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Traditional Chinese medicine — Test method of single-use acupuncture needles for electrical stimulation

Médecine traditionnelle chinoise — Méthode d'essai pour les aiguilles d'acuponcture à usage unique pour la stimulation électrique

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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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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.

Introduction

Electro-acupuncture is a form of acupuncture treatment that is used in many parts of the world. However, the electrical current produced by the electrical acupuncture stimulator could cause corrosion of the acupuncture needles. There are also some reports regarding possible harm to patients as a result of acupuncture needle corrosion and corrosion residuals. Therefore, it is necessary to check the corrosion resistance of the needles to ensure the safety of patients.

However, ISO 17218 does not include a test method for determining the corrosion resistance of needles used in electro-acupuncture treatment.

This document establishes a uniform test method with simulated body fluid to characterize the corrosion resistance of acupuncture needles to be used in electro-acupuncture treatment.

The use of this test method can provide useful data for comparison of different devices, materials, designs or manufacturing processes. However, it cannot provide safety information for real clinical practices. This in vitro test method is intended for artificial body fluids used for other similar standards, but the round-robin test to verify the validity and repeatability has not been done, and there are no studies on human subjects in clinical practice yet.

Accordingly, the result of this test method cannot be used to evaluate the safety of needles for clinical use and does not determine the quality of needles in clinical use directly.

The ultimate aim of this document is to protect patients who receive electro-acupuncture treatment from the potential risk of the side-effects of needle corrosion caused by electrical conduction.

This document is a necessary step toward establishing a guideline for the safe use of electro-acupuncture in clinics when a correlation between the human body and the simulated body fluid is known in the future.

Traditional Chinese medicine — Test method of single-use acupuncture needles for electrical stimulation

1 Scope

This document specifies a test method for characterizing the corrosion resistance of single-use acupuncture needles intended for use in electro-acupuncture treatment.

This document is applicable only to testing of acupuncture needles that conform with ISO 17218.

This document does not specify pass/fail criteria. Also, it is not intended to provide safety information for real clinical practice.

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 17218, *Sterile acupuncture needles for single use*

IEC 60601-2-10, *Medical electrical equipment — Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 17218 and IEC 60601-2-10 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
test method
process that conducts electricity from pulse generator to acupuncture needle in simulated body fluid

Note 1 to entry: This document established this methodology and refers to a shortened term – test method.

3.2
pulse generator
device for supplying electrical energy in the form of pulses to the acupuncture needle

3.3
electro-acupuncture stimulator
EA stimulator
electrical medical equipment for the application of electric currents via acupuncture needles inserted into the patient for the therapy of acupuncture

3.4
recorder
device which measures and records voltage for more than two channels

3.5
simulated body fluid
test solution which is used as a substitute for the human body

4 Principle

The test method specified in this document is intended to characterize the corrosion resistance of acupuncture needles to be used in electro-acupuncture treatment. The test method simulates the use of the acupuncture needle in the body by placing needles in simulated body fluid and then passing a constant electrical current from a pulse generator or electro-acupuncture stimulator to another needle. The needles under test are immersed at specified depths in the simulated body fluid. At specified times, the needles under test are visually inspected for signs of corrosion. The acupuncture needle to be tested shall either be final product, or a representative sample manufactured and processed by equivalent methods.

NOTE 1 The test method described in this document can be amended as required, subject to substantiation of data.

NOTE 2 For background and utilization of this test method, see Annex D.

5 Reagents and materials

5.1 Test solution (simulated body fluid) consisting of 1× phosphate-buffered saline (PBS) shall be used as the simulated body fluid.

5.2 Acupuncture needle conforming with ISO 17218.

6 Apparatus

6.1 Pulse generator

The stability of the output shall be ± 10 %, and the output of the pulse shall be balanced biphasic waveform.

6.2 Recorder

The recorder is used to calculate the voltage and the current flowing between the needles under test through the simulated body fluid. The recorder shall have a voltage resolution of at least 1 mV and a sampling frequency of at least 200 kHz.

