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Traditional Chinese medicine — General requirements for the basic safety and essential performance of electro-acupuncture stimulators

Médecine traditionnelle chinoise — Exigences générales pour la sécurité de base et les performances essentielles des stimulateurs d'électroacupuncture

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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.

Introduction

Acupuncture is an ancient healing technique in traditional Chinese medicine (TCM) which has been used for more than 2400 years. Traditional acupuncture treatment is performed by twisting needles manually. The application of electrical stimulation to acupuncture needles was first attempted in the first half of the 19th century by a French doctor, Sarlandiere. Acupuncture treatment began to attract the attention of medical practitioners in the 1970s after the report of acupuncture anaesthesia.[7] Today, electro-acupuncture (EA) stimulators are widely used in acupuncture treatment.

This document specifies the basic safety and essential performance for EA stimulators as medical electrical equipment. IEC 60601-2-10 on nerve and muscle stimulators excludes any medical electrical equipment intended to be implanted or connected to implanted electrodes. In terms of safety, the most important difference between the two techniques is what type of electrodes are used to deliver stimulation current. Acupuncture needles are inserted into the body in EA, whereas skin electrodes are used in nerve and muscle stimulation. Electro-acupuncture can cause tissue damage when the stimulating energy is too high or needle corrosion occurs when direct current component is applied. It is generally accepted that certain parameters of the pulses are essential for the therapeutic effect of EA.

Traditional Chinese medicine — General requirements for the basic safety and essential performance of electro-acupuncture stimulators

1 Scope

This document specifies general requirements for the basic safety and essential performance of electro-acupuncture (EA) stimulators.

It is not applicable to acupuncture needles, transcutaneous electrical nerve stimulators or electrical nerve and muscle stimulators.

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.

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
electro-acupuncture
EA
application of low-frequency electrical stimulation to acupuncture points through acupuncture needles

Note 1 to entry: Configuration of EA stimulator system is described in Annex A, Figure A.1.

3.2
electro-acupuncture stimulator
EA stimulator
electrical medical equipment for the application of electric currents via acupuncture needles inserted into the body for the therapy of acupuncture

[SOURCE: ISO 20487:2019, 3.3, modified]

3.3
lead
insulated conductor connecting an EA stimulator to the acupuncture needles to deliver electrical current

3.4
acupuncture needle
needle inserted into the body as an electrode in EA

3.5
needle clip
fixation device for the connection of a lead to an acupuncture needle to deliver electrical current

4 General requirements

4.1 General

IEC 60601-1:2005+A1:2012, Clause 4 shall apply.

5 General requirements for testing EA stimulators

IEC 60601-1:2005+A1:2012, Clause 5 shall apply.

The electrodes of the EA stimulator shall conform with this document when operated with either open-circuited or short-circuited electrodes.

Compliance shall be checked by measurement as specified in Annex B.

6 Classification of EA stimulators in medical electrical (ME) equipment and ME systems

6.1 General

IEC 60601-1:2005+A1:2012, 6.1, 6.3 to 6.5 shall apply in addition to the following subclause.

6.2 Protection against electric shock

IEC 60601-1:2005+A1:2012, 6.2 shall apply with the following amendment:

Type B applied part shall be excluded.

6.3 Mode of operation

IEC 60601-1:2005+A1:2012, Clause 6.6 shall apply with the following amendment:

The EA stimulator shall be classified as ME equipment with continuous operation.

7 Identification, marking and documents of EA stimulators

7.1 General

IEC 60601-1:2005+A1:2012, Clause 7 shall apply in addition to the following subclauses.

7.2 Electrical input power from the supply mains

IEC 60601-1:2005+A1:2012, 7.2.7 shall apply after replacing the fourth paragraph as follows:

The rated input power of a mains-powered EA stimulator shall be the maximum power averaged over any period of 5 s under the specified operating conditions set out by the manufacturer.

7.3 Instructions for use

7.3.1 General

IEC 60601-1:2005+A1:2012, 7.9.2 shall apply in addition to the following subclause.

