shall clarify the hazards of the device on the eyes in the instructions for use (IFU).

Conformity shall be checked by inspection.

6 Biological evaluation

The biocompatibility of parts intended to directly contact the skin shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Conformity shall be checked according to the methods and procedures in ISO 10993-1.

7 Electrical safety

The device shall satisfy the conditions of the electrical safety requirements in IEC 60601-1.

8 Electromagnet disturbances

The device shall meet the requirements and test for electromagnetic disturbances in IEC 60601-1-2.

9 Instructions for use (IFU)

The instructions for use shall include:

a) a warning to avoid irradiation of the eye;

b) for Class 3R and Class 3B laser products, information regarding protective eyewear for users and patients, such as recommended protective eyewear model or parameters;

c) a warning that the irradiation on acupoint at the skin ulceration shall be carried out under the supervision of a qualified health practitioner;

d) if a fixing unit is used, detailed instructions on the fixation process, including methods to remove fixtures;

e) for hand-held devices, a valid temporary fixation method between the acupoint and radiation probe;

f) a warning about the possibility of patient injury if the device has an output intensity greater than 5 mW;

g) the relevant technical specification for laser acupuncture treatment.

Conformity shall be checked by inspection of the instructions for use provided by the manufacturer.