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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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Contents

Page

Foreword

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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.

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 diagnosistic 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)