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Traditional Chinese medicine — Abdominal physiological parameter detectors

Médecine traditionnelle chinoise — Détecteurs de paramètres physiologiques abdominaux

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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 — Abdominal physiological parameter detectors

1 Scope

This document specifies the general requirements for basic performance and safety of abdominal physiological parameter detectors. It covers the material, basic parameters and testing method of abdominal parameter detectors but does not prescribe the clinical abdominal diagnosis associated with the findings obtained from the 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.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

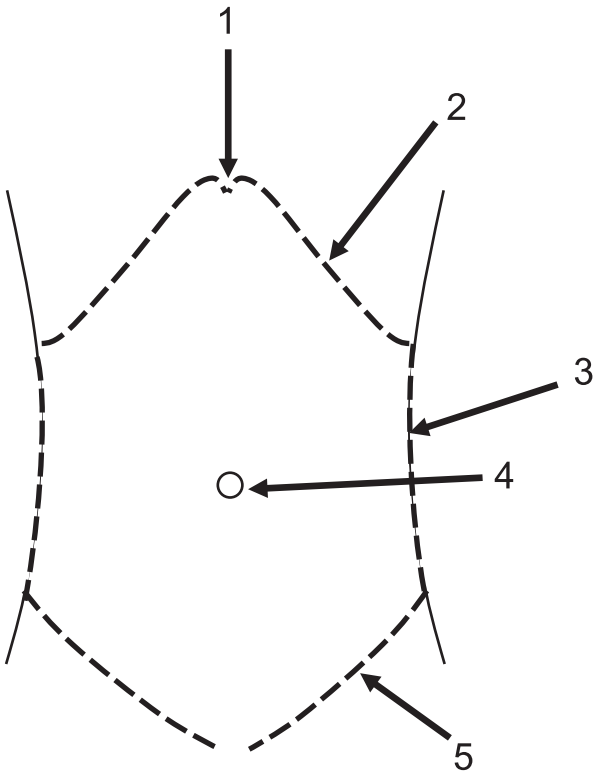
ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
abdominal physiological parameter detector
APPD
device which measures the force, abdominal deformation and temperature on the abdominal detection area using either stand-alone sensing heads or integrated sensing head

Note 1 to entry: The abdominal detection area is between the level of xiphoid process and the inguinal ligament inside of the dashed line shown in Figure 1.



Key

1 xiphoid process
2 costal margin
3 side of abdomen
4 umbilicus
5 inguinal ligament

Figure 1 — Abdominal detection area

3.2
applied force
force controlled by a doctor applied from outside into the abdominal detection area during abdominal physiological parameter detection

3.3
force detector
component of an APPD which measures the applied force

Note 1 to entry: The component can be, for example, the stand-alone type or the haptic type attached to a doctor's fingertips.

3.4
abdominal deformation
local change of the abdominal detection area caused by an applied force

3.5
dynamic signal
pulsation signal resulting from the abdominal aorta pulsation, which is detected in the substernal region or above/beside/below the periumbilical region

3.6
detection position
relative coordinate of the force detector to a pre-set coordinate origin expressed by coordinates (x, y)

3.7
abdomen temperature detector
component of an APPD which measures the local temperature of the abdominal detection area

Note 1 to entry: The component can be, for example, the stand-alone type or the haptic type attached to a doctor's fingertips.

4 Test conditions

4.1 Ambient temperature, humidity, atmospheric pressure

Tests shall be carried out within the range of the following environmental conditions. If ambient temperatures cannot be maintained, the test conditions shall be modified and results adjusted accordingly.

a) Ambient temperature range: 15 °C to 40 °C;

b) Relative humidity range: 30 % to 80 % (non-condensation);

c) Atmospheric pressure range: 86 kPa to 106 kPa.

4.2 Warm-up

Before testing, the testing instruments, regulated power supply and so on shall be preheated for 30 minutes.

4.3 Accuracy of the inspection equipment

The accuracy and resolution of relevant equipment used for testing shall be superior to three times the performance grade of the tested APPD (e.g. accuracy of the displaying instrument, regulated power supply).

5 Technical requirements

5.1 Force detection

5.1.1 Maximum applied force

The maximum applied force (F_{max}) on the force detector shall not be larger than 38 N. If the applied force is exerted automatically, the APPD shall have the functions to indicate and release the applied force under single fault condition, including power failure, component failure, or when the applied force on the abdomen exceeds either the prescribed maximum value or the maximum measuring range (rated load [F_n]) of the APPD.

Conformity shall be confirmed by inspection.

5.1.2 Force measurement range and accuracy

The value of the measuring range of the abdominal is referred to as rated load (F_n). The force detector's range shall include 0,4 N to 25 N.

Conformity shall be confirmed by inspection under an applied force onto the force detector.

5.1.3 Resolution

The value of the force detector's resolution shall be ≤ 0,3 N.

Test the output of the force detector, while loading the force detector with an outsider force generator. During testing, increase the load on the force detector from 0,4 N to 5 % of F_n at a step length less than or equal to 0,3 N. Record the change in output quantity as the load increases.

Conformity shall be confirmed by inspection.

