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INTERNATIONAL RECOMMENDATION

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Contact clinical thermometers

Part 1: Metrological and technical requirements

Thermomètres médicaux à contact

Partie 1: Exigences métrologiques et techniques

OIML R xxx-1 Edition 202x (E)

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Contents

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This publication - reference OIML R XXX-1, edition 202x (E) - was developed by the OIML Technical Subcommittee TC 18/SC 2 *Medical thermometers*. It was approved for final publication by the International Committee of Legal Metrology in 202x and supersedes OIML R 7:1979 (E), R 114:1995(E) and R 115:1995(E).

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Contact clinical thermometers

Part 1 - Metrological and technical requirements

1 Scope

This Recommendation specifies the metrological and technical requirements for clinical thermometers intended to measure temperature through contact with the human or animal body.

This Recommendation applies to clinical thermometers with a maximum device or intended for continuous measurement.

This Recommendation applies to mechanical or electrical clinical thermometers but does not apply to secondary indicators, printing devices or other auxiliary devices.

This Recommendation does not apply to thermometers for premature babies or ovulation thermometers.

2 Terminology

2.1 clinical thermometer

medical measuring instrument used for indicating the temperature of a body site

2.2 non-automated measurement mode

operating mode in which the clinical thermometer indicates the temperature of the probe

2.3 automated measurement mode

operating mode in which the clinical thermometer applies criteria or algorithms to estimate body site temperature without human intervention

2.4 body site

part of the patient that establishes thermal coupling with the clinical thermometer

2.5 probe

part of the clinical thermometer that provides a thermal coupling between the sensor and the patient

2.6 sensor

part of the clinical thermometer that converts thermal energy into an electrical signal

2.7 test mode

operating mode in which a clinical thermometer operates in non-automated mode and does not turn off without human intervention

3 Description of the category of instrument

Any contact clinical thermometer contains at least a sensing part and an output means. For mechanical thermometers, the sensor is usually a glass filled with liquid, and the output is a scale that can be marked directly on the glass (solid-stem type), or on a strip placed inside it (enclosed-scale type). When the thermometer meets the body site, the liquid moves inside the glass until thermal equilibrium is reached. In this situation, the temperature indication corresponds to the position of the meniscus on the scale.

Note: Some countries do not allow mercury to be used as a thermometric liquid.

For electrical thermometers, the sensor (e.g., thermistor or thermopile) is typically integrated into a probe that can be either interchangeable or permanently connected to the rest of the thermometer. To perform measurements, the probe is positioned at the body site to establish thermal coupling with the sensor, which then converts thermal energy into an electrical signal. An electronic circuit processes this signal and transmits it to an indicating unit appropriately. The temperature indication may either provide an estimate of the body site temperature with which the probe is or not in contact (automated mode), or the immediate body site temperature (non-automated mode) or thermodynamic system (the thermostatic water bath is an example) with which the probe is in contact (test mode).

4 Units of measurement

The temperature shall be indicated in degree Celsius (°C).

Note: An alternative means for indicating temperature in degrees Fahrenheit (°F), may be used where permitted by national regulations.

5 Metrological requirements

5.1 Minimum measuring range

The measuring range shall be a minimum of 35.5 °C to 42.0 °C. Greater measuring ranges may be subdivided into partial ranges; however, the range 35.5 °C to 42.0 °C shall be continuous.

5.2 Maximum permissible errors

For any set of conditions within an ambient temperature range from 10 °C to 40 °C, relative humidity from 15 % to 85 % and, for electrical thermometers, voltage supply within ±10% of the nominal value of the mains voltage (or within the specified range of battery voltage), the maximum permissible error for the indication of contact clinical thermometer in test mode at any point of the minimum measuring range shall be as follows:

Table 1 – Maximum permissible errors

Instrument	Maximum permissible error
Mechanical contact clinical thermometer	±0.15 °C
Electrical contact clinical thermometer	±0.20 °C

Outside the minimum measuring range, the maximum permissible error may be twice the values indicated above.

5.3 Thermal shock

For electrical contact clinical thermometers, the maximum permissible error for the indication when ambient temperature changes abruptly from -5 °C to +50 °C shall comply with 5.2.

