ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL RECOMMENDATION

Clinical electrical thermometers with maximum device

Thermomètres électriques médicaux avec dispositif à maximum

OIML R 115

Edition 1995 (E)

CONTENTS

FOREWORD

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States.

The two main categories of OIML publications are:

1) **International Recommendations (OIML R),** which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;

2) **International Documents (OIML D),** which are informative in nature and intended to improve the work of the metrological services.

OIML Draft Recommendations and Documents are developed by technical committees or subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis.

Cooperative agreements are established between OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may apply simultaneously OIML publications and those of other institutions.

International Recommendations and International Documents are published in French (F) and English (E) and are subject to periodic revision.

OIML publications may be obtained from the Organization's headquarters:

Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris - France
Telephone: 33 (1) 48 78 12 82 and 42 85 27 11
Fax: 33 (1) 42 82 17 27

*
* *

This publication - reference OIML R 115, edition 1995 (E) - was developed by the OIML subcommittee TC 18/SC 2 *Medical thermometers*. It was approved for final publication by the International Committee of Legal Metrology in 1994 and will be submitted to the International Conference of Legal Metrology in 1996 for formal sanction.

CLINICAL ELECTRICAL THERMOMETERS WITH MAXIMUM DEVICE

1 Scope

1.1 This Recommendation specifies the metrological and technical requirements for clinical electrical thermometers with a maximum device. Such instruments are designed to measure human or animal body temperature. They indicate a maximum temperature measured after a steady state is reached or predicted after a time specific to the design of the instrument. Until the maximum temperature is indicated, the actual temperatures may be indicated by the thermometer.

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*. Two accuracy classes, class I and class II, are covered by this Recommendation.

1.3 This Recommendation applies to battery-powered instruments which provide a digital indication of temperature.

1.4 Clinical electrical thermometers designed to measure skin temperature are not covered by this Recommendation. Clinical electrical thermometers for continuous measurement are covered by International Recommendation OIML R 114.

1.5 This Recommendation does not exclude the use of any contact device based on other measurement principles that meets equivalent performance standards in determining maximum body temperature at specified time intervals.

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 or tissue may be the mouth (sublingual), rectum, or armpit.

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

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

2.4 A maximum device is the component of a thermometer that monitors over a specified time the temperature measured by a probe in contact with a body cavity or tissue, after which it indicates the maximum temperature and maintains the indication until reset by the user.

2.5 A predicting clinical electrical thermometer calculates the maximum temperature of a probe in contact with a body cavity or tissue, without waiting for thermal equilibrium to occur, by using heat transfer data and a mathematical algorithm.

3 Description of the instrument

3.1 A complete thermometer consists of a temperature probe connected to an indicating unit.

3.2 The instrument may be of one of the following types:

- an interchangeable temperature probe connected to an indicating unit that is compatible with the characteristic response of the probe, or
- a temperature probe and an indicating unit permanently connected.

4 Metrological requirements

4.1 Unit of measurement - measuring range - 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:

- 0.01 °C for class I thermometers,
- 0.1 °C for class II thermometers.

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 for the two accuracy classes covered shall be as follows:

Accuracy class	Maximum permissible errors (range 32.0 °C to 42.0 °C)		
	Complete thermometer	Indicating unit	Temperature probe
Class I	± 0.15 °C	± 0.05 °C	± 0.1 °C
Class II	± 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.

4.3 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 the specified range of battery voltage (specified power supply conditions).

4.4 Time response

The thermometer shall be submitted by the manufacturer to a testing laboratory to determine its time response. The test shall be based on an analysis of a significant sample of human subjects.

The difference between the displayed calculated temperature and the corresponding measured temperature at thermal equilibrium of a calculating (predicting) thermometer shall not exceed 0.2 °C.

Annex G provides a description of this test.

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 when immersed in a reference water bath at 37 °C ± 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 approval 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 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 connections and transitions.

5.1.4 The location of the sensor in the probe shall be such that, when the probe is immersed to depths greater than 50 mm from its tip in a reference water bath at a temperature within the specified measuring range, the indicated temperature does not vary by more than 0.05 °C from that indicated at a depth of 50 mm.

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 when the applied part has been subjected to the cleaning and disinfecting procedures specified by the manufacturer.

Notes: (1) For small compact thermometers this applies to the complete instrument.
(2) 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 cable connecting it to an indicating unit varies by 20 °C.

