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Contact clinical thermometers

Part 2: Test procedures

Thermomètre médicaux à contact

Partie 2: Procédures d'essai

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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Foreword

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Contact clinical thermometers

Part 2 - Test procedures

1 Test for maximum permissible errors of the indication

1.1 Apparatus

The apparatus consists of the following:

- calibrated reference thermometer with a maximum expanded uncertainty of 0.06 °C (with 95 % coverage probability);
- water bath with a minimum volume of 1 L, temperature stability of ±0.02 °C and temperature gradient of ±0.01 °C;
- support for immersion of clinical thermometers under test;
- climatic chamber, non-uniformity of temperature within ±1 °C, instability of temperature within ±1 °C, non-uniformity of relative humidity within ±5 %, instability of relative humidity within ±5 %.

1.2 Procedure

Position the support for immersion of clinical thermometers in the central region of the bath and position the reference thermometer next to the support. For each condition in the table below, adjust the bath until the temperature indication of the reference thermometer is stable. Start the clinical thermometers (if applicable) in test mode, place them in the support and wait for the measurement.

Table 1 – Test conditions

Condition	Bath temperature	Environmental conditions	
		Ambient temperature	Relative humidity
1	35.5 °C	(20 ± 2) °C	(50 ± 15) %
2	37 °C	(12 ± 2) °C	(50 ± 5) %
3	37 °C	(20 ± 2) °C	(50 ± 5) %
4	37 °C	(38 ± 2) °C	(80 ± 5) %
5	42 °C	(20 ± 2) °C	(50 ± 5) %

1.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilized reading of the reference thermometer.

2 Test for thermal shock (only for electrical thermometers)

2.1 Apparatus

The apparatus consists of that listed in 1.1, but with one freezer and one oven (or two climatic chambers).

2.2 Procedure for electrical contact clinical thermometer

Place the clinical thermometer under test in freezer at (-5 ± 2) °C for 10 min, and then immediately place it in an oven at (50 ± 2) °C for 10 min. Repeat this process four times. Place the clinical thermometer under test at (20 ± 2) °C, wait 30 min, and perform the procedure stated in 1.2 with condition nº 3.

2.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilized reading of the reference thermometer.

3 Test for influence of immersion time (only for mechanical thermometers)

3.1 Apparatus

The apparatus consists of that listed in 1.1, except the climatic chamber.

3.2 Procedure

Place the clinical thermometer under test at temperature t_1 (15 °C ≤ t_1 ≤ 30 °C) for 10 min, and then immediately place it in a bath adjusted to temperature t_2 (35.5 °C ≤ t_2 ≤ 42 °C) and wait for 20 s (T_{wait}). Take the thermometer out of the bath, place it again at ambient temperature t_1 (15 °C ≤ t_1 ≤ 30 °C) and wait for 10 min. Perform the procedure stated in 1.2 with condition nº 3 and register the clinical thermometer indication (R_1).

Repeat the procedure with T_{wait} = 60 s and register the clinical thermometer indication (R_2).

3.3 Expression of results

Express the result in the following way:

a) The difference between R_1 and corresponding reading of the reference thermometer;
b) The difference between R_2 and corresponding reading of the reference thermometer;
c) The absolute value of the difference R_2-R_1.

4 Test for storage (only for electrical thermometers)

4.1 Apparatus

The apparatus consists of that listed in 1.1.

4.2 Procedure

Switch off (if applicable) the clinical thermometer under test, and place it in a climatic chamber at (-20 ± 2) °C for 24 h, followed by 60 °C ± 2 °C (non-condensing) for 24 h with a gradient of 1 °C/min. Return to ambient temperature, wait for 1 h and perform the procedure stated in 1.2 with condition nº 3.

4.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilised reading of the reference thermometer.

5 Test for relative humidity (only for electrical thermometers)

5.1 Apparatus

The apparatus consists of that listed in 1.1.

