INTERNATIONAL RECOMMENDATION

OIML R xxx-3
Edition 202x (E)

Contact clinical thermometers

Part 3: Test report format

Thermomètre médicaux à contact

Partie 3: Format du rapport d'essai

OIML R xxx-3 Edition 202x (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

Contents

Foreword

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

The main categories of OIML publications are:

- **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. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and which are intendedto harmonise and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intendedto give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B)**, which define the operating rules of the variousOIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Project Groups linked to Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been established between the OIML and certain institutions, such as ISO and the IEC,with the objective of avoiding contradictory requirements. Consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML participates in Joint Committees with other Institutions for the development of **Vocabularies (OIML V)** and **Joint Guides (G)** and periodically commissions legal metrology expertsto write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

This publication - reference OIML R xxx-2, 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).

OIML Publications may be downloaded from the OIML website in the form of PDF files. Additional information on OIML Publications may be obtained from the Organisation’s headquarters:

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Contact clinical thermometers

Part 3 - Test report format

Explanatory notes on the test report format:

i) General

This test report format, which is informative with regard to the implementation of R xxx-1 in national regulations, presents a standardised format for the results of the various tests and examinations to which a type of sphygmomanometer shall be submitted with a view to its approval as well as for the results of verification tests. The tests are listed in R xxx-2.

It is recommended that all metrology services or laboratories evaluating types of sphygmomanometers according to OIML R xxx or to national or regional regulations based on OIML R xxx use this test report format, directly or after translation into a language other than English or French.

It is also recommended that this test report format in English or in French (or in both languages) be transmitted by the country performing these tests to the relevant authorities of another country, under bi- or multi-lateral cooperation agreements.

In the framework of the OIML Certification System (OIML-CS), use of the test report format is mandatory.

ii) Page numbering and the use of report page formats

In addition to the sequential numbering at the bottom of each page, a space has been left at the top of each page for numbering the pages of reports established following this model. In particular, each test is reported individually on a separate page following the relevant format. For a given report, it is advisable to complete the sequential numbering of each page by indicating the total number of pages in the report.

Where required, these forms can be copied and used several times in cases where the test in question has to be repeated under varying conditions.

iii) Definitions and formula

For the purposes of this test report format, the following definitions and formula, taken from OIML V 2-200:2012 *International Vocabulary of Basic and General Terms in Metrology* (VIM) are used.

Contact clinical thermometers

Test report

Type approval test report ☐

Verification test report ☐

Note: For verification purposes, tick those fields which are appropriate for verification according to your national regulations or which are listed in 1.2 under the heading: Summary of test results for verification.

Number of report: _____

Object: _____

Type: _____

Serial number: _____

Manufacturer's name and address: _____

_____

_____

_____

_____

Customer's name and address: _____

_____

_____

_____

_____

Date of receipt: _____

Date/period of measurement: _____

Date of report: _____ Number of pages: _____

Issuing Institute's name and address: _____

_____

_____

_____

_____

Characteristic values (principle of measurement, measuring unit, measurement range, range of display):

_____

_____

_____

_____

_____

Additional devices (printer, interface, etc):

_____

_____

_____

_____

_____

Reference thermometer (model, serial number, expanded uncertainty, calibration certificate):

_____

_____

_____

_____

_____

Water bath (model, serial number):

_____

_____

_____

_____

_____

Stamp/signature: _____

1 Test review

1.1 Summary of test results for type approval

Clause from			Subject	Test result	OIML requirement	Pass	Fail
Rxxx-1	**Rxxx-2**	**Rxxx-3**					
6.2		2	Test mode				
5.10		3	Indication				
5.2	1	4	Maximum permissible errors of the indication				
7.1		5	Clinical investigation				
5.3	2	6	Thermal shock				
5.4	3	7	Influence of immersion time				
5.5	4	8	Storage				
5.6	5	9	Relative humidity				
5.7	6	10	Mechanical shock				
5.8	7	11	Effect of voltage variations of the power source				
5.9	8	12	Radiated electromagnetic fields				
5.9	9	13	Transients in power supply				
5.9	10	14	Electrostatic discharges				
6.3	11	15	Water resistance				
6.4	12	16	Alarms				
6.6	13	17	Cleaning and disinfection				
6.7	14	18	Signal input/output ports				
6.5		19	Stamping				

1.2 Summary of test results for verification

Clause from			Subject	Test result	OIML requirement	Pass	Fail
Rxxx-1	**Rxxx-2**	**Rxxx-3**					
5.2	1	4	Maximum permissible errors of the indication				

Note 1: The sequence of the different tests is arbitrary; it follows the sequence of the different clauses in the text. The sequence of testing is at the discretion of the person conducting the tests.

