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Traditional Chinese medicine — Skin electrical resistance measurement devices

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National foreword

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Contents

Page

Foreword ..... **iv**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Technical requirements **2**

4.1 Measurable range 2
4.2 Accuracy of measurement 2
4.3 Detection electrical signal 3
4.4 Electrode force indication device 3
4.5 Force sensing switch of exploratory electrode 3
4.6 Detection voltage 4
4.7 Detection current 4
4.8 Effective area of auxiliary electrode 4
4.9 Electrical safety 4
4.10 Electromagnetic compatibility 4
4.11 Biological evaluation 4

Annex A (informative) **Particular guidance and rationale** **6**

Bibliography **8**

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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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ranges, each measuring range is tested separately. Choose five measuring values including boundary value for detection specified by manufacturers within each measuring range.

Measure the resistance on the equivalent circuit of five measuring values for more than five times, non-reactive 1 % resistor corresponding as close as possible to each of the measuring points selected. Each measured value shall be within ±10 % of the stated value of the selected resistor.

4.3 Detection electrical signal

For either a detection voltage or detection current adjustable device, the error between the set value and actual value shall be no more than ±10 %.

Conformity is determined by carrying out the following test.

According to the technical documentation provided by the manufacturer, the output voltage value or the current value of detection electrical signal is set separately for each measuring range. The actual open circuit output voltage value of the device is detected or the actual short-circuit output current value is measured. The error percentage for each measuring range is calculated using Formulae (1) and (2):

$$V_{error} = \frac{V_{actual} - V_{set}}{V_{set}} \times 100\ \% \tag{1}$$

$$I_{error} = \frac{I_{actual} - I_{set}}{I_{set}} \times 100\ \% \tag{2}$$

where

V_{error} is the voltage error between set value and actual value;

V_{actual} is the actual voltage value of applied voltage;

V_{set} is the set value of applied voltage;

I_{error} is the current error between set value and actual value;

I_{actual} is the actual current value of applied current;

I_{set} is the set value of applied current.

The error percentage (V_{error} or I_{error}) shall not exceed ±10 %.

4.4 Electrode force indication device

For an auxiliary electrode or exploratory electrode with force indication, the error between the indicated value and the actual value shall be no more than ±10 %.

Conformity is checked by applying a force generating device for detection. The error between the actual value and the set value shall be no more than ±10%.

4.5 Force sensing switch of exploratory electrode

The repeatability error when activating the force sensing switch shall be no more than ±10 %.

Conformity is determined by carrying out the following test.

Gradually apply an increasing force until the force sensing switch is activated. Record the applied force value. Repeat the procedure 10 times.

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Identify the maximum applied force value (F_{max}) and the minimum applied force value (F_{min}) of the 10 measurements and calculate the mean (F_n) of the 10 measurements. Calculate the repeatable error (R_{error}) using Formula (3):

$$R_{error} = \frac{F_{max} - F_{min}}{F_n} \times 100\ \% \qquad (3)$$

where

F_{max} is the maximum force value of the ten measurements;

F_{min} is the minimum force value of the ten measurements;

F_n is the mean of ten measurements.

4.6 Detection voltage

The root mean square (RMS) value of the detection voltage shall not exceed 24 V.

Conformity is determined by carrying out the following test.

Adjust the detection voltage to its maximum value. Measure the RMS value of the open-circuit output voltage between the auxiliary electrode and the exploratory electrode.

The measured value shall not exceed 24 V.

4.7 Detection current

The RMS value of the detection current shall not exceed 0,5 mA.

Conformity is determined by carrying out the following test.

Adjust the detection current to its maximum value. Measure the RMS value of the short-circuit current between the auxiliary electrode and the exploratory electrode. For a device with short-circuit protection, the detection current is the RMS value of the maximum current that does not activate (trip) the short-circuit protection.

The measured value shall not exceed 0,5 mA RMS.

4.8 Effective area of auxiliary electrode

The effective area of the auxiliary electrode shall be greater than or equal to 300 mm^2.

4.9 Electrical safety

The skin electrical resistance measurement device shall meet the applicable electrical safety requirements of IEC 60601-1.

4.10 Electromagnetic compatibility

The skin electrical resistance measurement device shall meet the applicable requirements of IEC 60601-1-2.

4.11 Biological evaluation

Conformity shall be confirmed if records provided by the manufacturer establish that the biocompatibility of the materials selected has been demonstrated. The biocompatibility of the contact part of the auxiliary electrode and the exploratory electrode intended to come into contact with the patient shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

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Conformity is determined by:

a) analogy with published data, or

b) selection of materials intended to come into contact with patient already shown to be biocompatible by proven clinical use in a similar application, or

c) experience with similar devices already on the market, together with evidence of traceability to the materials used in those devices, or

d) conformity with published procedures for biological evaluation of medical devices.