5.2 Procedure

Switch off (if applicable) the clinical thermometer under test, and place it in a climatic chamber at a temperature between 20 °C and 32 °C and a relative humidity of 50 % for 4 h. Then increase the relative humidity to a value between 91 % and 95 %, and keep it there for 48 h. Return the relative humidity to the initial conditions, and keep it there for 48 h. Perform the procedure stated in 1.2 with condition nº 3.

5.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilised reading of the reference thermometer.

6 Test for mechanical shock (only for electrical thermometers)

6.1 Apparatus

The apparatus consists of that listed in 1.1, except the climatic chamber.

6.2 Procedure

Drop the clinical thermometer under test from a height of 1 m onto a flat, hard, wooden surface with the probe pointing downwards. Repeat the process once with the battery compartment pointing down, then with the display pointing down. Perform the procedure stated in 1.2 with condition nº 3.

6.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilised reading of the reference thermometer.

7 Test for effect of voltage variations of the power source (only for electrical thermometers with external power supply)

7.1 Apparatus

The apparatus consists of that listed in 1.1 (except the climatic chamber), an adjustable voltage supply and a voltmeter with a maximum permissible error within 5% of the measured value.

7.2 Procedure

Connect the clinical thermometer under test to the adjustable voltage supply and control it with the voltmeter. Perform the procedure stated in 1.2 with condition nº 3 at:

d) The maximum rated voltage (declared by the manufacturer) plus 5%;
e) The maximum rated voltage, declared by the manufacturer;
f) The mean value of the maximum and minimum rated voltage, declared by the manufacturer;
g) The minimum rated voltage, declared by the manufacturer;
h) The minimum rated voltage (declared by the manufacturer) minus 5%.

7.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilized reading of the reference thermometer when voltage of power source is within the range specified by manufacturer.

Express the results as the presence (or not) of temperature indication of the clinical thermometer under test when the voltage of power source is outside this range.

8 Test for radiated electromagnetic fields (only for electrical thermometers)

8.1 Apparatus

The apparatus consists of that listed in 1.1 (except the climatic chamber) and a semi-anechoic chamber or GTEM cell capable of generating signals as described in this test.

8.2 Procedure

Position the support for immersion of clinical thermometers in the central region of the bath and position the reference thermometer next to the support. Place the bath and reference thermometer inside the semi-anechoic chamber (or GTEM cell) and adjust it to 37 °C. Start the clinical thermometers (if applicable) in test mode, place them in the support and apply 1 kHz sinusoidal signals with 80 % AM modulation (in vertical and horizontal polarities) and electric field of 10 V/m for frequencies from 150 kHz MHz to 500 MHz with a sweep step of 1 % and a dwell time of 3 s.

Note: The bath and the reference thermometer must withstand the radiated electromagnetic fields without suffering interference.

8.3 Expression of results

Express the results as the maximum difference between the temperature indication of the clinical thermometer under test and the corresponding stabilized reading of the reference thermometer.

9 Test for transients in power supply (only for electrical thermometers with external power supply)

9.1 Fast transients

9.1.1 Apparatus

The apparatus consists of that listed in 1.1 (except the climatic chamber) and a current clamp.

9.1.2 Procedure

Perform the procedure stated in 1.2 with condition nº 3 with:

i) A transient (with peak voltage = ±1 kV and frequency = 5 kHz) applied with current clamp at the power supply lines;
j) A transient (with peak voltage = ±0,5 kV and frequency = 5 kHz) applied with current clamp at signal lines;

Note: The lastest version of IEC 61000-4-4 can be used as reference.

9.1.3 Expression of results

Express the results as the maximum difference between the temperature indication of the clinical thermometer under test and the corresponding stabilized reading of the reference thermometer.

9.2 Short duration power reductions (only for electrical thermometers with alternating current supply)

9.2.1 Apparatus

The apparatus consists of that listed in 1.1 (except the climatic chamber).

