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DE MÉTROLOGIE LÉGALE

INTERNATIONAL RECOMMENDATION

Clinical electrical thermometers for continuous measurement

Thermomètres électriques médicaux pour mesurage en continu

OIML R 114

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FOREWORD

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CLINICAL ELECTRICAL THERMOMETERS FOR CONTINUOUS MEASUREMENT

1 Scope

1.1 This Recommendation specifies the metrological and technical requirements for clinical electrical thermometers for continuous measurement of human or animal body temperature. Such instruments are normally used to monitor the temperature at appropriate body sites of a patient undergoing certain surgical procedures or during intensive care.

1.2 The measuring range of clinical temperature covered shall be a minimum of 35.5 °C to 42.0 °C, which is consistent with the range specified by International Recommendation OIML R 7 *Clinical thermometers, mercury-in-glass with maximum device.*

1.3 This Recommendation applies to battery- or mains-powered instruments.

1.4 The instruments may be equipped to accommodate secondary indicators, printing devices, and other auxiliary devices. The metrological requirements for such accessories are not covered by this Recommendation.

1.5 Clinical electrical thermometers designed to measure skin temperature are not covered by this Recommendation. Clinical electrical thermometers with maximum device are covered by International Recommendation OIML R 115.

1.6 This Recommendation does not exclude the use of any contact device based on other measurement principles that meets equivalent performance standards in continuously measuring temperature.

2 Terminology

Note: The metrological terms used in this Recommendation are consistent with those defined in the *International vocabulary of basic and general terms in metrology* (VIM), 1993 edition, and *Vocabulary of legal metrology* (VML), 1978 edition.

2.1 A clinical electrical thermometer, as covered by this Recommendation, is a contact thermometer comprising a temperature probe and an indicating unit, and that is designed to measure human or animal body temperature.

2.2 A temperature probe is the component of a thermometer of which part is applied to a body cavity or tissue with which it establishes thermal equilibrium. It comprises a temperature sensor with associated parts including coverings, seals, inner leads, and connecting plug, where appropriate.

Notes: (1) A body cavity may be the rectum, esophagus, or a surgically created cavity.

(2) The part of the probe in contact with a body cavity is called the applied part.

2.3 A special-purpose temperature probe is a probe that incorporates a temperature sensor and has also other functions.

Note: An example of a special-purpose temperature probe is an esophageal-stethoscope probe in which a temperature sensor is loosely contained within a plastic tube; however the primary purpose of the probe is to transmit chest cavity sounds through the air or gas within the tube to a stethoscope attached to its open end.

2.4 An indicating unit is the component of a thermometer that processes the output signal of the temperature sensor and displays the measured temperature.

3 Description of the instrument

A complete thermometer consists of the following components:

- a temperature probe that is disinfectable, interchangeable or permanently connected to the indicating unit; an interchangeable probe may be either reusable, single-use (disposable), or special- purpose;
- an indicating unit that displays the temperature and includes the measuring transducer, indicating device, self-checking device, alarm device, power supply or battery, and means for connecting auxiliary devices.

  Note: The measuring transducer and the indicating device including the power supply and battery may be physically separate components connected by appropriate cables. The measuring transducer in such cases is called a remote measuring transducer.

4 Metrological requirements

4.1 Unit of measurement, measuring range and scale interval

4.1.1 The unit of temperature shall be the degree Celsius, °C.

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

4.1.2 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.

4.1.3 The scale interval or digital increment shall not exceed:

- 0.2 °C for analogue scales that permit interpolation, and
- 0.1 °C for digital scales.

4.2 Maximum permissible errors

4.2.1 The maximum permissible errors under reference conditions for the temperature range 32.0 °C to 42.0 °C shall be as follows:

Maximum permissible errors (range 32.0 °C to 42.0 °C)		
Complete thermometer	Indicating unit	Interchangeable probe
± 0.2 °C	± 0.1 °C	± 0.1 °C

4.2.2 Outside the temperature range 32.0 °C to 42.0 °C, the maximum permissible errors shall be twice the values specified in 4.2.1.

4.2.3 For a self-checking device used with an indicating unit to simulate the output of a temperature probe, the maximum permissible errors shall be ± 0.1 °C.

4.2.4 For an indicating unit with an alarm device the maximum permissible error for activation of the alarm shall be ± 0.2 °C of its setting if analogue, or zero if digital.