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Annex A
(informative)

Particular guidance and rationale

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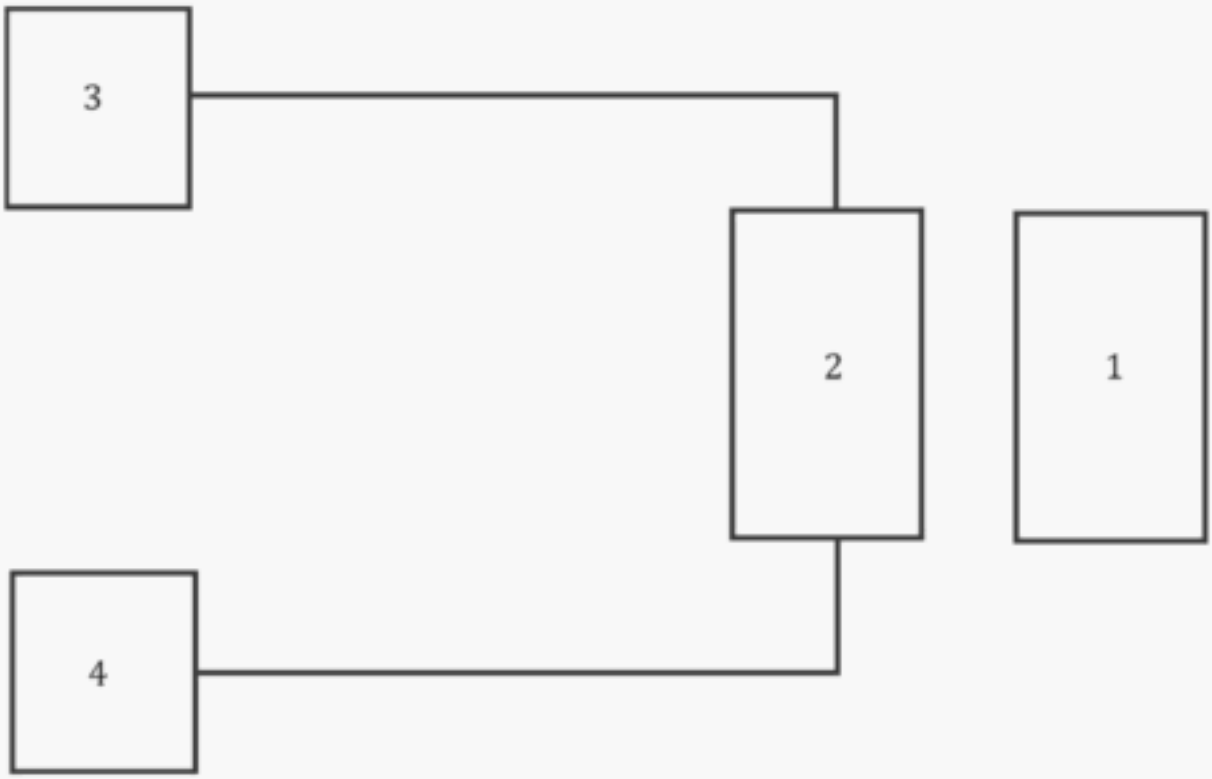
A.1 General guidance

It has been found that resistance on acupuncture points and other specific points of the body can reflect the health status of the human body based on the theory of TCM and clinical practice. A skin electrical resistance measurement device is a device 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 resistance of body.

Acupuncture points conform to parts of the human body defined in *WHO Standardization of Acupuncture Nomenclature* published by WHO Western Pacific Region in 1984[1]. Other specific points of the body surface refer to Ryodo points which are not the same as acupuncture points and specific points of medicinal value according to doctors.

A.2 Skin electrical resistance measurement device

This subclause describes a model of skin electrical resistance measurement devices. The model can be seen in Figure A.1.



Key

1 output device
2 electrical signal source
3 exploratory electrode
4 auxiliary electrode

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NOTE 1 The output device can display the detection value. It can be included in the device and also in software.

NOTE 2 An electrical signal source can provide electrical energy for detection, usually, AC source or DC source.

Figure A.1 — Skin electrical resistance measurement device

A.3 Accuracy of measurable value

The measurable range of electrical resistance specified in this document is based on a general measurable range applied widely in similar clinical devices. This document only specifies the minimum measurable range.

During detection of the accuracy of measurable value, choosing three values besides boundary values considers the linearity of the device. This document does not specify the choice of three values besides boundary values with the purpose of reducing the customized cost of non-reactive load resistance. The three values are evenly chosen within the range of boundary as much as possible.

A.4 Electrode force indication device

During detection of electrical resistance, the force applied on the exploratory electrode and auxiliary electrode will affect the result of detection. Electrode force indication displays the force applied on the exploratory electrode and auxiliary electrode.

A.5 Force sensing switch of electrode

For exploratory electrodes with a force sensing switch, the force sensing switch inside can reduce the effect arising from different forces applied on the exploratory electrode.

A.6 Detection voltage and detection current

Based on the theory of Chinese medicine, applied electrical energy will affect the result of electrical resistance detection under the condition of resistance measurement on acupuncture points. In order to minimize the effect, this document specifies the maximum value of detection voltage and detection current and encourages parties using this document to adopt as little as possible electrical energy for resistance detection.

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[1] World Health Organization. Standard acupuncture nomenclature. Manila: WHO Regional Office for the Pacific Western. 1984

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