5.2 Indicating unit

5.2.1 When connected to a resistance-type temperature probe, the indicating unit shall provide an energizing potential sufficiently low so that energy dissipation (I^2R) in the probe shall not cause an increase in indicated temperature of over 0.01 °C when the probe is immersed in a reference water bath at a temperature within the specified measuring range.

5.2.2 The indicating unit shall not indicate a temperature when connected to a battery charger.

5.2.3 The digital display of temperature shall be at least 4 mm in height or it shall be optically magnified so as to appear at least 4 mm in height.

5.2.4 The indicating unit shall provide a clear indication or warning signal when the measured temperature is outside the specified measuring range.

5.2.5 The indicating unit shall include a self-checking device that meets the requirements of 4.2. 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.

5.2.6 In the case of a predicting thermometer, the indicating unit shall provide a means of displaying the measured temperature after reaching the thermal equilibrium.

5.3 Complete thermometer

Note: The reference temperature is that indicated (either before the test, or before and 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 The thermometer shall provide a clear indication or warning signal when the battery voltage is outside the specified limits and it shall meet the requirements specified in 4.2 when the voltage is within these limits.

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 during exposure 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 ± 0.1 °C from the reference temperature after fall on to a hard surface from a height of 1 m from three different orientations.

5.3.8 Small and compact complete thermometers shall be water resistant.

6 Practical instructions

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

- description of appropriate uses and means of application,
- identification of the specified temperature measuring range of the complete thermometer taking into account, if applicable, the specified measuring ranges of both the interchangeable probes and the indicating unit,
- instructions and precautions for cleaning and disinfecting the complete thermometer or the interchangeable probes,
- identification of components and suitable interchangeable parts such as probes and batteries, including nominal voltage, if applicable,
- minimum time for achieving thermal equilibrium,
- description of the transition from the predicted temperature-measuring mode into the actual temperature-measuring mode,
- instructions for the self-checking device,
- 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,
- indication on instrument if a displayed value is calculated,
- test results,
- results of clinical test of time response (4.4 and Annex G), and
- 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 the International Document OIML D 11 *General requirements for electronic measuring instruments*.

- Probe
  - maximum permissible errors (4.2 and A.2.2.1)
  - long-term thermal stability (5.1.2)
  - electrical insulation and water resistance (5.1.3 and B.2)
  - location of sensor (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 and A)
  - power provided to probe (5.2.1 and B.1)
  - indication when connected to battery charger (5.2.2)
  - display of digital indicating device (5.2.3)
  - indication if the thermometer is outside the specified measuring range (5.2.4)
  - self-checking device (5.2.5)
  - display of predicting thermometer (5.2.6)
- Complete thermometer
  - maximum permissible errors (4.2 and A)
  - low battery indication (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)
  - mechanical shock (5.3.7 and B.9)
  - water resistance of small compact thermometers (5.3.8 and F)

7.1.3 For interchangeable probes submitted for approval 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 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 thermometer or indicating unit, if separate, 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 values or indications given by the self-checking device,
- indication of the orientation or position in use, where appropriate,
- indication if a displayed value is calculated.

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 a 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 authority 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 A.2 may be sufficient for verification.

7.4.4 The laboratory shall provide a 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 water resistance of small and compact complete thermometers shall be examined by means of the procedure described in F.2.

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

BIBLIOGRAPHY

- *Vocabulary of legal metrology* (VML), 1978 edition
- *International vocabulary of basic and general terms in metrology* (VIM), 1993 edition
- *Guide to the expression of uncertainty in measurement* (GUM), 1993 edition
- International Document OIML D 11 *General requirements for electronic measuring instruments,* 1994 edition
- IEC Publication 601-1 *Medical electrical equipment*
  - Part 1: *General requirements for safety,* 1988 edition
- IEC Publication 801 *Electromagnetic compatibility for industrial-process measurement and control equipment*
  - Part 1 (801-1) *General introduction,* 1984 edition
  - Part 2 (801-2) *Electrostatic discharge requirements,* 1991 edition
  - Part 3 (801-3) *Radiated electromagnetic field requirements,* 1984 edition
  - Part 4 (801-4) *Electrical fast transient/Burst requirements,* 1988 edition
- International Standard ISO 2859-1974 *Sampling procedures and tables for inspection by attributes,* 1974 edition
- International Standard IEC 68-1 *Environmental testing*
  - Part 1: *General and guidance,* 1988 edition

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.

