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Traditional Chinese medicine — Skin electrical resistance measurement devices

Médecine traditionnelle chinoise — Détecteurs de résistance électrique aux points d'acuponcture

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

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Traditional Chinese medicine — Skin electrical resistance measurement devices

1 Scope

This document specifies performance and test methods for skin electrical resistance measurement devices.

This document is applicable to skin electrical resistance measurement devices through which an electrical signal is applied on acupuncture points of the human body or specific points of the body surface in a non-invasive way so as to detect the resistance of the body.

This document is not applicable to software or functions for medical analysis of the test results.

Additional guidance and rationale are given in Annex A.

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*

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

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

3 Terms and definitions

For the purposes 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 http://www.iso.org/obp

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

3.1
skin electrical resistance
direct current (DC) resistance value or alternating current (AC) resistance value between acupuncture points on the skin surface of the patient (or specific points) and a reference point of the skin surface (point on the skin in contact with auxiliary electrode)

3.2
skin electrical resistance measurement device
device that can detect electrical resistance on acupuncture points or specific points of the body surface under the condition of electrical signals being applied to the human body

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3.3
detection electrical signal
voltage signal or current signal on device or for match use applied to patient for electrical resistance detection

3.4
auxiliary electrode
electrode that is fixed on specific points of the patient (e.g. hand-held or fixed on palm or forehead) for reference use, which is relatively fixed during detection

3.5
exploratory electrode
electrode that directly contacts acupuncture points or specific points of the patient's body surface, constituting a pair of electrodes with an auxiliary electrode for resistance detection

3.6
detection voltage
root mean square (RMS) of maximum open-circuit voltage between the auxiliary electrode and the exploratory electrode in the detection electrical signal

3.7
detection current
RMS of maximum current between the auxiliary electrode and the exploratory electrode in detection of the electrical signal

3.8
electrode force indication device
device on the exploratory electrode or auxiliary electrode whose function is to control or display the applied force during detection, including an exploratory electrode with force switch

3.9
force sensing switch of exploratory electrode
switch mounted in the exploratory electrode to reduce the error of detection result during use

3.10
effective dimension of electrode
accessible part that has electrical energy transmitting to the patient during detection of auxiliary electrode and exploratory electrode

4 Technical requirements

4.1 Measurable range

The skin electrical resistance measurement device shall be capable of measuring skin electrical resistance between 100 Ω and 10 K Ω.

Conformity inspection of technical documentation is provided by the manufacturer.

For the accuracy of measurable value, see A.3.

4.2 Accuracy of measurement

The error between any measured value and actual value shall be no more than ±10 %. The measured value may be expressed as electrical resistance (Ω), voltage (V), current (A) or a relative value.

Conformity is determined by carrying out the following test.

Within the measuring range of skin electrical resistance specified by manufacturers, choose five measuring values including boundary values for detection. For a device with multiple measuring

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