Note 2: To be considered as approved or verified, an instrument must have successfully passed all the applicable tests.

2 Test mode

Does the contact clinical thermometers (with an automated measurement mode) have a test mode which is accessible by operator without additional tools?

Yes	☐	Passed	☐
No	☐	Failed	☐

3 Indication

Is the unit of measurement accompanying the indication?

Yes	☐	Passed	☐
No	☐	Failed	☐

Is the resolution 0.1 °C or less?

Yes	☐	Passed	☐
No	☐	Failed	☐

3.1 Analogue scale

Does mechanical clinical thermometer have a clear, uniform, engraved (or printed) scale?

Yes	☐	Passed	☐
No	☐	Failed	☐

Is the distance between marks of clinical thermometer’s analogue scale 0.5 mm at least?

Yes	☐	Passed	☐
No	☐	Failed	☐

Are the scale marks clear, straight?

Yes	☐	Passed	☐
No	☐	Failed	☐

Is the thickness of scale marks less than 0.25 times the distance between two consecutive scale marks?

Yes	☐	Passed	☐
No	☐	Failed	☐

3.2 Digital indication

Does the display of temperature have 4 mm, at least, in height?

Yes	☐	Passed	☐
No	☐	Failed	☐

Does the display of temperature exhibit the indication for one second at least?

Yes	☐	Passed	☐
No	☐	Failed	☐

Does the indicating unit include a self-checking device?

Yes	☐	Passed	☐
No	☐	Failed	☐

4 Maximum permissible errors of the indication

Is the maximum deviation of all the readings of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

5 Clinical investigation

Does the contact clinical thermometer (with automated measurement mode) have approval in clinical investigation carried according to ISO XXX?

Yes	☐	Passed	☐
No	☐	Failed	☐

6 Thermal shock

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

7 Influence of immersion time (only for mechanical thermometers)

7.1 Thermometer reading after 20 seconds (R_1)

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

7.2 Thermometer reading after 60 seconds (R_2)

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

7.3 Difference between R_1 and R_2

Is the module of difference between thermometer readings R1 and R2 less than or equal to 0.005 x ($t_2 - t_1$)?

Yes	☐	Passed	☐
No	☐	Failed	☐

8 Storage (only for electrical thermometers)

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes ☐ Passed ☐

No ☐ Failed ☐

9 Relative humidity (only for electrical thermometers)

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes ☐ Passed ☐

No ☐ Failed ☐

10 Mechanical shock (only for electrical thermometers)

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes ☐ Passed ☐

No ☐ Failed ☐

11 Voltage variations of the power source (only for electrical thermometers)

Is the maximum deviation of all the readings of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes ☐ Passed ☐

No ☐ Failed ☐

Does the clinical thermometer display a temperature indication when the voltage of the power source is outside the range specified by the manufacturer?

Yes ☐ Passed ☐

No ☐ Failed ☐

12 Radiated electromagnetic fields (only for electrical thermometers)

Is the maximum deviation of all the readings of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

13 Transients in power supply (only for electrical thermometers with external power supply)

13.1 Fast transients

Is the maximum deviation of all the readings of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

13.2 Short duration power reductions

Is the maximum deviation of all the readings of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

14 Electrostatic discharges (only for electrical thermometers)

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

15 Water resistance (only for electrical thermometers)

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

16 Alarms

16.1 Temperature outside measuring range

Does the clinical thermometer display a clear indication or warning signal when the measured temperature is outside the measurement range specified by the manufacturer?

Yes	☐	Passed	☐
No	☐	Failed	☐

16.2 Low battery

Is the reading of the voltmeter meets the range specified by the manufacturer?

Yes	☐	Passed	☐
No	☐	Failed	☐

17 Cleaning and disinfection

Is the deviation of the reading of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

18 Signal input/output ports

Is the maximum deviation of all the readings of the instrument under test and the reference thermometers less than or equal to ±0.15 °C (for mechanical contact clinical thermometer) or ±0.20 ºC (for electrical contact clinical thermometer)?

Yes	☐	Passed	☐
No	☐	Failed	☐

19 Stamping

Does the mechanical clinical thermometer have a space for stamping?

Yes	☐	Passed	☐
No	☐	Failed	☐