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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

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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.

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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.

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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

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