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Infrared ear thermometers

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to proposal of establishing a Japanese Industrial Standard from Japan Measuring Instruments Federation (JMIF)/Japanese Standards Association (JSA), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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Infrared ear thermometers

Introduction This Japanese Industrial Standard is drafted to comply with **JIS T 0601-1** *Medical electrical equipment — Part 1: General requirements for safety* and to align with the items of **JIS T 1140** *Clinical electrical thermometers*.

1 Scope This Standard specifies the infrared ear thermometers (hereinafter referred to as “thermometers”) with the following specifications. They detect temperatures of or near the eardrum, use an infrared detector, are capable of measuring actual temperatures, convert them into actual temperatures or body region temperatures, display them digitally, and are driven by the internal power source. However, this Standard excludes those thermometers that are incorporated in other equipment as a part of system, or those thermometers that measure the skin temperatures instead of temperatures of or near the eardrum.

2 Normative references The following standards contain provisions which, through reference in this Standard, constitute provisions of this Standard. If the indication of the year of publication is given to these referred standards, only the edition of the indicated year constitutes the provision of this Standard but the revision and amendment made thereafter are not applied. The normative references without the indication of the year of coming into effect or the year of publication apply only to the most recent edition (including the amendment).

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 1140 *Clinical electrical thermometers*

3 Definitions For the purpose of this Standard, the following definitions apply.

a) Vocabulary related with the thermometer

- 1) **sensing element** an element that senses infrared ray and generates the electric signal corresponding to the infrared energy
- 2) **probe** a part of the thermometer that has the infrared detector and is inserted into the ear canal
- 3) **probe cover** a cover that covers the probe, and that is disposable or reusable
- 4) **radiance temperature** temperature of a blackbody whose radiance temperature is equal to that of the measured object
- 5) **actual temperature** radiance temperature of the measured region
- 6) **correction temperature** temperature value that is displayed after conversion correction with respect to the emissivity of the measured region and/or the human body region

- 7) **maximum allowable error** maximum value of allowable error
- 8) **basic ambient conditions** environment with a temperature range of 16 °C to 35 °C, and a relative humidity of 30 %RH to 75 %RH (without dewing)
- 9) **temperature drift** fluctuation of the display temperature that is caused by a changing temperature of the thermometer main body accompanying fluctuation of ambient temperature
- 10) **reference values** the average of temperatures measured 3 times under the condition of 7.1.1
- 11) **receptacle** a case that is to hold the thermometer and treated as a part of thermometer

b) Vocabulary related to measurement

- 1) **blackbody cavity** emission source that is used to realize blackbody radiation approximately that has the known temperature of cavity wall, and that has emissivity of one
- 2) **blackbody furnace** device having a blackbody and a heating or cooling mechanism
- 3) **emissivity** the ratio of the radiance of a body to the radiance of a blackbody at the same temperature
- 4) **reference heat source** the heat source that generates the radiance temperature equivalent to the blackbody furnace of nearly 37°C

4 Requirements for construction

4.1 Range of display temperatures The range of display temperatures shall include 35.5 °C to 42.0 °C.

4.2 Unit of minimum display The unit of minimum display shall be either 0.01°C or 0.1°C.

4.3 Display temperature If the thermometer has functions of correcting, calculating and displaying temperatures of other regions (armpit, oral, rectum etc.), it shall be capable of identifying the said region, together with the temperature value.

4.4 Alarm signal ⁽¹⁾ If the following items are outside the specified values, and/or if the thermometer having normally a probe cover attached is left uncovered, the thermometer shall be capable of generating visible alarm and/or audible alarm. It shall not display measured values. Inspection shall be performed by visual inspection and/or sound inspection.

- a) Power supply voltage
- b) Range of display temperature
- c) Ambient temperature

Note ⁽¹⁾ If the thermometer has no function of detecting whether a probe cover is attached or not, the main body or the case shall display the following warning: "Attach a probe cover. If a probe cover is not attached, correct measurement is impossible."

5 Performance requirements

5.1 General The thermometer having normally a probe cover attached in use shall meet these requirements with the thermometer and the probe cover being integrated as a single unit.

