#

ASIA–PACIFIC LEGAL METROLOGY FORUM

**APLMF WORKING GROUP ON MEDICAL MEASUREMENTS (2009)**

**SURVEY ON INFRARED EAR THERMOMETERS**

According to discussions at the 15th APLMF Conference in 2008, the Working Group on Medical Measurements was asked to conduct a survey on infrared ear thermometers. The results of the survey will be provided to all the member economies in order to promote harmonization of regulatory practices among member economies.

This survey is based on the standard specifications of ASTM E 1965-98, BS EN 12470-5:2003, and JIS T4207: 2005. It is suggested that this survey be filled out by those who work in organizations authorized to carry out legal metrology in your economy, and the opinions of those in your infrared ear thermometers industry should be also included in this survey.

Responses to this survey will assist the Working Group on Medical Measurements to prepare for reports that can be discussed at the WG meeting. A reply to this survey should be sent to the following address before **June 30, 2009.**

**Send a survey result to:**

 APLMF Secretariat

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**1. General information about the APLMF Member submitting this survey**

|  |  |
| --- | --- |
| Organization: |  |
| Economy: |  |
| Internet Home Page Address: |  |
| Name of Contact Person: |  |
| Professional Title |  |
| E-mail Address: |  |
| Telephone No.: |  |
| Fax No.: |  |

**2. Regulations and Standards**

* 1. Please describe in brief the competent authority (ies) as well as their jurisdiction that approve the manufacturing and import of medical devices; including infrared ear thermometers; for marketing in your economy.

Response / Comments:

* 1. What kind of medical devices subjected to regulated by your legal metrology competent authorities?
* All medical devices
* None of them
* Some of them (Please specify below)

Response / Comments:

* 1. In your economy, the infrared ear thermometers are affiliated with what risk level of medical device?
* Low risk medical devices
* Mid risk medical devices
* High risk medical devices
* Others (Please specify below)

Response / Comments:

* 1. Are infrared ear thermometers required to receive pattern approval in your economy?
* Yes
* No (Go to question 2.4 directly)

Response / Comments:

2.4.1 What are the regulations or standards that infrared ear thermometers must comply with for pattern approval in your economy?

Response / Comments:

* + 1. At what level is pattern approval administered?
* Central/National - valid for the whole country/economy
* State/Regional - valid for a segment of the country/economy
* Local/Municipal - valid for a city or local jurisdiction

Response / Comments:

* + 1. Who performs the pattern approval testing? (More than one selection is permissible.)
* Central/National government
* State/Regional governments
* Local/Municipal governments
* Private organizations entrusted by government (inside or outside the country/economy)
* Foreign governments (e.g. recognizing pattern approval of other countries/economies through MRA, etc.)

Response / Comments:

* + 1. What are the testing items requested to receive the pattern approval in your economy?

Response / Comments:

* 1. Are infrared ear thermometers required to receive verification and/or inspection in your economy?
* Yes, for all thermometers
* Yes, for some thermometers (Please specify below)
* No. (Go to question 2.5 directly)

Response / Comments:

* + 1. What is the frequency of verification and/or inspection for infrared ear thermometers?
* Once a year
* Once every two years
* Others (Please specify below)

Response / Comments:

2.5.2 What are the regulations or standards that infrared ear thermometers must comply with for verification and/or inspection in your economy?

Response / Comments:

* + 1. At what level are verification and/or inspection administered?
* Central/National - valid for the entire country/economy
* State/Regional - valid for a segment of the country/economy
* Local/Municipal - valid for a city or local jurisdiction

Response / Comments:

* + 1. Who performs the testing for verification/inspection? (More than one selection is permissible.)
* Central/National government
* State/Regional governments
* Local/Municipal governments
* Private organizations entrusted by government (inside or outside the country/economy)
* Foreign governments (e.g. recognition of verification and/or inspection results of foreign countries through MRA, MAA, etc.)

Response / Comments:

* + 1. What are the testing items requested for the verification/inspection in your economy?

Response / Comments:

* + 1. Regarding the maximum permissible error, please specify the designated testing temperatures and the required equipment for verification/inspection?

Response / Comments:

2.6 Is the competent authority for registration and market approval of medical devices as the same as that for legal metrology in your economy?

