
**Traditional Chinese medicine —
General requirements of electric
radial pulse tonometric devices**

*Médecine traditionnelle chinoise – Exigences générales relatives aux
tonomètres à impulsions électriques radiales*

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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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Traditional Chinese medicine — General requirements of electric radial pulse tonometric devices

1 Scope

This document specifies the general requirements for basic safety and essential performance of electric radial pulse tonometric devices.

This document does not apply to the accuracy of differential diagnosis or interpretation of the diagnostic data obtained from the use of such devices.

This document applies to pressure-based radial pulse tonometric devices.

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/AMD1:2012, *Medical electric equipment — Part 1: General requirements for basic safety and essential performance*

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 <https://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

3.1

electric radial pulse tonometric device

non-invasive medical electrical (ME) equipment that incorporates a transducer to measure the *radial pulse* (3.5) while pressure is applied to the skin and radial artery using a rigid flat surface

Note 1 to entry: ME equipment includes all applied parts and accessories.

3.2

pulse diagnosis

examination of the pulse for diagnostic purposes

[SOURCE: Adapted from WHO *International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 2007]

3.3

position

location on the wrist for pulse measurement

3.4.1

inch/cun

section of the *pulse diagnosis* (3.2) *position* (3.3) located on the distal side of the radial artery, next to the *bar/guan* (3.4.2), where the tip of the physician's index finger rests

[SOURCE: Adapted from WHO *International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 2007]

3.4.2

bar/guan

section of the *pulse diagnosis* (3.2) *position* (3.3) located just central to the radial artery at the wrist, where the tip of the physician's middle finger is placed

[SOURCE: Adapted from WHO *International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 2007]

3.4.3

cubit/chi

section of the *pulse diagnosis* (3.2) *position* (3.3) located on the proximal side of the radial artery, where the tip of the physician's fourth finger is placed

[SOURCE: Adapted from WHO *International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 2007]

3.5

radial pulse

pulsation of the radial artery felt at the wrist

[SOURCE: WHO *International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 2007]

3.6

pressure transducer

device for converting pressure into an electrical signal

Note 1 to entry: Pressure transducer can be single or array.

3.7

transducer module

module of a tonometric device that includes a transducer, case, cable and *actuator* (3.8) (if applicable)

3.8

actuator

device to apply pressure to the *radial pulse* (3.5)

Note 1 to entry: The actuator is included in an automatic pressing system. It is not included in a non-automatic pressing system.

3.9

pulse waveform

pulse contour of the *radial pulse* (3.5)

Note 1 to entry: See [Figure A.1](#).

3.10

applied pressure

pressure applied to the *pulse position* (3.3) by the *transducer module* (3.7)

3.11

pulse pressure

measure of pulse signal when pressure is applied at the *pulse diagnosis* (3.2) *position* (3.3)