9.2.2 Procedure

Perform the procedure stated in 1.2 with condition nº 3 with:

k) Voltage of power supply reduced to 0 for 8 ms;
l) Voltage of power supply reduced to 0 for 16 ms;
m) Voltage of power supply reduced by 30% for 480 ms;
n) Voltage of power supply reduced to 0 for 4.8 s.

Each transient shall be repeated for 10 times, with 10 s, at least, between repetitions.

Note: The lastest version of IEC 61000-4-11 can be used as reference.

9.2.3 Expression of results

Express the results as the maximum difference between the temperature indication of the clinical thermometer under test and the corresponding stabilized reading of the reference thermometer.

10 Test for electrostatic discharges (only for electrical thermometers)

10.1 Apparatus

The apparatus consists of that listed in 1.1 (except the climatic chamber) and suitable equipment to apply electrostatic discharges as described in this test.

10.2 Procedure

With a relative humidity between 30 % and 60 %, apply ten repeated electrostatic discharges of 8 kV on the insulating surfaces of the clinical thermometer under test. Perform the procedure stated in 1.2 with condition nº 3.

10.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilised reading of the reference thermometer.

11 Test for water resistance (only for electrical thermometers)

11.1 Apparatus

The apparatus consists of that listed in 1.1 (except the climatic chamber) and a container with a minimum depth of 15 cm.

11.2 Procedure

Immerse the clinical thermometer under test at a depth of 15 cm in the container filled with water at ambient temperature, and wait for 30 min. Remove the thermometer from the container, and perform the procedure stated in 1.2 with condition nº 3.

11.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilised reading of the reference thermometer.

12 Tests for alarms

12.1 Temperature outside measuring range

12.1.0 Apparatus

The apparatus consists of that listed in 1.1, except the climatic chamber.

12.1.1 Procedure

Perform the procedure stated in 1.2 with condition nº 3 and bath adjusted to LI – 0.5 °C and LS + 0.5 °C where LI and LS are, respectively, the lowest and highest temperature of measurement range of the clinical thermometer under test, as specified by manufacturer.

12.1.2 Expression of results

Express the result as the presence (or not) of a clear indication or warning signal when the measured temperature is outside the measuring range specified by the manufacturer.

12.2 Low battery (only for clinical thermometers supplied by battery)

12.2.1 Apparatus

The apparatus consists of that listed in 7.1.

12.2.2 Procedure

Replace the internal electrical power source of the clinical thermometer with a DC voltage supply having an impedance which is equivalent to the impedance of the internal electrical power source specified by the manufacturer. Reduce the voltage of the source until a low battery indication or warning signal is activated at the level specified by the manufacturer and measure it with a voltmeter.

12.2.3 Expression of results

Express the result as value of the voltmeter indication.

13 Test for cleaning and disinfection

13.1 Apparatus

The apparatus consists of that listed in 1.1 (except the climatic chamber) and materials for cleaning and disinfection as specified by manufacturer.

13.2 Procedure

Perform the cleaning and disinfecting procedure, as specified by manufacturer, 20 times, and then perform the procedure stated in 1.2 with condition nº 3.

13.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test and the corresponding stabilised reading of the reference thermometer.

14 Test for data signal (digital) signal input/output ports

14.1 Apparatus

The apparatus consists of that listed in 1.1 (except the climatic chamber).

14.2 Procedure

Perform the procedure stated in 1.2 with condition nº 3 with the following:

a) Without any contact at signal input/output ports of the clinical thermometer under test;
b) Whilst short circuiting all contacts of the signal input/output ports belonging to the clinical thermometer under test;
c) Whilst applying the maximum voltage specified by the manufacturer to each contact belonging to the clinical thermometer under test;

14.3 Expression of results

Express the results as the difference between the temperature indication of the clinical thermometer under test in a) with the indicated values under b) and c).