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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

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.

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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.

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.

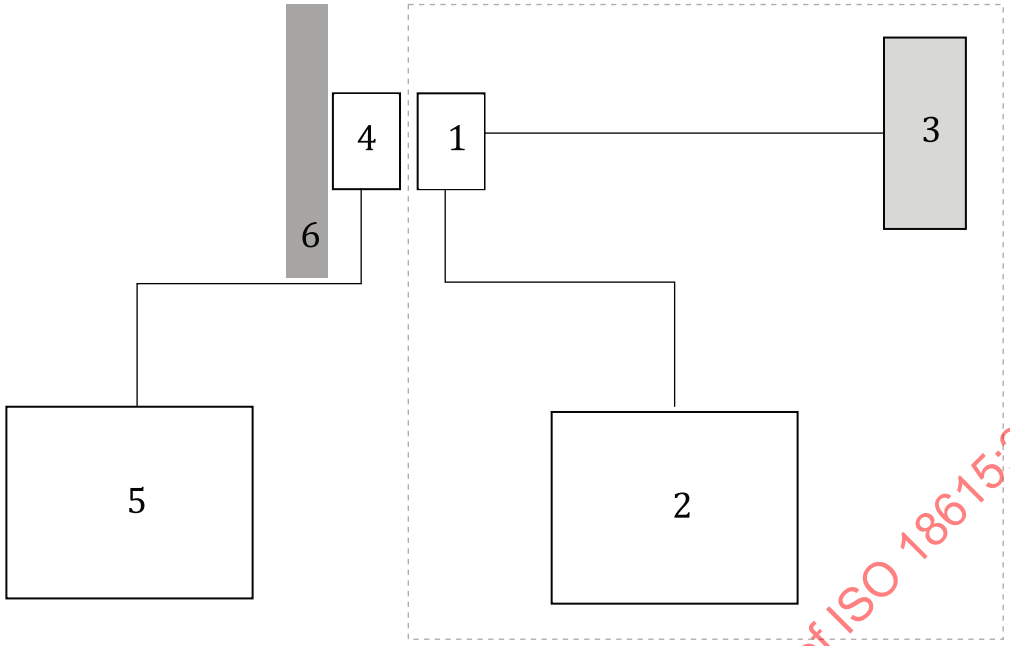
Conformity is checked using the following test.

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).



Key

1, 2 reference pressure measuring system consisting of transducer (1) and monitor (2); reference pressure accurate to ±0,4 mmHg (±0,5 g·f/cm^2)

3 pulse waveform simulator to generate applied pressure and pulse-wave pressure

4 transducer module

5 ME equipment under test

6 basement for transducer module

Figure 1 — Test for accuracy of applied pressure measurements

12.2.2 Accuracy of pulse pressure measurements

The pulse pressure measurement range shall be at least 0 mmHg to 105 mmHg (14 kPa, 143 g·f/cm^2). The resolution of the pulse pressure measurement shall be 1 mmHg (0,12 kPa, 1,3 g·f/cm^2) or below. The accuracy of the pulse pressure shall be within ±5 % of the reading or ±5 mmHg (±0,7 kPa, ±7 g·f/cm^2), whichever is greater at a frequency of 1 Hz.

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 a static pressure until the reference pressure measuring system (Figure 1, key reference 2) output display reads 35 mmHg (4,7 kPa, 48 g·f/cm^2) ± 20 %.

d) While maintaining static pressure, use a pulse waveform simulator (Figure 1, key reference 3) to apply a 1 Hz pulse-wave pressure of 40 mmHg, 60 mmHg, 80 mmHg and 105 mmHg (54 g·f/cm^2, 82 g·f/cm^2, 109 g·f/cm^2 and 143 g·f/cm^2) or any four divided steps within 0 % to 100 % of the pulse pressure range. For this test, the first option is the simulated blood pressure waveform; sine waveform and seesaw waveform are the secondary options. Target parameter to test could be H1 from Figure A.1 in Annex A.

e) The output pulse-wave pressure shall be within ±5 % of the reading or ±5 mmHg (±0,7 kPa, ±7 g·f/cm^2), whichever is greater at a frequency of 1 Hz compared with the reference measurement.

12.2.3 Accuracy of pulse rate measurements

The pulse rate measurement range shall be at least 40 bpm to 150 bpm (beats per minute). The resolution of pulse rate measurement shall be 1 bpm or below. The accuracy of the pulse rate shall be within ±5 bpm.

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 with Figure 1, key reference 2, to obtain zero pressure output with zero pressure input.

c) Using the pulse waveform simulator (Figure 1, key reference 3), apply a static pressure until the reference pressure measuring system (Figure 1, key reference 2) output display reads 35 mmHg (4,7 kPa, 48 g·f/cm^2) ± 20 %.

d) While maintaining static pressure, apply a pulse-wave pressure of any five divided steps within 0 % to 100 % of the pulse rate range using a pulse waveform simulator. For this test, the first option is the simulated blood pressure waveform; sine waveform and seesaw waveform are the secondary options. Target parameters to test could be T from Figure A.1 in Annex A.

e) The output pulse rate shall be within ±5 bpm of the comparative reference measurement.

12.2.4 Requirements of geometric measurements

Geometric parameters of pulsation are length, width, area and volume for an array transducer. Geometric parameters can have units of mm or cm for length and width; mm^2 or cm^2 for area; and g·f (mN) for volume.