5.2 Maximum allowable error

5.2.1 The maximum allowable error under basic ambient conditions When tested by 7.2.1, the maximum allowable error under basic ambient conditions shall not exceed the ambient temperature range indicated in the instruction manuals specified in 8.2 and/or inner package specified in 8.3, specifically the values indicated in table 1 ($\pm 0.2^{\circ}\text{C}$ for display temperature range of 35.5°C to 42.0°C , $\pm 0.3^{\circ}\text{C}$ outside this display temperature range).

5.2.2 Maximum allowable error outside basic ambient conditions When tested by 7.2.1 with necessary modifications, the maximum allowable error outside basic ambient conditions shall not exceed the ambient temperature range indicated in the instruction manuals specified in 8.2 and/or inner package specified in 8.3, specifically the values indicated in table 1.

Table 1 Maximum allowable error

Display temperature	Environment	
	Under basic ambient conditions	Outside basic ambient conditions
Minimum display temperature $< 35.5^{\circ}\text{C}$	$\pm 0.3^{\circ}\text{C}$	$\pm 0.3^{\circ}\text{C}$
$35.5^{\circ}\text{C} \leq \text{display temperature} \leq 42.0^{\circ}\text{C}$	$\pm 0.2^{\circ}\text{C}$	$\pm 0.3^{\circ}\text{C}$
$42.0^{\circ}\text{C} < \text{maximum display temperature}$	$\pm 0.3^{\circ}\text{C}$	$\pm 0.3^{\circ}\text{C}$

5.3 Environment

5.3.1 Influence of temperature drift When tested by 7.2.3, the difference of the measured value and reference value shall satisfy 5.2.1.

In addition, if this requirement cannot be satisfied, the measured value shall not be displayed.

5.3.2 Influence of storage When tested by 7.2.4, the value shall not exceed the value of table 1.

5.3.3 Electromagnetic compatibility The thermometer shall satisfy the requirements of JIS T 0601-1-2.

- a) **Electrostatic discharge** When tested by 7.2.8, the value shall not exceed the value of table 1.
- b) **Radiation electromagnetic field** When tested by 7.2.9, the value shall not exceed the value of table 1. Moreover, while radiating, check that the malfunction has not arisen.

- c) **Radiation interference electric field strength** When tested by 7.2.10, it shall satisfy allowable strength value specified by **JIS T 0601-1-2**.

5.3.4 Mechanical shock When tested by 7.2.5, the value shall not exceed the value of table 1.

5.3.5 Line voltage variation When tested by 7.2.7, the value shall not exceed the value of table 1.

5.4 Probe cover The thermometer having normally a probe cover attached in use shall be tested by 7.2.2, with an exchangeable probe cover being attached. The value shall not exceed the value of table 1.

6 Requirements for safety

6.1 General The thermometer and accessories shall satisfy the requirements of **JIS T 0601-1**.

6.2 Materials⁽²⁾ The materials for the thermometry that constitute the thermometer shall satisfy the requirements in 5.3) (Eluates) in **JIS T 1140**.

Note ⁽²⁾ The materials of the parts that are touched by a user or an examinee.

6.3 Cleaning and disinfection About the thermometer which can be cleaned or disinfected, etc., manual for those procedures shall be attached. The thermometers that have been cleaned and disinfected according to manufacturer's instructions shall not exceed the value of table 1, when tested by 7.2.6.

In addition, display in the thermometer shall not be influenced by the procedures of cleaning, disinfection, etc.

7 Performance test

7.1 Test conditions

7.1.1 Standard conditions of test environment It shall be based on **JIS T 0601-1**.

7.1.2 Testing apparatus The testing apparatus specified in each test item of 7.2 shall be used. Moreover, the main testing apparatus for temperature measurement that are used in this Standard shall be as follows.

- a) **Standard thermometer** It shall be selected from among resistance thermometer sensors specified by **JIS C 1604**, thermistor thermometers, glass thermometers, or equivalent thermometers. It shall be traceable to the national measurement standards.
- b) **Standard blackbody furnace** It shall be so constructed as to measure the temperature of blackbody cavity by using the standard thermometer. It shall be traceable to the national measurement standards.
- c) **Blackbody furnace for testing** It shall have sufficient performance for testing.