5.1.4 Accuracy

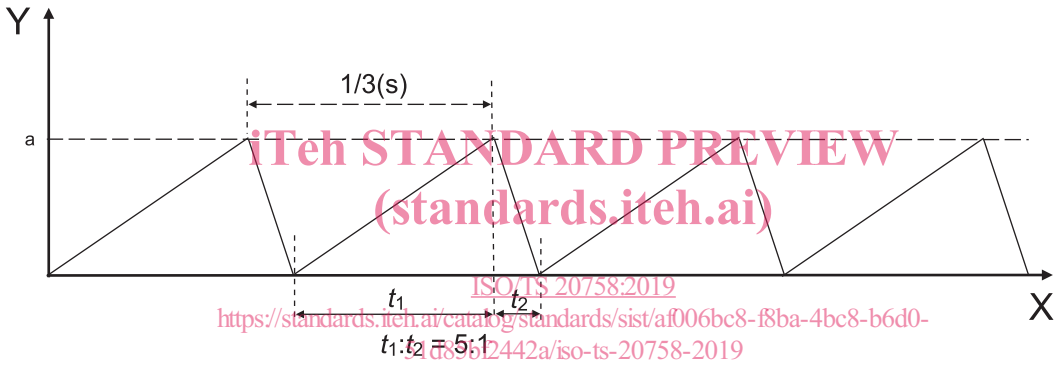
Accuracy, combining the effects of sensitivity, repeatability, nonlinearity and hysteresis, shall be within ± 5 % of the reading or ± 0,4 N, whichever is greater.

Conformity shall be confirmed by inspection.

5.2 Dynamic signal

If the APPD has this function, the largest distortion between the response waveform and the load waveform of force shall be within ± 5 % of the reading or ± 0,4 N, whichever is greater.

The dynamic response shall be detected under a 5:1 saw-tooth waveform load with a 3 Hz frequency and amplitude equal to the rated load, as shown in Figure 2.



Key

X time

Y load

a The rated load.

Figure 2 — The typical testing method and condition for inspection of the dynamic signal

Conformity shall be confirmed by inspection.

5.3 Overload capacity

Overload capacity of the force detector ≥ 250 % F_n.

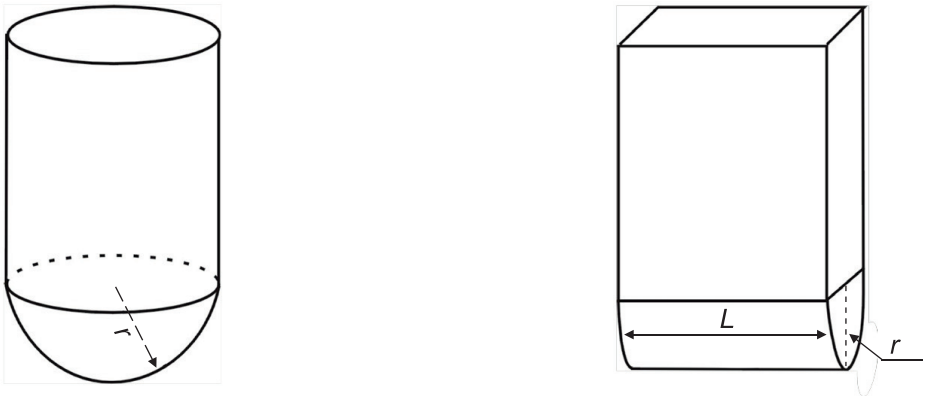
Test: under overload, continuously apply load to the force-sensing head for 1 minute and then release the load. Carry out three overload tests according to this method. Recover for 10 minutes after the test and then repeat steps 5.1.2 to 5.1.4.

Conformity shall be confirmed by inspection.

5.4 Geometrical shape of force detector

a) If the forcing detector is the stand-alone type, to avoid acute contact with abdomen skin, the geometrical shape of the stand-alone type force detector shall be hemispherical or hemicylindrical, as shown in Figure 3. For the hemispherical shape [see Figure 3 a)], the radius (r) of the hemisphere

shall not be smaller than 10 mm. For the hemicylindrical shape (see Figure 3 b)], the radius (r) and the width (L) of the hemicylinder shall not be smaller than 10 mm and 20 mm, respectively.



a) Hemispherical **b) Hemicylindrical**

Figure 3 — The geometrical shape of the sensor head

b) The haptic type force detector can be attached to the practitioner's fingertips when conducting the force measurement. In this case, the sensor shall be adequately flexible and thin so as not to cause acute contact with the skin of the abdomen area, and at the same time not to degrade the haptic sense of the doctor's fingertips. The sensing area shall not be larger than 100 mm^2.

5.5 Abdominal deformation along the direction of applied force

a) The abdominal deformation measurement shall be synchronized with the force sensing.

b) The abdominal deformation measurement shall be conducted along the direction of applied force.

c) The measurement ranges of deformation along the direction of applied force shall not be narrower than 20 mm.

d) The measurement resolution of deformation shall not be larger than 1 mm.

e) The measurement accuracy shall be within ± 5 % of reading or ± 1 mm, whichever is greater.

Conformity shall be confirmed by inspection.

5.6 Detection position (x, y)

The measurement and recording of the force detector and the abdomen temperature detector position are optional. This subclause only applies to APPD which have the ability to measure and record the position of the force detector.

The detection area should not be narrower than 0,550 0 m × 0,500 m. The measurement resolution of the detection position (x, y) should be not greater than 1 mm.

The measurement accuracy of the detection position (x, y) should be within ± 5 % of the reading or ± 1 mm, whichever is greater.

Conformity shall be confirmed by inspection.