6.3 Water bath

A water bath or other equivalent equipment shall be used to maintain the temperature of the simulated body fluid with an accuracy of ± 1 °C.

6.4 Resistor

The resistor (R) used in the experimental set-up in Figure A.1 shall be 10 Ω with a relative tolerance of ± 1 %. The resistor (R) may vary from 1 Ω to 500 Ω in accordance with the capacity of the pulse generator.

7 Procedure

7.1 Test environment

The test environment, such as temperature and humidity, shall conform with the manufacturer's instructions for apparatus described in Clause 6.

7.2 Test set-up

The test set-up and test procedure shall be in accordance with Annex A.

7.3 Temperature of the simulated body fluid

The temperature of the simulated body fluid shall be maintained at (37 ± 1) °C.

7.4 Test condition

7.4.1 Position of acupuncture needles

The acupuncture needles should be positioned as specified in Table 1.

If there is evidence to justify distances other than those listed in Table 1, they may be used in place of those in Table 1.

Table 1 — Position of acupuncture needles

Symbol	Distance
d_1	(10 ± 1) mm to (30 ± 3) mm
d_2	5 mm ± 0,3 mm
	10 mm ± 0,3 mm
	20 mm ± 0,3 mm
d_3, d_4	≥ 10 mm
NOTE The position of acupuncture needles (d_1, d_2, d_3, d_4) is described in Figure A.1.	

7.4.2 Parameters of pulse generator

The parameters of the pulse generator are described in Table 2. The frequency of the pulse generator shall be ≤ 1 000 Hz.

If necessary, the reference needles as experimental controls shall be prepared with the same test procedures except the application of electricity.

Table 2 — Example of the parameters of pulse generator

Parameter	Conditions
Current	(1 ± 0,1) mA[a]
	(3 ± 0,3) mA[a]
	(5 ± 0,5) mA[a]
Electrical quantity	10 C[b]
Time	15 min
	30 min
	45 min
	≤ 5 h[b]

[a] The "current" is the RMS value, see IEC 60050 (103-02-02).

[b] Apply for the biological safety test.

7.5 Number of tests

A minimum of five sets of needles should be tested for each condition in Table 2.

7.6 Optional test

For further investigation, see Annex B.

8 Test report

The test report of the electricity conducting test shall include the following:

a) date of the test;

b) type and size of the body of the needle, in SI units;

c) information of the test solution used;

d) output conditions of pulse generator (voltage, current, pulse waveform, frequency and others);

e) records of data (voltage, current, pulse waveform, frequency, electric quantity and others);

f) distance between the electrodes (d_1), immersion depth of the needles (d_2), distance between the electrodes and the bottom of the beaker (d_3), distance between the electrodes and the side wall of the beaker (d_4) (see Figure A.1);

g) manufacturer and model name of the pulse generator or electrical acupuncture stimulator;

h) manufacturer and model name of the recorder;

i) test results chart (see Annex C);

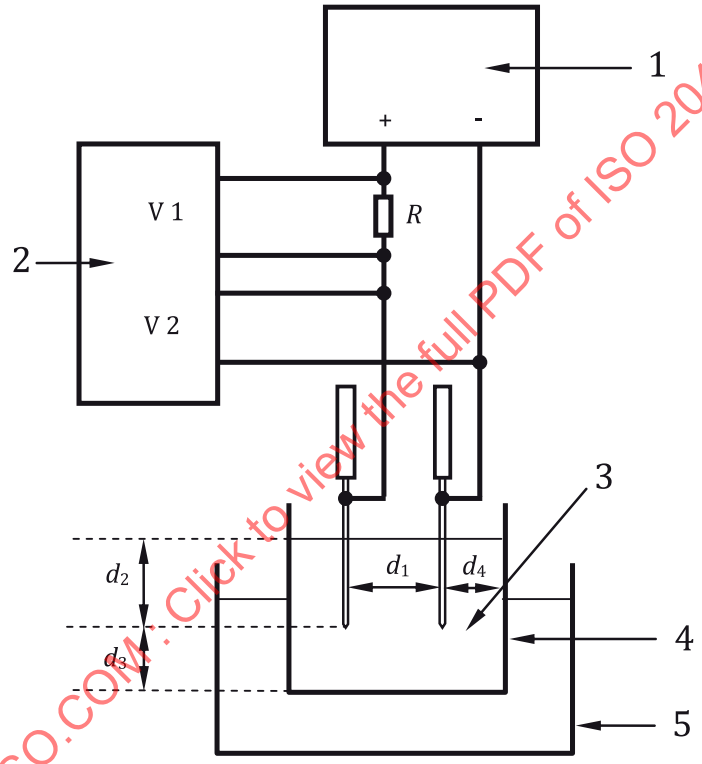
j) if applicable, justification for any deviations from the procedure and any unusual features observed.