4.3 Reference conditions

The reference conditions for the requirements of 4.2 shall be:

- ambient temperature of 23 °C ± 5 °C
- relative humidity of 50 % ± 20 %
- the instrument operating within ± 10 % of the nominal value of the mains voltage, or within the specified range of battery voltage (specified power supply conditions).

5 Technical requirements

5.1 Temperature probe

5.1.1 For an interchangeable probe of the resistance type, the manufacturer shall specify the maximum power that may be supplied to the probe by an indicating unit; this power shall not cause energy dissipation (I^2R) giving rise to an increase in temperature by more than 0.02 °C for reusable or single-use probes (0.04 °C for special-purpose probes) when immersed in a reference water bath at 37 °C ± 0.1 °C.

Notes: (1) For a description of the reference water bath, see Annex A.

(2) A test of this requirement is only applicable to interchangeable probes submitted for pattern evaluation without a specific indicating unit. When a probe is submitted with an associated indicating unit, the requirement in 5.2.1 applies.

5.1.2 The thermal stability of the probe, after exposure for 100 hours at 80 °C or for 300 hours at 55 °C, shall be such that the requirement for maximum permissible errors specified in 4.2.1 is met.

5.1.3 The electrical insulation of the probe shall be sufficient to prevent a change in indicated temperature greater than ± 0.02 °C when the probe is immersed in an electrically conducting liquid. This insulation includes that between the inner lead wires, that between the wires and the surface of the probe, and that encasing and protecting connection and transitions.

5.1.4 The dependence of the sensor of the probe on immersion depth shall be such that the indicated temperature does not vary by more than 0.05 °C from that indicated at a specified minimum depth as measured from the tip of the probe when immersed to greater depths in a reference water bath at a temperature within the specified measuring range. The specified minimum depth shall not be greater than 8 cm from the tip of a reusable or single-use probe, or not greater than the minimum depth as specified by the manufacturer for any other probe.

5.1.5 The probe shall be strong enough to withstand mechanical stresses expected under normal conditions of use.

5.1.6 If the probe is interchangeable, it shall be fitted with either a plug-in or quick-disconnectable electrical connector. The contact resistance of the connector or the insulation resistance between the circuits of the connector or to ground shall not cause a variation in indicated temperature greater than 0.02 °C.

Note: The connector is not required to be water resistant.

5.1.7 The probe shall meet the requirements for maximum permissible errors specified in 4.2.1 when the applied part has been subjected to the cleaning and disinfecting procedures specified by the manufacturer.

Note: The materials of the probe that come into contact with the body should be selected for compatibility with body tissue.

5.1.8 The output signal of the probe shall not vary by more than ± 0.05 °C when the temperature of the connecting cable varies by 20 °C.

5.2 Indicating unit (including the measuring transducer)

5.2.1 The indicating unit shall provide a resistance-type temperature probe with an energizing potential sufficiently low so that energy dissipation (I^2R) in the probe meets the requirements specified in 5.1.1.

5.2.2 The indicating unit shall provide a clear indication of the specified measuring range.

5.2.3 The indicated temperature shall be unaffected when auxiliary devices are connected to the indicating unit. This requirement may be tested by short circuiting each output of the indicating device and then applying 30 volts dc to the output. Test requirements for variation in logic signals shall be provided by the manufacturer.

5.2.4 The digital display of temperature shall be at least 4 mm in height and shall last at least one second. The height requirement does not apply to cathode-ray tube display.

5.2.5 The operation of an analogue indicating device shall be independent of its orientation unless a required position of use is clearly identified. The indicating device shall be equipped with a mechanical means of adjusting to a mark or temperature value that lies outside or at the limit of the specified measuring range. The scale division for such device shall be at least 1.0 mm, and the scale lines shall be of uniform thickness not greater than one fifth of one scale division. The needle or pointer shall have a width no greater than one fifth of one scale division.

5.2.6 The indicating unit may include an alarm device meeting the requirements for maximum permissible errors specified in 4.2.4.

5.2.7 The indicating unit shall include a self-checking device meeting the requirements of 4.2.3. The 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 an faulty operation caused by a defective component or other disturbance.

5.2.8 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.