* Yes.
* No. (Please specify below)

Response / Comments:

2.6.1 For the manufacturing of infrared ear thermometers, what documents shall be filed with the competent authority for registration and market approval (More than one selection is permissible.)?

* Administrative papers □ ISO 13485 □ ISO 109393 □ Testing certificate
* Operation manual □ IEC 6060-1-1 □ ISO 14971 □ Original testing data
* Maintenance manual □ IEC 6060-1-2 □ ISO 13485 □ Others (Please specify)

Response / Comments:

2.6.2 For the import of infrared ear thermometers, what documents shall be filed with the competent authority for registration and market approval (More than one selection is permissible.)?

* Administrative papers □ ISO 13485 □ ISO 109393 □ Testing certificate
* Operation manual □ IEC 6060-1-1 □ ISO 14971 □ Original testing data
* Maintenance manual □ IEC 6060-1-2 □ ISO 13485 □ Others (Please specify)

Response / Comments:

2.7 Do you agree that OIML should soon (1) establish infrared ear thermometers recommendation as the model regulations or (2) integrate infrared ear thermometers into MAA (Mutual Acceptance Arrangement) system?

* (1)
* (2)
* None of the above (Please describe reasons below)

Response / Comments:

* 1. Should the following standards be harmonized?

ASTM E 1965-98 (Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature), EN 12470-5:2003 (Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device)), and JIS T4207:2005 (Infrared ear thermometers)

* Yes
* No
* Not familiar with the above specifications

Response / Comments:

2.9 Please advise on harmonizing the regulations of importing infrared ear thermometers among Asia Pacific economies.

Response / Comments:

**3. Comparisons of ASTM E 1965-98, EN 12470-5:2003, and JIS T 4207:2005**

* 1. The IR ear thermometer shall display a subject’s temperature over a minimum range of:
* 34.4 to 42.2 °C (94.0 to 108.0 °F) (ASTM E 1965-98)
* 35.5 °C to 42.0 °C (EN 12470-5:2003)
* 35.5 °C to 42.0 °C (JIS T 4207:2005)
* Other measuring range
* Not familiar with the specifications above

Response / Comments:

* 1. In your opinion, the digital increment of 0.1 °C for the indicating unit of IR ear thermometer is adequate?
* The resolution of a display shall be 0.1 °C (0.1 °F) (ASTM E 1965-98)
* The digital increment of the indicating unit shall be 0.1 °C or smaller (EN 12470-5:2003)
* The unit of minimum display shall be either 0.01 °C or 0.1 °C (JIS T 4207:2005)
* Others (Please specify below)
* Not familiar with the specifications above

Response / Comments:

* 1. Which of the following tables is appropriate to express the maximum permissible error?
* ASTM E 1965-98
* EN 12470-5:2003
* JIS T 4207:2005
* Not familiar with the specifications above

Response / Comments:

**ASTM E 1965-98**

|  |  |
| --- | --- |
| **Temperature** | **Maximum permissible Laboratory error** |
| 36 °C to 39 °C within the manufacturer’s specified operating ambient conditions | 0.2 °C |
| Less than 36 °C or greater than 39 °C within the manufacturer’s specified operating ambient conditions | 0.3 °C |

**EN 12470-5 6.2.3**

|  |  |
| --- | --- |
| **Temperature** | **Maximum permissible errors** |
| 35.5 °C to 42.0 °C within the ambient temperature range from 18 °C to 28 °C | 0.1 °C |
| Outside 35.5 °C to 42.0 °C orOutside18 °C to 28 °C | 0.2 °C |

**JIS T 4207 Table 2 Unit: °C**

|  |  |  |
| --- | --- | --- |
| **Use** | **Temperature range** | **Maximum allowable deviation** |
| General use | 30 to 43 | ± 0.1 |
| Woman use | 35 to 38 | ± 0.05 |

* 1. The specification required / would be preferable in your economy for the testing apparatus of maximum permissible error is followed by::
* ASTM E 1965-98
* EN 12470-5:2003
* JIS T 4207:2005
* Not familiar with the specifications above

