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**Clinical electrical thermometers with
maximum device**

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare, and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law.

Consequently JIS T 1140 : 1998 is replaced with this Standard.

This Standard has been made based on OIML R115 : 1995 *Clinical electrical thermometers with maximum device* for the purposes of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Ministers and Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

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the original JIS is to be the final authority.

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Clinical electrical thermometers with maximum device

Introduction This Japanese Industrial Standard has been prepared based on the first edition of OIML R115 *Clinical electrical thermometers with maximum device* published in 1995 with some modifications of the technical contents. Resistance clinical thermometers, as the specific measuring instruments specified in the Measurement Law shall comply with annex 1 (normative).

Portions given sidelines or dotted underlines in this Standard (excluding annex 1) are the matters modified from the original International Standard. A list of modifications with explanations is given in annex 2 (informative).

The terms in bold in this Standard are the terms specified in 3 (definitions).

WARNING Persons using this Standard should be familiar with normal laboratory practice. This Standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices.

1 Scope This Standard specifies the clinical electrical thermometers with maximum device with the following features (hereafter referred to as “clinical thermometers”):

- a) Detection of human body temperature
- b) Provided with a thermo-sensing element to detect body temperature
- c) Provided with maximum temperature holding mechanism
- d) Operated by internal power source
- e) Provision of digital indication of body temperature
- f) Detection of body temperature based on the principle of thermal conduction

Remarks 1 Thermometers to be incorporated on other devices as part of the system are excluded.

2 Thermometers to detect skin temperature are excluded.

3 The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified) and NEQ (not equivalent) according to ISO/IEC Guide 21.

OIML R115: 1995 *Clinical electrical thermometers with maximum device*
(MOD)

2 Normative references The following standards contain provisions which, through reference in this Standard, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS C 1604 *Resistance thermometer sensors*

JIS T 0601-1 *Medical electrical equipment —Part 1: General requirements for safety*

JIS T 0601-1-2 *Medical electrical equipment —Part 1: General requirements for safety —2: Collateral standard : Electromagnetic compatibility —Requirements and tests*

JIS T 1005 *Style manual for instruction manuals*

JIS T 1011 *Glossary of terms used in medical electrical equipment (general terms)*

JIS Z 8802 *Methods for determination of pH of aqueous solutions*

3 Definitions The main terms used in this Standard shall be in accordance with definitions in JIS T 0601-1 and JIS T 1011, and for others the following definitions shall be applied:

- a) **thermo-sensing element** an element that can convert temperature to quantity of electricity
- b) **maximum temperature holding mechanism** a mechanism to maintain actually measured maximum temperature and to display it for a specified period or until reset
- c) **prediction mechanism** a mechanism to predict by calculation and display the final reaching temperature, at an earlier time point than actually reaching the temperature
- d) **actual measuring mechanism** a mechanism to indicate actually measured value of body temperature at **temperature probe**
- e) **temperature probe** a component of the clinical thermometer with a built-in thermo-sensing element, to detect body temperature
- f) **body temperature indicator** a constituent part of the clinical thermometer to indicate the measured temperature
- g) **actual measuring type (clinical thermometer)** a clinical thermometer which is provided with **maximum temperature holding mechanism** only
- h) **predicting type (clinical thermometer)** a clinical thermometer which is provided with **prediction mechanism** and **maximum temperature holding mechanism**
- i) **general use (clinical thermometer)** a clinical thermometer used for measurement of body temperature for the ordinary purpose
- j) **use by women (clinical thermometer)** a clinical thermometer used for measurement of basal body temperature of women as well as measurement of the ordinary purpose

- k) **integrated temperature probe type (clinical thermometer)** a clinical thermometer of such construction that its **temperature probe** can not be separated from the **body temperature indicator** (the main body) without using tools
 - l) **separated temperature probe type (clinical thermometer)** a clinical thermometer of such construction that its **temperature probe** can be separated from the **body temperature indicator** (the main body) without using tools
 - m) **interchangeable type (clinical thermometer)** a clinical thermometer with unselective combination of a **temperature probe** and a **body temperature indicator** (a main body) designated by manufacturers, and the guaranteed performance and safety for the combination
 - n) **non-interchangeable type (clinical thermometer)** a clinical thermometer with only peculiar combination of a **temperature probe** and a **body temperature indicator** (a main body), and the guaranteed performance and safety for the combination
 - o) **water resistance type (clinical thermometer)** a clinical thermometer whose whole body has water resistance properties to penetration of liquids such as physiological saline
 - p) **partial water resistance type (clinical thermometer)** a clinical thermometer with a part of which, including temperature probe, has water resistance properties to penetration of liquids such as physiological saline
 - q) **maximum permissible errors** the limit value of permissible errors
 - r) **reference temperature** the temperature indicated by a temperature probe immersed in a reference water bath (before, or before or after the test whichever appropriate, according to the purpose), and maintained constant within a working area
- 4 **Classification** The classification shall be as follows:
- a) **Classification by measuring type of clinical thermometer**
 - 1) Actual measuring type
 - 2) Predicting type
 - b) **Classification by use of clinical thermometer**
 - 1) For general use
 - 2) For use by women
 - c) **Classification by construction of clinical thermometer**
 - 1) Integrated temperature probe type
 - 2) Separated temperature probe type
 - 2.1) Interchangeable type
 - 2.2) Non-interchangeable type

- d) **Classification by the level of water resistance of clinical thermometer to penetration of liquids**
- 1) Water resistance type
 - 2) Partial water resistance type
- 5 Safety** Matters relating to safety shall be as follows:
- a) The type and degree of protection against electric shock shall comply with the following classifications specified in clause 14 (classification) of JIS T 0601-1 :
- 1) Classification by type of protection against electric shock: Internal power source appliance
 - 2) Classification by degree of protection against electric shock: Appliance with B type or BF type connecting parts
- b) **Constituent materials of temperature probes, cleaning and disinfection**
- 1) **Temperature probes** shall have sufficient mechanical strength to bear the stresses of normal applications and shall be constructed with materials as not to inflame on human skin.
 - 2) Temperature probes that contact with skin other than normal healthy skin (mucosa, damaged skin, etc.) shall meet the test specified in clause 48 (biocompatibility) of JIS T 0601-1.
 - 3) During the test specified in 8.4.1, the value of clinical thermometer indicator shall be within the specified maximum permissible errors.
- c) **Eluates** The eluates from synthetic resin and adhesives used for envelope of temperature probes during the test specified in 8.4.2 shall comply with the limits given in table 1.