5.3 Complete thermometer

Note: The reference temperature is that indicated (either before or after the test, as appropriate) by the thermometer probe immersed in the reference water bath according to Annex A.1.1, the temperature being held constant within the working range of the thermometer.

5.3.1 In the case of mains power supply, the indicated temperature of the thermometer shall not show a measurable change from the reference temperature indication for variations from nominal values of voltage by ± 10 % and of frequency by ± 2 %.

In the case of power supplied by battery or an auxiliary power source, the thermometer shall be fitted with a device that provides a clear indication or warning signal when the voltage is at or below the level specified by the manufacturer. The thermometer shall show no significant variation from the reference temperature, if the supply voltage is above the specified level.

5.3.2 The indicated temperature shall not vary by more than ± 0.1 °C from the reference temperature when the temperature of the thermometer casing varies from + 10 °C to + 40 °C.

5.3.3 The indicated temperature shall not vary by more than ± 0.1 °C from the reference temperature after a thermal shock resulting from an abrupt change in temperature from – 5 °C to + 50 °C.

5.3.4 The indicated temperature shall not vary by more than ± 0.1 °C from the reference temperature after storage for 24 hours at – 20 °C ± 2 °C and at + 60 °C ± 2 °C.

5.3.5 The indicated temperature shall not vary by more than ± 0.1 °C from the reference temperature after storage at a relative humidity of 91 % to 95 % at a temperature constant within ± 2 °C in the range 20 °C to 32 °C.

5.3.6 The indicated temperature shall not vary by more than ± 0.3 °C from the reference temperature when subjected to an electromagnetic field having a frequency between 150 kHz and 500 MHz and a field strength of 10 V/m.

5.3.7 The indicated temperature shall not vary by more than ± 0.2 °C from the reference temperature when the mains supply is subjected to short duration power reduction, spikes, and bursts.

5.3.8 The indicated temperature shall not vary by more than ± 0.2 °C from the reference temperature when at least ten repeated electrostatic discharges of 8 kV are applied to the thermometer casing or other accessible parts.

5.3.9 The electrical isolation between the mains power supply and the patient shall meet the requirements concerning patient safety for BF- or CF-type equipment specified in IEC Publication 601-1, 1988 edition.

6 Practical instructions

6.1 Manufacturers shall provide an operating manual, or instructions, including the following information:

- list of the components of the thermometer and a block circuit diagram clearly indicating the principle of operation of the instrument,
- identification of the specified temperature measuring range of the complete thermometer taking into account the specified ranges of both the interchangeable probes and the indicating unit,
- installation, operation procedures, and mains voltage and frequency, if applicable,
- identification of components and suitable interchangeable parts such as probe and, if applicable, cables and batteries including nominal voltage,
- instructions for the self-checking device and the alarm device, if provided,
- instructions and precautions for disinfecting and cleaning the temperature probe,
- precautions with respect to the safety of operators and patients,
- information on the correct environmental conditions of use, storage, and transport of the thermometer.

6.2 Specific information should be provided by the manufacturer, on request, regarding possible substandard performance if used under the following conditions:

- outside the prescribed environmental temperature and humidity range,
- after an accidental mechanical shock.

7 Metrological controls

Note: The tests shall be carried out by testing or verifying laboratories that are acknowledged either for the OIML Certificate System or for other purposes according to national regulations of the countries concerned.

7.1 Pattern evaluation

7.1.1 Manufacturers shall provide the following information:

- location of sensor from tip of probe,
- description and principles of measurement of complete thermometer,
- description of electrical principles and of any necessary equipment provided,
- description of test for self-checking device,
- specified working range for battery,
- nominal and specified temperature measuring ranges,
- nominal values of calibration data for type of temperature probe, as applicable,
- precautions for cleaning and disinfecting complete thermometer or temperature probes, as appropriate, including test results as specified in B.3,
- test results,
- operating manual and/or instructions (see clause 6)

7.1.2 Thermometers shall be subjected to the following tests.

Note: Requirements for the reference water bath and the test for maximum permissible errors are provided in Annex A. The performance requirements for the instrument and its major components are provided in clauses 4 and 5. Where appropriate, an additional description of required tests is provided in Annex B. Further details of some tests are provided in International Document OIML D 11 *General requirements for electronic measuring instruments*.