Response / Comments:

|  |  |  |  |
| --- | --- | --- | --- |
| Requirements | ASTM E1965-98 | EN 12470-5:2003 | JIS T4207:2005 |
| Volume of water bath | 2 L or greater  | A minimum volume of 3 L | Approximately 5 L or more |
| Stability of water bath | within ± 0.02 °C  | within ± 0.02 °C over 1 h | Better than ± 0.02 °C /hour |
| Spatial uniformity |  | within ± 0.01 °C | Small than 0.01 °C |
| True temperature of the water | An uncertainty no greater than ± 0.03 °C by an immersed contact thermometer traceable to a national standard of temperature | An uncertainty not greater than 0.03 °C (k=2) by an immersed contact thermometer traceable to a national standard of temperature  | NAThe uncertainty of standard thermometer selected from among resistance thermometer, thermistor thermometers, glass thermometers, or equivalent thermometers should be ± 0.02 °C or less. |
| Emissivity of blackbody cavity | approaching unity  | Greater than 0.95 in the wavelength range from 8 μm to 15 μm  | 0.95 or more |
| Radiance temperature of blackbody radiator |  | An uncertainty not greater than 0.07 °C (k=2)  | Shall have sufficient performance |

* 1. The test method adopted / would be preferable in your economy for maximum permissible error is according to:
* ASTM E 1965-98
* EN 12470-5:2003
* JIS T 4207:2005
* Not familiar with the specifications above

Response / Comments:

|  |  |  |  |
| --- | --- | --- | --- |
| Test method | ASTM E1965-98 | EN 12470-5:2003 | JIS T4207:2005 |
| Environmental condition | 1)16 to 18 °C less than 50 %2)16 to 18 °C 90 to 95 %3)24 to 26 °C 40 to 60 %4)38 to 40 °C less than 25 %5)38 to 40 °C 75 to 85 % | 1)16 to 18 °C less than 50 %2)16 to 18 °C 80 to 85 %3)24 to 26 °C 40 to 60 %4)33 to 35 °C less than 25 %5)33 to 35 °C 80 to 85 % | 1) 17 °C±1 °C 30 %RH to 50 %RH2) 17 °C±1 °C 70 %RH to 75 %RH3) 23 °C±2 °C 40 %RH to 60 %RH4) 34 °C±1 °C 30 %RH to 50 %RH5) 34 °C±1 °C 70 %RH to 75 %RH |
| Temperature setting of blackbody | 1) 35 °C±0.5 °C2) 37 °C±0.5 °C3) 41 °C±0.5 °C | Three black body temperatures approximately equally spaced throughout the range of displayed temperature. | 1) 35.5 °C±0.2 °C2) 37.0 °C±0.2 °C3) 42.0 °C±0.2 °C |
| The number of measurements for each blackbody temperature | At least six measurements | At least three readings | Repeat three times or more |

* 1. To characterize the effects of storage as well as long term stability on ear thermometers, in your economy, the procedure and storage test were executed in accordance with what kind of standard?
* ASTM E 1965-98
* EN 12470-5:2003
* JIS T 4207:2005
* Not familiar with the specifications above

Response / Comments:

|  |  |  |  |
| --- | --- | --- | --- |
| Storage | ASTM E1965-98 | EN 12470-5:2003 | JIS T4207:2005 |
| Procedure | An IR thermometer shall be maintained in an environmental chamber at temperature **-20°C**, relative humidity below **50 %**, for a period of **30 days** and at **50 °C**, relative humidity **no less than 75 % noncondesing**, for a period of **30 days**.  | Lower the temperature to **(-25±3) °C**. Keep this temperature for **16 h** then raise the temperature to **(55±2) °C** and a relative humidity of **85 % (non-condensing)**. Maintain this climate for **720 h**. Lower the temperature to (-25±3) °C and maintain it for **16 h**. Raise the temperature to (25±3) °C. Remove the thermometers from the chamber and keep them at **room temperature** for at least **24 h**.  | Keep the thermometer for **16 hours** at **-25 °C±3 °C**, and then raise the temperature to **55 °C±2 °C** with **85 %** relative humidity (without dewing). After leaving the thermometer in this condition for **720 hours**, lower the temperature to -25 °C±3 °C and leave it for a further **16 hours**. Raise the temperature to 25 °C±3 °C, and leave it in the **room temperature** for at least **24 hours**. |
| Test | After each exposure the IR thermometer shall be tested according to 6.3.2 and 6.3.3. | Testing shall be performed in accordance with 7.4Testing for compliance of the maximum permissible error within ambient operating range. | One point in the range of **37 °C±0.5 °C** Before and after each test, perform 7.1. |