Table 1 Eluates and their limits

Item	Limit
Appearance	To be almost clear and colourless, no visible foreign matters
pH	Difference of pH from blank test solution is not more than 2.0
Heavy metal (Pb)	2.0 µg/ml or less
Potassium permanganate reducing substance	Difference of consumption amount from blank test solution is not more than 2.0 ml
Evaporation residue	2.0 mg or less

6 Performance

6.1 Maximum permissible errors The maximum permissible errors of temperature indication during the test specified in 8.5.1 shall comply with the values given in table 2.

Table 2 Maximum permissible errors of indicated value of temperature

Unit : °C

Application	Temperature range	Maximum permissible error
General use	30 to 43	± 0.1 (1)
Use by women	35 to 38	± 0.05 (1) (2)

Notes (1) In the case of separated temperature probe type clinical thermometers, the error of combination of a temperature probe and a body temperature indicator (main body) shall be within the specified maximum permissible errors.

(2) The maximum permissible errors for thermometers with a temperature range outside of 35 °C to 38 °C shall be the value for general use thermometers.

6.2 Supply voltage The clinical thermometer shall, after tested according to 8.5.2, have the error of the indicated temperature value within ± 0.2 °C for general use and ± 0.1 °C for use by women.

6.3 Ambient temperature The difference of indicated temperature values of a clinical thermometer before and after the test, after tested according to 8.5.3, shall be within ± 0.1 °C for general use and ± 0.05 °C for use by women. Integrated temperature probe type thermometers shall be tested as they are and separated temperature probe type thermometers shall be tested properly and connected to the temperature probe to the body temperature indicator (main body).

6.4 Response characteristic The response time of clinical thermometers shall be within 30 s when tested in accordance with 8.5.4, excluding predicting type clinical thermometers.

6.5 Leaving at high temperature After the test specified in 8.5.5 is carried out on separated temperature probe type clinical thermometers, the error of indicated temperature value shall be within ± 0.1 °C for general use and ± 0.05 °C for use by women.

6.6 Storage temperature The difference of indicated temperature values of clinical thermometers before and after the test specified in 8.5.6 shall be within ± 0.1 °C for general use and ± 0.05 °C for use by women.

6.7 Storage humidity The difference of indicated temperature values of clinical thermometers before and after the test specified in 8.5.7 shall be within ± 0.1 °C for general use and ± 0.05 °C for use by women.

6.8 Thermal shock resistance The difference of indicated temperature values of clinical thermometers before and after the test specified in 8.5.8 shall be within ± 0.1 °C for general use and ± 0.05 °C for use by women.

6.9 Water resistance When a clinical thermometer is tested in accordance with 8.5.9,

the differences of indicated temperature values between the first test and the second test, and between the first test and the third test shall not be more than the following:

- a) In the case the minimum scale interval is 0.01°C : 0.04°C
- b) In the case the minimum scale interval is 0.1°C : 0.1°C

6.10 Mechanical shock resistance The difference of indicated temperature values of clinical thermometers before and after the test specified in 8.5.10 shall be within $\pm 0.1^{\circ}\text{C}$ for general use and $\pm 0.05^{\circ}\text{C}$ for use by women. Integrated temperature probe type thermometers shall be tested as they are and separated temperature probe type thermometers shall be tested under the condition that the temperature probe is properly connected to body temperature indicator (main body).

6.11 Withstand voltage After the test specified in 8.5.11 is carried out on a separated temperature probe type thermometers, the error of the indicated temperature value shall be within $\pm 0.1^{\circ}\text{C}$ for general use and $\pm 0.05^{\circ}\text{C}$ for use by women.

6.12 Electromagnetic compatibility Clinical thermometers shall comply with the requirements of JIS T 0601-1-2.

At the test under requirements for temperature, the variation of temperature indication shall be within $\pm 0.3^{\circ}\text{C}$.

6.13 Power consumption When clinical thermometers are tested in accordance with 8.5.12, the temperature rise of temperature probes shall not exceed 0.01°C .

6.14 Prediction error The error of predicted values [error of actual measurements at the same region for 5 min or more in mouth or rectum, 10 min or more in axilla] shall be $\pm 0.2^{\circ}\text{C}$.

7 Construction

7.1 Temperature measuring range and minimum scale interval

7.1.1 Temperature measuring range The temperature measuring range shall be as follows:

- a) The range from 35.5°C to 42°C shall be included.
- b) The measuring range shall be within 30°C to 43°C .

7.1.2 Minimum scale interval The minimum scale interval shall be as follows:

- a) For general use: The minimum scale interval shall be 0.01°C or 0.1°C .
- b) For use by women: The minimum scale interval shall be 0.01°C .

7.2 Prediction mechanism The prediction mechanism shall be as follows:

- a) When predicted value is displayed, an indication or mark shall be displayed on the body temperature indicator (main body) as a predicted value.
- b) When an actually measured value is displayed, a value based on the maximum temperature holding mechanism shall be indicated.