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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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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.

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).