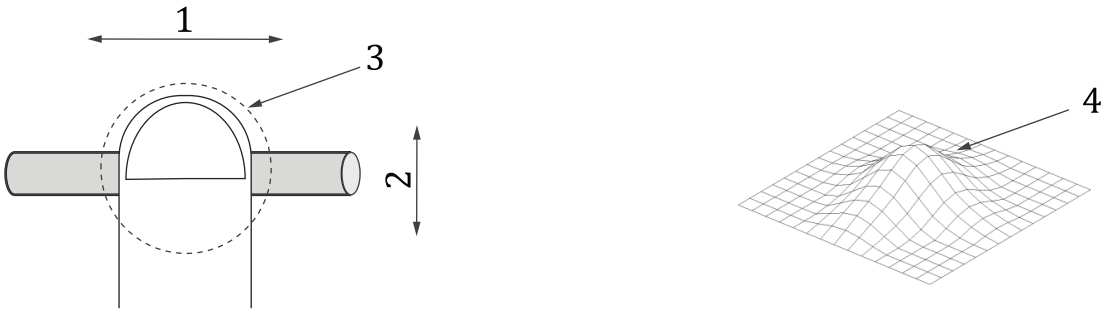
The measurement ranges of each parameter are as follows:

a) pulsation contact length (Figure 2, key reference 1) range shall be at least 3 mm;

b) pulsation contact width (Figure 2, key reference 2) range shall be at least 3 mm;

c) pulsation contact area (Figure 2, key reference 3) range shall be at least 9 mm^2;

d) pulsation contact volume (Figure 2, key reference 4) range shall be defined by the manufacturer.



Key

1 pulsation length
2 pulsation width
3 pulsation area
4 pulsation volume

Figure 2 — Description of geometry parameters of pulsation

Conformity is checked by a review of the array transducer size or contact area.

12.2.5 Accuracy of measurement position

ME equipment that has a function of confirming the measurement position with an array transducer shall have an accuracy of position within ±1 mm.

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) Align the centre position of the ME equipment transducer and pulse waveform simulator.

d) Using the pulse waveform simulator (Figure 1, key reference 3), apply a static pressure until the reference pressure measuring system (Figure 1, key reference 2) output display reads 35 mmHg (4,7 kPa, 48 g·f/cm²) ± 20 %.

e) While maintaining static pressure, apply a pulse-wave pressure of 60 bpm using a pulse waveform simulator. For this test, the first option is the simulated blood pressure waveform; sine waveform and seesaw waveform are the secondary options.

f) The result of confirmation of the position by ME equipment shall be within ±1 mm of the comparative reference position.

13 Hazardous situations and fault conditions

IEC 60601-1:2005/AMD1:2012, Clause 13, applies.

14 Programmable electrical medical systems (PEMS)

IEC 60601-1:2005/AMD1:2012, Clause 14, applies.

15 Construction of ME equipment

15.1 General

IEC 60601-1:2005/AMD1:2012, Clause 15, applies.

15.2 Drop test

Transducer module, if separable from the ME equipment by the clinical operator, shall not present a hazardous situation after a free fall from a height of 0,8 m onto a hard surface.

Conformity is checked using the following test.

a) Place a 50-mm-thick hardwood board (e.g. hardwood > 600 kg/m^3) flat on a rigid base (such as concrete block).

b) Drop the transducer module sample from a height of 0,8 m onto the hardwood board. Do this once.

c) Do a leakage current test with test finger. No accessible parts shall exceed the values of the leakage currents when touched with the test finger.

d) Do a visual inspection. Cracks that are not visible to the naked eye and surface cracks in fibre-reinforced mouldings and the like shall be ignored.

e) Do the operating test. All requirements shall be satisfied, and the ME equipment shall function normally.

15.3 Detection of pressure transducer and pressure transducer cable fault

Means to detect transducer faults shall be provided. An indicator or message shall be activated when any wire in the transducer or transducer cable is exposed or shorted to any other wire that causes an operational malfunction, or when the transducer connector is unplugged.

16 ME systems

IEC 60601-1:2005/AMD1:2012, Clause 16, applies.

17 Electromagnetic compatibility of ME equipment and ME systems

IEC 60601-1:2005/AMD1:2012, Clause 17, applies.

NOTE An electric radial pulse tonometric device is not considered life-supporting ME equipment or ME system as defined in IEC 60601-1-2.

18 Requirements of transducer and transducer module of ME equipment

18.1 Lifespan of transducer

For safety reasons, the lifespan of the transducer shall be defined, and each manufacturer shall ensure this defined lifespan is not exceeded.

Conformity is checked using the following test.

Energize the ME equipment as follows:

a) Balance the transducer to obtain zero pressure output with zero pressure input.

b) Using the pulse waveform simulator (Figure 1, key reference 3), apply a static pressure until the reference pressure measuring system (Figure 1, key reference 2) output display reads 35 mmHg (4,7 kPa, 48 g·f/cm^2) ± 20 %.

c) While maintaining static pressure, use a pulse waveform simulator (Figure 1, key reference 3) to apply a 1 Hz pulse-wave pressure of 30 % to 70 % of the pulse pressure range. For this test, the first option is the simulated blood pressure waveform; sine waveform and seesaw waveform are the secondary options.

d) Count the contact number of the transducer.

e) The contact number of the transducer shall be more than the defined life span.

18.2 Reliability of transducer

To confirm the reliability of the transducer, the manufacturer should perform the reliability test in Annex B.