- Probe
  - maximum permissible errors (4.2.1, 4.2.2, and A)
  - energy dissipation (5.1.1 and B.1)
  - long-term thermal stability (5.1.2)
  - electrical insulation and water resistance (5.1.3 and B.2)
  - dependence on immersion depth (5.1.4)
  - mechanical strength (5.1.5)
  - electrical contact resistance of connector (5.1.6)
  - cleaning and disinfecting (5.1.7 and B.3)
  - stability with changes in temperature of cable (5.1.8)
- Indicating unit
  - maximum permissible errors (4.2.1, 4.2.2, and A)
  - power provided to probe (5.2.1 and B.1)
  - effect of connecting auxiliary devices (5.2.3)
  - display of digital indicating device (5.2.4)
  - display of analogue indicating device (5.2.5)
  - alarm device, if included (4.2.4 and 5.2.6)
  - self-checking device (4.2.3, 5.2.7 and 5.2.8)

- Complete thermometer
  - maximum permissible errors (4.2.1, 4.2.2, and A)
  - variation of supply voltage of mains (5.3.1)
  - low-voltage indication of battery or auxiliary power source (5.3.1 and B.4)
  - ambient temperature (5.3.2 and B.5)
  - thermal shock (5.3.3 and B.6)
  - storage temperatures (5.3.4)
  - humidity (5.3.5 and B.7)
  - electromagnetic radiation interference (5.3.6 and B.8)
  - electrical interference (5.3.7 and B.9)
  - electrical discharges (5.3.8 and B.10)

7.1.3 For interchangeable probes submitted for evaluation without an indicating unit, all tests for the probe indicated in 7.1.2 shall be carried out and in addition the following:

- maximum permissible errors (4.2.1, 4.2.2, and A)
- maximum power to be supplied by an indicating unit to meet energy dissipation requirements (5.1.1 and B.1).

7.1.4 A report of the results of tests required in 7.1.2 and 7.1.3 shall be prepared and shall contain as a minimum the information listed in the test report format given in Annex C (subject to any adaptation to comply with national preferences). The manufacturer shall be provided with information or comments on any test failures.

7.2 Marks and labels

7.2.1 Manufacturers shall provide a space for marks and labels.

7.2.2 Manufacturers shall affix on the indicating unit the following marks or labels:

- name and address of manufacturer or supplier, and/or trademark,
- model or type designation, and serial or lot number,
- temperature value(s) or indication(s) given by the self-checking device(s), where appropriate,
- indication of the orientation or position in use, where appropriate.

7.2.3 Interchangeable temperature probes shall bear the following marks or labels:

- name and address of manufacturer and/or trademark,
- type designation,
- serial or lot number, or relevant manufacturing production data.

7.2.4 A single-use temperature probe shall be sealed in a package on which the information specified in 7.2.3 and the measuring range shall be indicated. In addition, sufficient space on the package shall be provided for the application of official approval marks. It shall be clear if the package has been opened and the instructions shall stipulate that the user only opens the package immediately before use.

7.2.5 The testing laboratory shall permit the application in an easily conspicuous place, of the following:

- pattern approval mark or label, on each complete thermometer or indicating unit and associated temperature probe(s),
- indication of the specified temperature measuring range if the total range of the thermometer is greater.

7.3 Certificate of approval

If the thermometers meet all requirements and tests for pattern approval, the testing officials shall issue a certificate of approval. An outline of the information contained in a certificate is given in Annex D.

7.4 Verification

7.4.1 The laboratory shall examine the information provided by manufacturers as specified in clause 6.

7.4.2 The laboratory shall examine the instrument's pattern approval certificate and mark(s) or label(s).

7.4.3 The laboratory shall carry out any of the tests indicated in 7.1.2 that may be critical for the designated application of the instrument.

Note: The tests indicated in Annex A.2 may be sufficient for verification.

7.4.4 The laboratory shall provide the verified instrument with a mark or label.

7.4.5 Single-use temperature probes shall be examined following the sampling plan described in Annex E.

7.4.6 The laboratory shall indicate the period of validity of the verification.

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ANNEX A

ESTABLISHING REFERENCE TEMPERATURES AND DETERMINING MAXIMUM PERMISSIBLE ERRORS

(Mandatory)

A.1 Reference temperatures

A.1.1 A well-regulated and stirred water bath containing at least one litre in volume shall be used to establish reference temperatures over the measuring range for conducting various performance tests on an instrument. The bath shall be controlled to a temperature stability of better than ± 0.02 °C over the specified temperature range and shall not have a temperature gradient greater than ± 0.01 °C within its working space at a specified temperature. This temperature gradient shall be assured under all conditions and methods of loading temperature probes.

