
**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

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.

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.^[2] 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]