Annex A
(normative)

Set-up, conditions and procedure

A.1 Experimental set-up

The experimental set-up to reproduce electro-acupuncture stimulation is shown in Figure A.1.



Key

1 pulse generator
2 recorder
3 simulated body fluid
4 beaker
5 water bath
R resistor
V1 voltage 1
V2 voltage 2
d_1 distance between the electrodes
d_2 immersion depth of the needles
d_3 distance between the electrodes and the bottom of the beaker
d_4 distance between the electrodes and the side wall of the beaker

Figure A.1 — Example of experimental set-up

A.2 Conditions and procedure

The following conditions and procedure apply.

a) Place the beaker with simulated body fluid in the water bath. Maintain the temperature as stipulated in 7.3.

b) Set the electrodes as shown in Figure A.1 and Table 1.

c) Set the output condition of the pulse generator as stipulated in Table 2.

d) Connect the equipment as shown in Figure A.1 and measure the voltage wave form between electrodes and of resistance. The current value can be calculated from the resistance and the voltage applied to the resistor by Ohm's law.

e) The electrical quantity can be derived from the area calculated by current (mA) multiplied by time (s).

f) In cases of a constant voltage generator, the resistance of the solution could alter throughout the test. To maintain the current constant in such cases, the output voltage shall be adjusted by hand while running the test. The result will be different between positive and negative electrodes, therefore the test should be conducted for both needles.

NOTE There is a device which only gets corroded on one side. If the repeatability of such a device is confirmed, then it is not necessary to test for both.

Annex B
(informative)

Optional test for comparison

Table B.1 shows the optional test to compare the difference of the performances of the acupuncture needle before and after the EA stimulation.

The performance is considered sufficient in the following cases:

a) analogy with published data;

b) the selection of materials already shown to be biocompatible by proven clinical use in a similar application;

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

d) by conformity to test methods after the electrical stimulation load test method described in Clause 7 (see Table B.1).

NOTE This provides only a result of the in vitro test and does not reflect the result of real clinical treatment. It can be used as evidence of how electronic conduction affects the needle in simulated body fluid.

Table B.1 — Optional test for comparison by purpose

Purpose	Optional test
a) To show the test result of the changes in resistance to breakage of the needle body after EA stimulation	ISO 17218:2014, 5.3.4
b) To show the test result of the corrosion of the needle body after EA stimulation	ISO 17218:2014, 5.3.1.2
c) To show the test result of the changes in biocompatibility of the needle body after EA stimulation	ISO 17218:2014, 5.1

Annex C
(informative)

Test result chart for corrosion

The test result for corrosion should be recorded as shown in Table C.1, with the time (min) and RMS value of current (mA). When tested multiple times, it is regarded as corroded even if one corroded part is found.

Table C.1 — Example of a test result chart for corrosion

Current	Time		
	15 min	30 min	45 min
1 mA[a]	—	No	No
3 mA[a]	No	Yes	Yes
5 mA[a]	Yes	Yes	—

Key

No: No corrosion found

Yes: Corrosion found

— Not tested

[a] The "current" is the RMS value.