International Standard

ISO 18615-1

Traditional Chinese medicine — Electric radial pulse tonometric devices —

Part 1: General requirements

Médecine traditionnelle chinoise — Tonomètres à impulsions électriques radiales —

Partie 1: Exigences générales

Second edition
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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 document 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 medicine*, Subcommittee SC1, *Traditional Chinese medicine*.

This second edition of ISO 18615-1, cancels and replaces the first edition of ISO 18615:2020, which has been technically revised.

The main changes are as follows:

— The document has been split into a series and renumbered accordingly.

— Performance test methods have been separated from this document and are intended to be specified in a future part of ISO 18615.

A list of all parts in the ISO 18615 series can be found on the ISO website.

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 — Electric radial pulse tonometric devices —

Part 1: General requirements

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 https://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: WHO Guidelines, 2007, p. 101[2] modified — "for making diagnosis" has been revised to "for diagnostic purposes"]

3.3
position
location on the wrist for pulse measurement

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