7.3.2 Additional information

Instructions for use shall also include the following:

a) information on the output waveform(s), pulse duration, pulse frequencies, maximum amplitude of output voltage and/or current and the effect of load impedance on these parameters;

b) advice on selection of acupuncture needles based on the corrosion resistance of the needles;

c) instruction that a patient with an implanted electronic device (e.g. a cardiac pacemaker) should not be subjected to EA unless specialist medical opinion has first been obtained;

d) warnings on the following potential hazards:

   — simultaneous connection of a patient to a high-frequency surgical ME equipment can result in burns at the site of the needle electrodes and damage to the EA stimulator;

   — operation in close proximity (e.g. within 1 m) to shortwave or microwave therapy ME equipment can produce instability in the EA stimulator output;

   — application of EA to needles inserted near the thorax can increase the risk of cardiac fibrillation;

e) advice to show caution when stimulation is applied to needle electrodes placed on the chest and/or upper back or across the heart.

8 Protection against electrical hazards from EA stimulators

8.1 General

IEC 60601-1:2005+A1:2012, 8.1 to 8.2, 8.4 to 8.11 shall apply in addition to the following subclause.

8.2 Classification of applied parts

IEC 60601-1:2005+A1:2012, 8.3 shall apply with following amendment:

Type B applied part shall be excluded.

9 Protection against mechanical hazards of EA stimulators

9.1 General

IEC 60601-1:2005+A1:2012, Clause 9 shall apply in addition to the following subclauses.

9.2 Disconnection prevention

The EA stimulator system shall have minimal risk of disconnection caused by small force. Needle clips shall have sufficient force to fix the clips to the needle body in fluctuating conditions to prevent disconnection. Instructions for use shall include the conditions needed to prevent the risk. Compliance is checked by inspection.

10 Protection against unwanted and excessive radiation hazards

IEC 60601-1:2005+A1:2012, Clause 10 shall apply.

11 Protection against excessive temperatures and other hazards

IEC 60601-1:2005+A1:2012, Clause 11 shall apply.

12 Accuracy of controls and instruments and protection against hazardous outputs

12.1 Accuracy of controls and instruments

12.1.1 General

When applicable, the manufacturer shall address the risks associated with accuracy of controls and instruments during the risk management process.

Compliance is checked by inspection of the risk management file.

12.1.2 Output amplitude

Adjustment of the output level of an EA stimulator from minimum to maximum should be continuous or in discrete increments with no more than 10 % of the maximum output of the device in each increment.

Compliance is checked by measurement with an error not exceeding ± 10 %.

The test method specified in Annex B shall be applied. Information on the available test methods for various impedance conditions is described in Annex D.

12.1.3 Pulse parameters

The values of pulse durations, pulse repetition frequencies and amplitudes of the EA stimulator shall not deviate by more than 20 % when measured with a load resistance.

Compliance is checked by measurement with an error not exceeding ± 10 %.

The test method specified in Annex B shall be applied. Information on the available test methods for various impedance conditions is described in Annex D.

12.1.4 Independent control of multiple output channels

Each individual output channel shall be controlled independently, including the on-off switch and intensity control.

12.2 Usability of ME equipment

The manufacturer shall address the risk(s) of poor usability, including those associated with identification, marking and documents, through a usability engineering process in accordance with IEC 60601-1-6.

Compliance is checked as specified in IEC 60601-1-6.

12.3 Alarm systems

If the manufacturer has implemented an alarm system, it shall conform with IEC 60601-1-8.

Compliance is checked as specified in IEC 60601-1-8.

12.4 Protection against hazardous output

12.4.1 General

IEC 60601-1:2005+A1:2012, 12.4.1 to 12.4.4 applies, in addition to the following subclauses.

12.4.2 Supply voltage fluctuations

Supply voltage fluctuations of ± 10 % shall not affect the EA stimulator output amplitude, pulse duration or pulse repetition frequency by more than ± 10 %.

Compliance is checked by measurement.

12.4.3 Output interlock

An EA stimulator shall not be activated unless the output amplitude of all channels is first set to zero or its minimum level. This requirement shall also apply to the restoration of the supply mains following a temporary interruption or replacement of the internal electrical power source.

Compliance shall be checked by measurement specified in Annex B.

12.4.4 Output indicator

In single fault conditions, the EA stimulator shall indicate if it is capable of delivering an output of more than 1,0 mA (r.m.s.) or 1,0 V or can deliver pulses with energy exceeding 30 mJ per pulse, into a load resistance of 500 Ω. If the indication is by means of a signal lamp, its colour shall be red.

Compliance is checked by inspection and functional test.