5.4 Influence of immersion time

For mechanical contact clinical thermometers at temperature t_1 (15 °C ≤ t_1 ≤ 30 °C), which is suddenly immersed in a well stirred water bath having a constant temperature t_2 (35.5 °C ≤ t_2 ≤ 42 °C) and is withdrawn after 20 seconds, the thermometer reading (R_1), after cooling to ambient temperature (15 °C to 30 °C) must comply with maximum permissible error requirements (5.2)

Repeat the procedure at the same temperature set for the thermostatic bath (t_2), but withdrawn the thermometers after 60 seconds. The thermometer reading (R_2), after cooling to ambient temperature (15 °C to 30 °C) must comply with maximum permissible error requirements (5.2).

The module of the difference between thermometer readings ($R_2 – R_1$) must be less than or equal to 0.005 x ($t_2 – t_1$).

5.5 Storage

For electrical contact clinical thermometers, the maximum permissible error for the indication after storage for 24 h at -20 °C ± 2 °C, followed by additional storage for 24 h at 60 °C ± 2 °C (non-condensing) shall be comply with 5.2.

5.6 Relative humidity

For electrical contact clinical thermometer, the maximum permissible error for the indication after 4 h at an ambient temperature between 20 °C and 32 °C and a relative humidity of 50 %, followed by 48 h at a relative humidity between 91 % and 95 %, and followed by 48 h in reference conditions shall comply with 5.2.

5.7 Mechanical shock

For electrical contact clinical thermometers, the maximum permissible error for the indication after falling on to a hard surface from a height of 1 m from three different orientations shall comply with 5.2.

A fixed contact clinical thermometer (e.g., wall mounted) is exempt from the requirements of this subclause.

5.8 Effect of voltage variations of the power source

Changes in the voltage within the working range of power source specified by the manufacturer shall not influence the temperature indication.

Outside this working range no temperature indication shall be displayed.

5.9 Electromagnetic interference

For electrical contact clinical thermometers, the maximum permissible error for the indication shall comply with 5.2 under each of the following conditions:

- when the thermometer is subjected to an electromagnetic field having a frequency between 150 kHz and 500 MHz with a field strength of 10 V/m;
- when the main supply of the thermometer is subjected to short duration power reductions, spikes and bursts. In this situation, if performance assessment during application of the transient is not possible, assessing performance before and after the test is acceptable;

- when at least ten repeated electrostatic discharges of 8 kV are applied to the thermometer casing or other accessible parts. In this situation, if performance assessment during application of the transient is not possible, assessing performance before and after the test is acceptable;
- when the thermometer is subjected to the field produced by high frequency surgical equipment (only applicable to thermometer intended to be used with high frequency surgical equipment).

5.10 Indication

The unit of measurement must accompany the indication.

The resolution shall be 0.1 °C at least.

For mechanical contact clinical thermometers, the scale must be clear and uniform, and must be engraved or printed clearly and indelibly.

For analogue scales, the distance between the marks must be at least 0.5 mm. The scale marks must be clear, straight and of thickness less than 0.25 times the distance between two consecutive scale marks. The marks lines must be perpendicular to the axis of the thermometer. The lines corresponding to degrees must be numbered, and the numbers must be clear and legible. The line corresponding to 37 °C may be indicated specially, using a different colour and/or by additional marking such as a dot, asterisk or arrow.

For digital indication, the display of temperature shall last at least one second, and shall be at least 4 mm in height, or shall be optically magnified to appear at least 4 mm in height.

The indicating unit shall include a self-checking device that meets the requirements of 5.2. This device, which may be manual or automatic, shall input a predetermined electrical signal. Failure shall be clearly indicated.

Note: This device checks only the operation of the indicating unit and does not ensure that a temperature measurement is correct. It provides a means of detecting a faulty operation caused by a defective component or other disturbance.

Where the indicating device is fitted with a remote measuring transducer, its self-checking device shall periodically and automatically test the entire indicating unit at two or more values within the specified measuring range. The remote measuring transducer shall be fitted with a digitized output signal, and data transmission shall be verified by a checking device contained within the indicating unit.

6 Technical requirements

6.1 General

The thermometer must be free from any defects which might prevent it from operating normally, or which might lead to errors by its users.

6.2 Test mode

For contact clinical thermometers with an automated measurement mode, the instrument shall have a test mode which shall be accessed by the operator without additional tools.

6.3 Water

Electrical contact clinical thermometers that probe is not interchangeable, shall be water resistant.

6.4 Alarms

Audible or visual alarms built into contact clinical thermometers shall not confuse the user.

Contact clinical thermometers shall provide a clear indication or warning signal when the measured temperature is outside the specified measuring range.