Note: The water bath described above is referred to as a "reference water bath" in this Recommendation.

A.1.2 A reference thermometer with an expanded uncertainty no greater than 0.03 °C (calculated for a coverage factor k = 3) shall be used to determine the temperature of the water bath. The calibration shall be traceable to national measurement standards.

A.2 Determining maximum permissible errors

A.2.1 Complete thermometer

A.2.1.1 The temperature probe of a complete thermometer shall be immersed in a reference water bath at a constant temperature until temperature equilibrium is established. The temperature indicated by the thermometer shall be compared to that indicated by the reference thermometer. The bath temperature shall then be increased or decreased, the temperature equilibrium re-established, and the measurement process repeated. The difference between the measured and reference temperatures shall meet the requirements for maximum permissible errors as specified in 4.2.1 and 4.2.2.

A.2.1.2 The number of measurements at different temperatures depends on the measuring range of the instrument; however, measurements shall be carried out for at least the following number of temperatures within the measuring range:

Measuring range	Number of temperatures
≤ 10 °C	3
> 10 °C	5

A.2.2 Interchangeable and single-use probe

A.2.2.1 An interchangeable or single-use probe shall be immersed in a reference water bath as specified in A.2.1.1. A measured physical property of the probe shall be converted to a temperature value by using an appropriate instrument to measure a change in that property as a function of temperature. For a resistance-type probe, an appro-

priate instrument for measuring its output signal may be an ohmmeter that can apply power to the probe at a level below that specified in 5.2.1, and the temperature value is obtained from the manufacturer's data of resistance versus temperature. The expanded measurement uncertainty of the appropriate instrument shall not be greater than a value equivalent to 0.01 °C (calculated for a coverage factor k = 3), referring to the manufacturer's data at a temperature of 37 °C. The calibration shall be traceable to national measurement standards. Each temperature value obtained for the probe in this way shall be compared to that indicated by the reference thermometer in the bath. The difference between these temperature values shall meet the requirements for maximum permissible errors as specified in 4.2.1 and 4.2.2.

A.2.2.2 The number of measurements required shall be the same as specified in A.2.1.2.

A.2.3 Indicating unit

A.2.3.1 The performance of an indicating unit shall be tested using a device that simulates the relevant physical properties of the appropriate probe type. The expanded measurement uncertainty of the appropriate instrument shall not be greater than a value equivalent to 0.01 °C (calculated for a coverage factor k = 3), referring to the manufacturer's data at a temperature of 37 °C. The calibration shall be traceable to national measurement standards.

Note: For example, a calibrated decade resistance box may be used to provide a variable resistance to simulate a resistance-type probe. Values of resistance for input to the indicating unit over its specified measuring range shall be selected from the manufacturer's data of resistance versus temperature for appropriate probes. Similarly, variable voltage sources may be used to simulate a thermocouple.

A.2.3.2 The difference between the temperatures displayed by the indicating unit and the corresponding simulated values of temperature shall meet the requirements for maximum permissible errors specified in 4.2.1 and 4.2.2.

A.2.3.3 The number of measurements shall be the same as specified in A.2.1.2.

ANNEX B

BRIEF DESCRIPTION OF INSTRUMENT PERFORMANCE TESTS

(Mandatory)

B.1 Energy dissipation of a resistance-type probe

B.1.1 The probe shall be placed in a reference water bath as specified in A.1.1 at a temperature of 37 °C ± 1 °C. Measurements shall be carried out at three or more DC currents with the highest power being 2 mW. For each applied current, the voltage and current shall be measured.

B.1.2 The equivalent resistance values shall be calculated and then converted to temperature values using the manufacturer's characteristic (resistance versus temperature) table for the probe type. A linear (least-squares fit) curve of temperature as a function of applied power shall be drawn. From this curve, power corresponding to the maximum energy dissipation that will cause a change in indicated temperature by 0.02 °C for reusable or single-use probes or by 0.04 °C for special-purpose probes shall be determined. This value is the maximum power that may be provided by an indicating unit for the type of probe tested and the manufacturer's specified value shall be equal to or less than the value determined.