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 appropriate instrument for measuring its output signal may be an ohmmeter that can apply power to the probe at a level below the limit 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.

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 simulating device 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. 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.

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 interchangeable 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 0.01 °C for reusable, interchangeable, or single-use 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 probe

B.2.1 The resistance of the temperature probe shall be determined at one or more temperatures using the procedure specified in A.2.1.1. or 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 or of the complete compact 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 shall be met.

B.4 Low battery indication

Note: In clauses B.4 to B.9, it is to be understood that the temperature indication of a complete thermometer shall be generated within the measuring range by inserting the probe in a reference water bath or in another bath with similar qualities. The temperature indication of an indicating unit designed for use with interchangeable probes shall be generated by replacing the 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 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. The test shall be carried out at three different temperatures: 37 °C ± 1 °C, and the lower and upper limits of the measuring range.

B.5 Ambient temperature

B.5.1 The complete thermometer or 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 complete thermometer or indicating unit to reach thermal equilibrium with the chamber.

B.5.2 At each temperature tested, the requirements specified in 4.2 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 complete thermometer or 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 complete thermometer or 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 complete thermometer or 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 complete thermometer or 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 complete thermometer or 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 Mechanical shock

B.9.1 The complete thermometer or indicating unit shall be allowed to fall from a height of 1 m on to a hard surface (for example, a block of hard wood of density greater than 700 kg/m^3 and of suitable size lying flat on a rigid base). This drop shall be performed once for three different orientations of the complete thermometer or indicating unit.

B.9.2 After the test, the requirements specified in 5.3.7 shall be met.

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 probes only, all clauses apply except C.10.2 and C.10.3; for testing indicating units only, all clauses apply except C.10.1.

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

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

C.3 Identification of the pattern to which the test report applies, e.g. common and trade names and model, and a brief description including drawings, diagrams, and inscriptions, specifically including the following:

- types of probes and characteristics,
- measuring range,
- specification of the battery.

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 Dates 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)

- Long-term thermal stability:

Probe number	Change in indicated temperature

Pass: _____ Fail:_____

- Electrical insulation and water tightness:

Pass: _____ Fail:_____

- Location of sensor:

Pass: _____ Fail:_____

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

- Maximum permissible errors:

Simulated temperature	Indicated temperature	Difference of temperature

Pass: _____ Fail:_____

- Dissipation power provided for probe: _____ mW

Pass: _____ Fail:_____

- Display of digital indicating device:

Pass: _____ Fail:_____

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

Pass: _____ Fail:_____

- Means for indicating that thermometer is out of its measuring range:

Pass: _____ Fail:_____

- Display of predicting thermometer:

Pass: _____ Fail:_____

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

- Maximum permissible errors (if not tested under C.10.1 and C.10.2):

Sample number	Temperature of bath	Indicated temperature	Difference of temperature

Pass: _____ Fail:_____

- Nominal battery voltage: _____ V
- Lower limit of battery voltage specified by the manufacturer: _____ V

Pass: _____ Fail:_____

- Low-voltage indication of battery:

Pass: _____ Fail:_____

- Cleaning and disinfecting:

Pass: _____ Fail:_____

- Ambient temperature:

Pass: _____ Fail:_____

- Thermal shock:

Pass: _____ Fail:_____

- Storage temperatures:

Pass: _____ Fail:_____

- Humidity:

Pass: _____ Fail:_____

- Electromagnetic radiation interference:

Pass: _____ Fail:_____

C.10.4 Interchangeable probes submitted for approval without an indicating unit (at least ten probes shall be tested).

Perform all tests indicated in C.10.1 and in addition the following:

- Maximum permissible errors:

Probe number	Temperature of bath	Indicated temperature	Difference of temperature

Pass: _____ Fail:_____

- Electrical contact resistance of the 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:_____

- Mechanical shock:

  Pass: _____ Fail:_____

- Water resistance:

  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

(Mandatory)

E.1 Sampling plan for the verification of single-use temperature probes

E.1.1 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.1.2 The size of the lots encompassed shall be 1 201 units as a minimum and 35 000 units as a maximum.

E.1.3 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 to 3 200	first	32	32	0	3
	second	32	64	3	4
3 201 to 10 000	first	50	50	1	4
	second	50	100	4	5
10 001 to 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.2 Sampling plan for the verification of water-resistant-type thermometers

E.2.1 The size of the lots encompassed shall be 501 units as a minimum and 35 000 units as a maximum.