For contact clinical thermometers with power supplied by a battery, the instrument shall provide a clear indication or warning signal when the battery voltage is outside the specified limits.

6.5 Stamping

Space for stamping must be provided on the stem of solid-stem thermometers and on the sheath of enclosed-scale thermometers.

6.6 Cleaning and disinfection

The clinical thermometer shall meet the requirements for maximum permissible errors when it has been subjected to the cleaning and disinfecting procedures specified by the manufacturer.

6.7 Signal input and output ports

The construction of the signal input and output ports relevant to the temperature measurement shall ensure that incorrectly fitted or defective accessories shall not result in erroneous indication of temperature.

7 Metrological controls

Regional or national regulations may prescribe type approval, initial and/or subsequent verification for contact clinical thermometers.

7.1 Type approval

At least three samples of a new type of contact clinical thermometer or its parts shall be tested, but national regulations may prescribe more samples.

The tests to verify conformity with metrological and technical requirements shall be carried out in accordance with R XXX-2. A test report shall be prepared according to R XXX-3.

For contact clinical thermometers with automated measurement mode, the manufacturer (or responsible organization) must present the clinical investigation report carried out in accordance with ISO XXX for each type of interchangeable probe that is compatible.

7.2 Verification

After type approval has been granted, initial verification shall be carried out before the contact clinical thermometer or it parts are placed on the market.

Each instrument of an approved type of contact clinical thermometer in use shall be verified periodically in accordance with applicable metrological laws and regulations of a member state, or after repair.

During verification, testing can be conducted at any set of climatic conditions within the temperature range from 15 °C to 40 °C and a relative humidity range from 15 %to 85 %. At least the requirements of 5.2 shall be fulfilled.

7.3 Sealing

For contact clinical thermometers that are part of a patient-monitor, metrological control marks should prevent the manipulation of the metrologically relevant parts used for measuring temperature.

The metrological control marks shall be in place to prevent the opening of the casing. If the clinical thermometer is too small, the metrological control marks shall be put on the package.

7.4 Marking of the device

7.4.1 Markings required on the indicating unit

The indicating unit of the contact clinical thermometer shall be marked with the following information:

- name and/or trademark of the manufacturer;
- name and/or trademark of the responsible organisation;
- model designation of contact clinical thermometer;
- units of measurement, positioned close to the displayed values;
- measurement range;
- type approval number (if applicable);
- serial number (or lot number);
- country of origin.

7.4.2 Markings required on the interchangeable probe

The interchangeable probe shall be marked with the following information:

- name and/or trademark of the manufacturer;
- name and/or trademark of the responsible organisation;
- type of interchangeable probe;
- type of contact clinical thermometers that are compatible;
- type approval number (if applicable);
- serial number (or lot number);

7.4.3 Markings required on the interchangeable probe

The individual package of a contact clinical thermometer or it parts shall be marked with the following information:

- name and/or trademark of the manufacturer;
- name and/or trademark of the responsible organisation;
- type of contact clinical thermometer;
- thermometric liquid (if applicable);
- units of measurement, positioned close to the displayed values;
- measurement range;
- type approval number (if applicable);
- year of fabrication;
- country of origin.

7.5 Manufacturer's information

Information supplied by the manufacturer shall comply with the specifications and requirements given in this Recommendation. The manufacturer's instruction manual shall contain the following information:

- reference to OIML R XXX including the complete title;
- name and address of manufacturer;
- name and address of responsible organization;
- maximum permissible errors and results of clinical investigation;
- explanation of the operating procedures which are important for correct application (such as use of probe cover or the procedure to change the probe);

- description of all symbols, abbreviations and error codes used on the instrument;
- measurement range;
- methods for cleaning or disinfection;
- proper identification of interchangeable components and parts, such as temperature probe and batteries, including rated voltage, if applicable;
- explanation about self-checking device;
- information on suitable environmental conditions for use, storage and transport;
- information on the use of a single-use thermometer or temperature probe and the risks involved in case of reuse;
- nature and frequency of the maintenance which is required to ensure that the device always operates correctly and safely;
- disclosure that applicable national or regional metrological laws and regulations must be considered, if national regulation requires the disclosure;
- warm-up time, if applicable;
- troubleshooting, if applicable;
- specification of the signal input/output port(s);
- specification of the rated voltage of power source, if applicable;

Application software manuals and others manuals shall also comply with the specifications and requirements given in this Recommendation.