B.2 Electrical insulation resistance of the probes

B.2.1 The resistance of the temperature probe shall be determined at one or more temperatures using the procedure specified in A.2.2.1. The probe shall then be immersed to a length equal to that intended to be in contact with the body, or 50 mm, whichever is greater, in a physiological saline solution (9.5 g of NaCl per litre of distilled water).

B.2.2 After at least one minute, the resistance between the electrical connections of the probe taken together and an electrode immersed in the physiological saline solution shall be measured using an instrument that applies a voltage of 10 V ± 1 V between the probe connections and the electrode. The resistance measured shall be greater than the shunt resistance that would correspond to a change in indicated temperature of 0.02 °C.

B.2.3 The probe shall be left in the physiological saline solution for 24 hours, after which its resistance shall be remeasured as specified in B.2.1. The difference in indicated temperature between measurements shall not be greater than 0.02 °C.

B.3 Cleaning and disinfecting the probe

B.3.1 The applied part of the temperature probe of the thermometer shall be cleaned and disinfected twenty times according to the manufacturer's instructions (see IEC-Publication 601-1 No 44.7).

B.3.2 After cleaning and disinfecting as specified in B.3.1, the requirements of 4.2.1 shall be met.

B.4 Low battery indication

Note: In clauses B.4 to B.10, the temperature indication shall be generated within the measuring range of the thermometer by replacing the temperature probe by an auxiliary device, such as an appropriate precision resistor simulating the temperature of a resistance probe. The reference temperature indication is that obtained under the reference conditions described in 4.3.

B.4.1 The battery or the power source of the indicating unit shall be replaced by a variable DC voltage source.

B.4.2 The voltage of the source shall be reduced until a low battery indication or warning signal is activated at the level specified by the manufacturer.

B.5 Ambient temperature

B.5.1 The indicating unit shall be placed in a test chamber, and the temperature of the chamber varied from 10 °C to 40 °C with each temperature setting constant within ± 2 °C. Sufficient time shall be allowed at each temperature setting to permit the indicating unit to reach thermal equilibrium with the chamber.

B.5.2 At each temperature tested, the requirements specified in 4.2.1 shall be met.

B.6 Thermal shock

B.6.1 The indicating unit shall be placed in a test chamber at – 5 °C ± 2 °C.

B.6.2 After thermal equilibrium has been established, the indicating unit shall be placed in a test chamber at 50 °C ± 2 °C until thermal equilibrium has been established and all traces of condensed moisture have evaporated.

B.6.3 The process described in B.6.1-B.6.2 shall be performed five times.

B.6.4 The indicating unit shall be allowed to achieve thermal equilibrium at room temperature after which the indicated temperature shall not change by more than ± 0.1 °C as a result of exposure to the thermal shocks described in B.6.1-B.6.2.

Note: Thermal equilibrium may be achieved more quickly and completely by opening the casing of the thermometer, if possible.

B.7 Humidity

B.7.1 The indicating unit shall be stabilized at a temperature t within the range 20 °C to 32 °C for 4 hours or more. During this time, t shall remain constant within ± 2 °C.

B.7.2 After achieving a stable temperature as specified in B.7.1, the indicating unit shall be placed in a humidity test chamber containing air at a temperature between t and t + 4 °C and a relative humidity between 91 % and 95 % for a period of 48 hours.

B.7.3 After exposure as specified in B.7.2, the indicating unit shall be removed from the test chamber and allowed to stabilize at room temperature for 48 hours. The indicated temperature shall not vary by more than ± 0.1 °C as a result of this test.

B.8 Electromagnetic radiation interference

B.8.1 The indicating unit shall be exposed to an electromagnetic field with a field strength of 10 V/m at frequencies between 150 kHz and 500 MHz modulated by a 1 kHz sine wave and 80 % amplitude modulation.

B.8.2 The specific field strength shall be established prior to testing and without the instrument being placed in the electromagnetic field. The field strength may be generated as follows:

- a strip line for low frequencies (below 3 MHz or in some cases 150 MHz) for small instruments,
- dipole antennas, or antennas with circular polarization, placed 1 m from the instrument at higher frequencies.