E.2.2 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	Thermometers required (sample size)		Number of defective thermometers	
		Simple	Cumulative	Accept	Reject
501 to 1 200	first	50	50	0	2
	second	50	100	1	2
1 201 to 3 200	first	80	80	0	3
	second	80	160	3	4
3 201 to 10 000	first	125	125	2	5
	second	125	250	6	7
10 001 to 35 000	first	200	200	5	9
	second	200	400	12	13

Note: This table corresponds to International Standard ISO 2859, 1974 edition, inspection level II, AQL = 0.65 (501 to 3 200), AQL = 1.0 (3 201 to 10 000), AQL = 1.5 (10 001 to 35 000).

E.3 In either subclauses E.1.3 or E.2.2, a first sample of probes or thermometers shall be tested. If the number of defective probes or thermometers does not exceed the number for acceptance, then the lot shall be accepted. If the number of defective probes or thermometers reaches the number for rejection, then the lot shall be rejected. If the number of defective probes or thermometers is larger than the number for acceptance but smaller than the number for rejection, then a second sample of probes or thermometers shall be tested. Acceptance or rejection of the second sample shall be based on the total number of defective probes or thermometers obtained in both tests.

ANNEX F

TEST OF WATER RESISTANCE OF COMPLETE THERMOMETERS

(Mandatory)

F.1 Pattern approval

F.1.1 A total of 10 samples shall be tested.

F.1.2 The battery casing shall be opened and closed several times before the tests if the thermometer is equipped with replaceable batteries.

F.1.3 The thermometer shall be totally immersed in an equivalent physiological solution (9.5 g NaCl per litre of distilled water) to a depth of 15 cm and at temperatures of 50 °C and 20 °C for the following periods of time and in the sequence indicated:

- 1 hour at 50 °C ± 2 °C
- 1 hour at 20 °C ± 2 °C
- 24 hours at 50 °C ± 2 °C
- 24 hours at 20 °C ± 2 °C

F.1.4 The indicated values shall be measured at two or more temperatures near the lower and upper limit of the measuring range before the first immersion and after the second and last immersion. The thermometers shall have reached equilibrium with room temperature before recording the indicated values. After the last immersion, the thermometers shall be stored for 14 days in air at room temperature before taking the last measurement.

F.1.5 The test may be discontinued if it is obvious that water has penetrated into the casing of a thermometer.

F.1.6 The thermometer pattern shall be declared to be water resistant if, for nine out of ten thermometers, the difference in indicated temperatures for any individual thermometer is less than:

- 0.04 °C for thermometers with a minimum digital increment of 0.01 °C (class I),
- 0.1 °C for thermometers with a minimum digital increment of 0.1 °C (class II).

F.2 Verification

F.2.1 The water resistance test shall be carried out according to the sampling plan specified in E.2.

F.2.2 The thermometers shall be totally immersed in an equivalent physiological solution at a temperature of 50 °C ± 2 °C to a depth of 15 cm for one hour, after which they shall be immersed for another hour under same conditions but at a temperature of 20 °C ± 2 °C. Before the first immersion and after the second immersion, the indicated values shall be measured at two temperatures.

F.2.3 A thermometer shall be accepted if the performance requirements specified in F.1.6 are met.

ANNEX G

CLINICAL TEST OF RESPONSE TIME

(Mandatory)

G.1 Non-predicting clinical electrical thermometers

The minimum time for achieving thermal equilibrium at each appropriate body site shall be determined on the basis of testing at least ten persons.

G.2 Predicting (calculating) clinical electrical thermometers

G.2.1 The difference between the displayed calculated temperature and the corresponding measured temperature at thermal equilibrium of a calculating (predicting) thermometer shall be determined on the basis of testing at least 100 persons. The predicted temperature of each person at an appropriate body site shall be determined by the method specified by the manufacturer. After the predicted indication, the thermometer shall remain at that site for measuring and indicating the actual temperature of its sensor. The total time allowed shall be sufficient to attain thermal equilibrium. The difference in the first and second indicated temperatures for 95 % of the persons tested shall not be more than 0.2 °C.

G.2.2 If an oral (sublingual) test has been carried out, the minimum number of persons required for rectal measurement shall be twenty.

Printed in France

GRANDE IMPRIMERIE DE TROYES
130, rue Général-de-Gaulle, 10000 Troyes