12.4.5 Limitation of output parameters

12.4.5.1 Pulse frequency and current limits

The EA stimulator output shall not contain a direct current component. The biphasic pulse shall be symmetrical and balanced. The output current shall not exceed 1 mA (r.m.s.) with a load resistance of 500 Ω. The pulse frequency shall not exceed 1 000 Hz. Total current per single session is not limited in this document because of the need for more evidence. See Annex C for further information.

12.4.5.2 Limitation of single pulse energy

For pulse duration of less than 10 ms, the pulse energy with a load resistance of 500 Ω shall not exceed 30 mJ per pulse. The output voltage shall not exceed a peak value of 100 V when measured under open-circuit conditions.

13 Hazardous situations and fault conditions

IEC 60601-1:2005+A1:2012, Clause 13 shall apply.

14 Programmable electrical medical systems (PEMS)

IEC 60601-1:2005+A1:2012, Clause 14 shall apply.

15 Construction of ME equipment

15.1 General

IEC 60601-1:2005+A1:2012, Clause 15 shall apply, in addition to the following subclauses.

15.2 Needle clips and leads

Needle clips shall have enough insulation to prevent a short circuit when acupuncture needles are placed close to each other. Compliance is checked by inspection of the risk management file. Leads shall have enough insulation, strength and flexibility against stretching and repeated bending.

16 ME systems

IEC 60601-1:2005+A1:2012, Clause 16 shall apply.

17 Electromagnetic compatibility of ME equipment and ME system

IEC 60601-1:2005+A1:2012, Clause 17 shall apply.

18 Electromagnetic compatibility – requirements and tests

18.1 General

IEC 60601-1-2:2014, Clause 4 and 5 shall apply.

18.2 Emissions tests

18.2.1 General

IEC 60601-1-2:2014, 7.1 shall apply, in addition to the following subclauses.

18.2.2 Patient lead

IEC 60601-1-2:2014, 7.1.11 shall apply, except as follows:

Acupuncture needles as electrodes for EA stimulators shall be connected to the contents of a 1-l capacity phantom filled with physiological buffer solution (PBS). The phantom shall be positioned within 0,4 m of the EA stimulator system as shown in Figure 1.

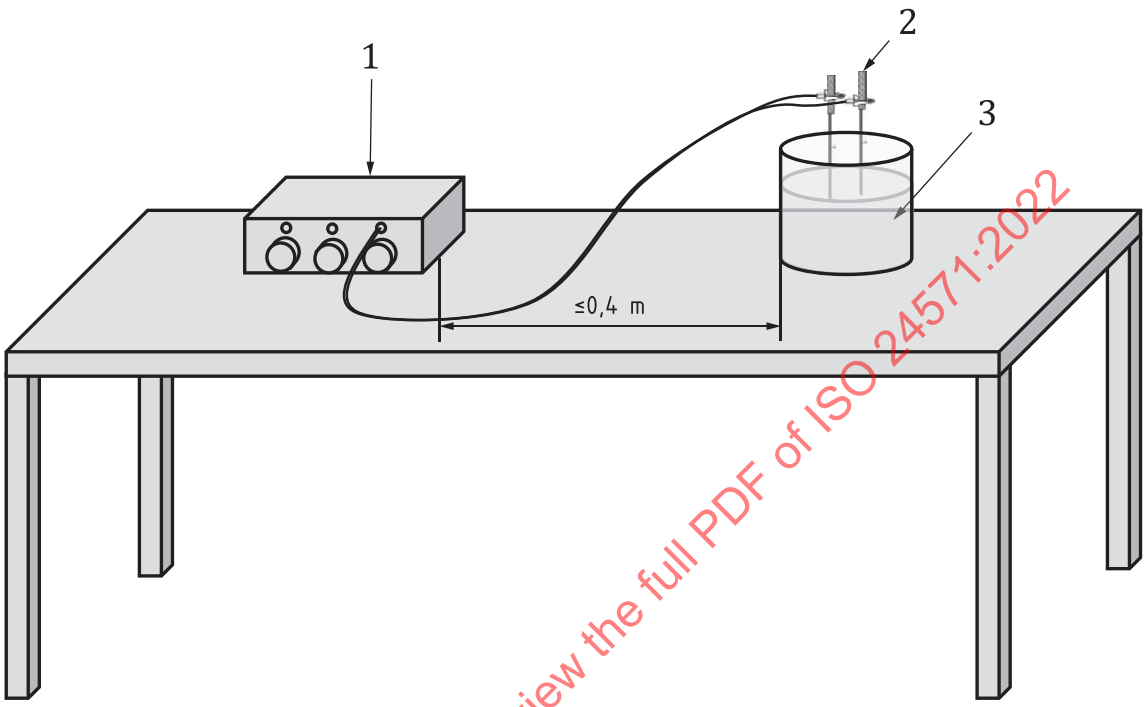
18.3 Immunity

18.3.1 General

IEC 60601-1-2:2014, 8.1 shall apply, in addition to the following subclause.

