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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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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)

3.12
pulse waveform simulator
device for generating the virtual *pulse waveform* (3.9) and *applied pressure* (3.10)

3.13
static pressure
pressure applied by a *pulse waveform simulator* (3.12) or other mechanical tester

3.14
one-finger method
pulse-taking method using pressure from one finger at a time on each pulse section

3.15
three-finger method
pulse-taking method using pressure from three fingers simultaneously on the three pulse sections

4 General requirements

IEC 60601-1:2005/AMD1:2012, Clause 4, applies.

5 General requirements for testing of ME equipment

IEC 60601-1:2005/AMD1:2012, Clause 5, applies.

6 Classification of ME equipment and ME systems

IEC 60601-1:2005/AMD1:2012, Clause 6, applies.

7 ME equipment identification, marking and documents

7.1 General

IEC 60601-1:2005/AMD1:2012, Clause 7, applies.

7.2 Marking on the transducer module or wristband

A transducer module or wristband for electric radial pulse tonometric devices shall have a visible radial artery position mark and a position identification mark to prevent the incorrect pulse position(s) being measured.

For the one-finger method, ME equipment shall have a visible indicator to identify the pulse position (e.g. left-hand, right-hand, inch/cun, bar/guan or cubit/chi) to prevent the measuring software program measuring the pulse location at the incorrect position.

For the three-finger method, ME equipment shall have a visible indicator of the pulse position on the transducer module or wristband.

7.3 Instructions for use

Instructions for use shall include the following:

a) intended use including the environment of use;

b) for ME equipment, a list of the specified accessories such as transducer(s) or transducer module;

c) for transducer(s) or transducer module, a list of ME equipment that conforms with the requirements of this document when used with these transducer(s);

d) descriptions of how to connect the transducer(s) and accessories, and how to prepare the ME equipment;

e) a description of how to locate the transducer module on the pulse position;

f) information on the appropriate processes for cleaning, disinfection, packaging and, where appropriate, any restriction on the number of reuses;

g) precautions to be taken when a patient has an injury on the measurement position to prevent cross-infection to other patients;

h) precautions to be taken in the event of changes in performance of the transducer as a result of ageing or environmental conditions;

i) performance specification (e.g. accuracy, measurement range) of ME equipment, including the specified transducer;

j) simple fault-finding methods for troubleshooting problems by which the clinical operator can locate problems if the ME equipment appears to be functioning incorrectly.

7.4 Messages

Instructions for use shall list all system messages, error messages and fault messages that are generated and are visible to the operator, unless these messages are self-explanatory.

8 Protection against electrical hazards from ME equipment

IEC 60601-1:2005/AMD1:2012, Clause 8, applies.

9 Protection against mechanical hazards of ME equipment and ME systems

9.1 General

IEC 60601-1:2005/AMD1:2012, Clause 9, applies.

9.2 Safety pressure range of actuator

Actuators are classified as non-automatic and automatic systems. For all actuators, the safety pressure for patients shall be limited to 600 mmHg (80 kPa, 816 g·f/cm^2).

Non-automatic actuators shall have a mechanical limiter not exceeding the safe pressure limit value.

Automatic actuators shall have a mechanical limiter and not exceed the safe pressure limit. In single fault condition, the applied pressure shall be limited to 660 mmHg (88 kPa, 897 g·f/cm^2).

9.3 Stability of actuator movement

There are two types of actuators: mechanical and air-bladder. Applied pressure by the actuator shall ensure stability of signal. Applied pressure produced by the actuator shall not cause baseline fluctuation noise as this could affect the pulse signal.

Conformity is checked by visual inspection or signal analysis.

10 Protection against unwanted and excessive radiation hazards

IEC 60601-1:2005/AMD1:2012, Clause 10, applies.

11 Protection against excessive temperatures and other hazards

IEC 60601-1:2005/AMD1:2012, Clause 11, applies.

12 Accuracy of controls and instruments and protection against hazardous outputs

12.1 General

IEC 60601-1:2005/AMD1:2012, Clause 12, applies.

12.2 Accuracy of controls and instruments

12.2.1 Accuracy of applied pressure measurement

The applied pressure measurement range shall be at least 0 mmHg to 120 mmHg (16 kPa, 160 g·f/cm^2). The resolution of applied pressure measurement shall be 2 mmHg (0,3 kPa, 2,7 g·f/cm^2) or below. The difference between the device and the reference shall be within ±5 % of the reading or ±6 mmHg (±0,8 kPa, ±8 g·f/cm^2), whichever is greater.

If the system can measure only force unit, then force should be divided by unit area.

Conformity is checked using the following test.

a) Energize the ME equipment.

b) Balance the ME equipment to obtain zero pressure output with zero pressure input.

c) Using the pulse waveform simulator (Figure 1, key reference 3), apply pressures of any five divided steps within the largest full-scale pressure range.

d) The output pressure shall be within ±5 % of the reading or ±6 mmHg (±0,8 kPa, ±8 g·f/cm^2), whichever is greater compared with the reference measurement (Figure 1, key reference 2).