B.8.3 The field shall be generated with two orthogonal polarizations and then slowly scanned through the frequency range. Antennas with circular polarization may be used to generate the electromagnetic field without a change in their positions. The test shall be carried out in a shielded enclosure to comply with international laws prohibiting interference with radio communications, but care shall be taken to minimize reflections.

B.8.4 During the test, the requirements specified in 5.3.6 shall be met.

Note: With reference to testing and test equipment, see IEC Publication 801-3.

B.9 Electrical interference (thermometers connected to mains)

B.9.1 Short-time power reduction

A test generator suitable for reducing the mains voltage by 100 % for ten half cycles shall be used. It shall be adjusted before connecting it to the instrument. The mains voltage interruptions and reductions shall be repeated ten times with an interval of at least 10 seconds between each.

B.9.2 Spikes

The test consists of exposing the instrument's power source to double exponential wave form voltages of 1 500 volts in amplitude (peak). These transients shall have a rise time of 35 ns and decay times between 1 µs and 3 µs. The transient generator shall have an output impedance of 50 ohms and it shall be adjusted before connecting to the instrument. At least ten positive and ten negative randomly spaced transients shall be applied at a repetition rate of 1 Hz.

B.9.3 Bursts

The test consists of exposing the instrument's power source to bursts of voltage spikes having a double exponential wave form. Each spike shall have a rise time of 50 ns and a half amplitude duration of 5 ns. The burst length shall be 15 ms with a

repetition of 300 ms. The burst generator shall be adjusted before connecting it to the instrument. At least ten positive and ten negative randomly spaced transients shall be applied at a repetition rate of 1 Hz.

Note: With reference to testing and test equipment, see IEC Publication 801-4.

B.9.4 Allowed variations

During the exposure to each test specified in B.9.1, B.9.2, and B.9.3, the indicated temperature shall not change by more than ± 0.2 °C.

B.10 Electrostatic discharge

B.10.1 A capacitor of 150 pF shall be charged to 8 kV by a suitable DC source. Then it shall be discharged through the instrument by connecting one terminal to the instrument's ground and the other through an 150 ohm resistor to the instrument's surface normally accessible to the operator. An instrument without a ground terminal shall be placed on a ground plate that projects at least 0.1 m beyond all sides. The grounded connection to the capacitor shall be as short as possible.

B.10.2 The discharge electrode shall be brought into close contact with the instrument until discharge occurs and shall be removed before repeating the procedure to produce another discharge. At least ten successive discharges shall be applied with a time interval between discharges of at least 10 seconds.

B.10.3 After the test described in B.10.2, the indicated temperature shall not change by more than ± 0.02 °C.

Note: With reference to testing and test equipment, see IEC Publication 801-2.

ANNEX C

TEST REPORT FORMAT

Note: This Annex is informative with regard to implementation of this Recommendation in national regulations; however, use of the test report format is mandatory for the application of the Recommendation within the OIML Certificate System.

A test report intended for use in the OIML Certificate System and for other purposes shall include the following information.

Note: This format is for testing complete thermometers. For testing indicating units only, all clauses apply except C.10.1; for testing probes only, all clauses apply except C.10.2 and C.10.3.

C.1 Name and address of testing laboratory(ies)

C.2 Reference (number and year of the edition) to this Recommendation

C.3 Identification of the pattern to which this test report applies, e.g. common and trade names and model, inscriptions, and a brief description with drawings, diagrams, if not included in the operating manual

C.4 Identification of samples tested

C.5 Name and address of manufacturer

C.6 Name and address of applicant if other than manufacturer

C.7 Date of beginning and end of test

C.8 Location or name of laboratory where tests were performed if other than the address given in C.1

C.9 Information and identification

C.9.1 Operating manual and other documents submitted for the evaluation have clear and complete instructions:

Yes _____ No _____

Comments (including a list of the documents provided by the manufacturer): _____

_____

C.9.2 Markings:

Pass: _____ Fail: _____

C.10 Summary of tests carried out as specified in 7.1.2, and conditions specified in this International Recommendation

C.10.1 Probes (at least ten probes shall be tested)

- Maximum permissible errors:

Probe number	Temperature of bath	Indicated temperature	Difference of temperature

Pass: _____ Fail: _____

- Dependence on immersion depth:

Pass: _____ Fail: _____

- Long-term thermal stability:

Probe number	Change in indicated temperature

Pass: _____ Fail: _____

- Electrical insulation and water resistance:

Pass: _____ Fail: _____

- Mechanical strength:

Pass: _____ Fail: _____

- Electrical contact resistance of connector:

Pass: _____ Fail: _____

- Cleaning and disinfecting:

Pass: _____ Fail: _____

- Stability with changes in temperature of the cable (values shall be calculated using the temperature coefficient of the electrical conducting material of the cable):

Pass: _____ Fail: _____

C.10.2 Indicating unit (at least one unit shall be tested)

- Maximum permissible errors:

Unit number	Simulated temperature	Indicated temperature	Difference of temperature

Pass: _____ Fail: _____

- Dissipation power provided for the probe: _____ mW
- Effect of connecting auxiliary devices:

Pass: _____ Fail: _____

- Display of digital indicating device:

Pass: _____ Fail: _____

- Display of analogue indicating device:

Pass: _____ Fail: _____

- Digital alarm device included:

Yes: _____ No: _____

- Analogue alarm device included:

Yes: _____ No: _____

- Maximum permissible error:

Pass: _____ Fail: _____

- Self-checking device (with description of test method):

Pass: _____ Fail: _____

C.10.3 Complete thermometer (at least one thermometer shall be tested)

- Maximum permissible errors:

Sample number	Temperature of bath	Indicated temperature	Difference of temperature

Pass: _____ Fail: _____

- Stability in changes to supply voltage:
  - Nominal mains voltage: _____ V
  - Nominal battery voltage: _____ V
  - Lower limit of battery voltage specified by the manufacturer: _____ V
  - Variations in mains voltage:

    Pass: _____ Fail: _____
  - Low-voltage indication of battery:

    Pass: _____ Fail: _____

- Ambient temperature:

  Pass: _____ Fail: _____
- Thermal shock:

  Pass: _____ Fail: _____
- Storage temperatures:

  Pass: _____ Fail: _____
- Humidity:

  Pass: _____ Fail: _____
- Electromagnetic radiation interference:

  Pass: _____ Fail: _____
- Electrical interferences:
  - short time power reduction:

    Pass: _____ Fail: _____
  - spikes:

    Pass: _____ Fail: _____
  - bursts:

    Pass: _____ Fail: _____
- Electrical discharges:

  Pass: _____ Fail: _____

C.11 Description of any other tests applied and their results

C.12 Brief statement of conclusions as to whether the samples tested meet the requirements of this International Recommendation and are suitable for the designated application

C.13 Signature of the person(s) responsible, date, and test report number.

ANNEX D

OUTLINE OF A CERTIFICATE FOR PATTERN APPROVAL

(Informative)

D.1 Name and address of manufacturer or distributor

D.2 Identification of manufacturer of each thermometer component, if different, including indicating unit and temperature probe(s)

D.3 Temperature measuring range(s)

D.4 List of performance tests applied

D.5 Identification of approval mark(s) or label(s), and its (their) location

D.6 Description of tests to be carried out on verification, if appropriate

ANNEX E

STATISTICAL SAMPLING PLANS
FOR VERIFICATION OF SINGLE-USE TEMPERATURE PROBES

(Mandatory)

E.1 This sampling plan shall be carried out at verification and is not intended to replace the sampling by a manufacturer after production which would normally require more rigorous testing.

E.2 The size of the lots encompassed shall be 1 201 units as a minimum and 35 000 units as a maximum.

E.3 The number of samples of a lot required for a test and the acceptance and rejection criteria shall be:

Range in total units of a lot	Sample sequence	Probes required (sample size)		Number of defective probes	
		Simple	Cumulative	Accept	Reject
1 201 à 3 200	first	32	32	0	3
	second	32	64	3	4
3 201 à 10 000	first	50	50	1	4
	second	50	100	4	5
10 001 à 35 000	first	80	80	2	5
	second	80	160	6	7

Note: This table corresponds to International Standard ISO 2859, 1974 edition, inspection level I, AQL = 1.5

E.4 A first sample of probes shall be tested. If the number of defective probes does not exceed the number for acceptance, then the lot shall be accepted. If the number of defective probes reaches the number for rejection, then the lot shall be rejected. If the number of defective probes is larger than the number for acceptance but smaller than the number for rejection, then a second sample of probes shall be tested. Acceptance or rejection of the second sample shall be based on the total number of defective probes obtained in both tests.

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