18.3.2 EA stimulator with acupuncture needle

Patient-coupled ME equipment and ME systems are prepared as shown in Figure 1. Acupuncture needles as electrodes for EA stimulators shall be connected and applied to the contents of a 1-l capacity phantom filled with PBS. The phantom shall be positioned within 0,4 m of the EA stimulator system as shown in Figure 1.



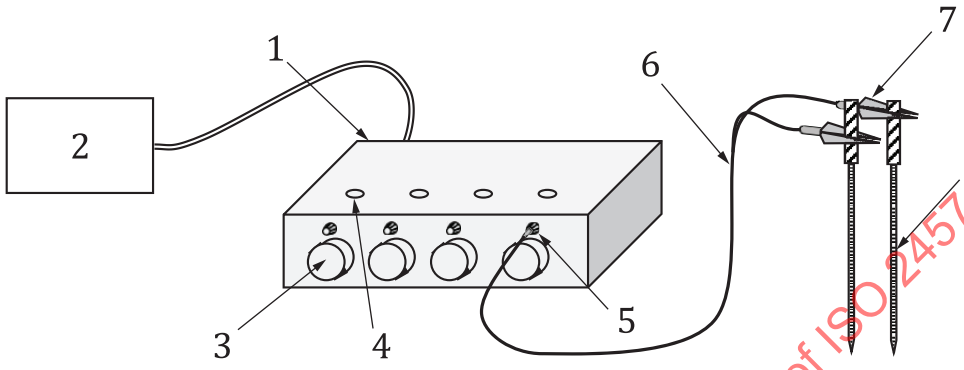
Key

1 electro-acupuncture stimulator
2 acupuncture needle
3 1-l PBS

Figure 1 — Testing layout

Annex A
(informative)

Configuration of EA stimulator system



Key

1 controller of EA stimulator
2 power (AC plug or battery)
3 output controller
4 indicator
5 socket
6 lead
7 needle clips
8 acupuncture needle

NOTE The acupuncture needles are included to help understand the configuration but are not a component of an EA stimulator.

Figure A.1 — Configuration of EA stimulator component

Annex B
(normative)

Test methods for EA stimulator

B.1 Electrode

Operate the EA stimulator with all output controls set to the maximum position. Each pair of output terminals are kept open-circuited for 10 min and then short-circuited for a further 5 min. This test shall be completed before any other test.

Total output parameters of the EA stimulator shall not deviate by more than ± 20 % when the load resistance is set to 500 Ω.

B.2 Needle clips

Under visual inspection, the outside of the needle clips shall be insulated and the gap between interlocking parts shall not be exposed. Needle clips shall be coupled with hard-biting steel wire (thickness > 100 μm).

B.3 Needle clips and lead

The lead should be tested by applying 20 N force for at least 1 min. The change in length after test should not exceed 1 %. The direct current impedance should not increase by more than 10 %.

B.4 Output interlock

The EA stimulator shall not start operation if the output controller is not positioned at '0' or at minimum setting under any conditions.

Compliance is checked by functional check (see 12.4.3).

Annex C
(informative)

The safety issue of excessive total current per session

It is well recognized that the prolonged treatment with an EA device can cause corrosion of acupuncture needles, especially when a strong electric current is used. The requirement that EA simulators have zero direct current should effectively reduce corrosion but might not be able to completely eliminate it. Limitations on the maximum total current per session of treatment may also help to reduce needle corrosion. Some countries have regulations on the total amount of current per session of treatment. However, it is likely that in addition to the total current, many other factors, such as the types and quality of the needle, the wave forms of pulses and depth of needle insertion, may also have an impact. Therefore, the limitation has been under consideration but has not been included in this document due to the lack of sufficient scientific data for the selection of a safe level of the maximum current per session of EA.