* 1. To determine clinical accuracy of ear thermometers, your economy will adopt/ has adopted which kind of clinical trial?
* ASTM E 1965-98
* EN 12470-5:2003
* Not familiar with the specifications above

Response / Comments:

|  |  |  |  |
| --- | --- | --- | --- |
| Clinical trial | ASTM E1965-98 | EN 12470-5:2003 | JIS T4207:2005 |
| Age group | 1. Infant-newborn to one year
2. Children-greater than one to five years
3. Adults-greater than five years old.
 | 1. new-born up to 1 year
2. between one year and five years
3. older than five years
 | NA |
| No. of subjects | The number of subjects in each group is sufficiently large to minimize the effects of random components of the measurement error. For example, paragraph 19.3 on Bias in Practice recommends **30** or more test subjects. | The number of subjects of each age group shall be sufficiently large to minimize the effect of random components of measurement error i.e. at least **50**. The **total number** of subjects shall be **not less than 100**. In **each age group at least 30 %** of the subjects shall be **febrile** (temperature above 38 °C). |  |
| Clinical bias | Clinical bias is a mean value of a set of individual clinical biases obtained from a representative group of patients. To evaluate clinical bias, **at least two measurements** should be taken from an ear canal by an IR ear thermometer under test, and the other should be taken by a reference contact thermometer.To determine clinical bias (), a mean value of ear to reference differences for all subjects in the test group should be calculated.The value of clinical bias should be accompanied by a statement of uncertainty, which has a meaning of one standard deviation and generally is calculated as root-sum-of-squares (RSS) of standard deviation of data and other uncertainty components. | The clinical bias Δtb and its standard deviation specify an average difference between temperature measured by the device under test and temperature of subjects as measured by the non-predictive contact reference thermometer. **Three** consecutive readings should be taken by the same operator with a time interval less than 1 min.Where Δtbi is the bias of subject itij is the reading of subject itRi is the reference reading of subject in is the total number of subjects in the corresponding age groupThe standard deviation of the clinical bias sb can be calculated by: |  |
| Clinical repeatability | Three sequential IR readings should be taken in the same ear of each subject by the same operator to determine clinical repeatability Sr.D1j=ti2j-ti1jD2j=ti3j-ti2jD3j=ti1j-ti3jWhere ti1j, ti2j, and ti3j, are the first, second, and third IR temperature readings from the same ear canal of a subject numbered j.**X.2.3.3.4** The following formula should be used to calculate the **pooled standard deviation Sr** of all Dij for all N tested subjects:where Sr the value of is the measure of clinical repeatability.  | Calculate the clinical repeatability according to equation 2 below.The clinical repeatability With With For j=1……LWhereis the estimated standard deviation of the readings from subject in is the total number of subjects in the corresponding age groupRRi is the span between the maximum read temperature and the minimum read temperature of all taken readings of subject iL is the total number of readings per subject (L=3)q is the proportional factor q (L=3)=1.65tij is the reading j of subject i. |  |

* 1. What information that an IR ear thermometer shall be marked? e
* ASTM E 1965-98
* EN 12470-5:2003
* JIS T 4207:2005
* Not familiar with the specifications above

Response / Comments:

|  |  |  |
| --- | --- | --- |
| ASTM E1965-98 | EN 12470-5:2003 | JIS T4207:2005 |
| **5.10.1.1** A thermometer shall clearly indicate **the units** of its temperature scale**5.10.1.2** An IR thermometer housing shall be clearly marked with the **trade name or type** of the device, **or both**, **model designation**, **name of the manufacturer or distributor**, and lot number or serial number.**5.10.1.3** An IR thermometer intended for professional use shall be conspicuously **labeled with indication of the unadjusted or adjusted mode(s), or both**, that correspond to the temperature value(s) capable of being displayed by the instrument. As required in 7.2.1.3, the instruction manual for both professional and non-professional use IR thermometers shall specify the **body site(s)** (that is, oral, rectal, core) used to reference the adjusted temperature value(s) displayed. | **8.1 General**Information supplied by the manufacturer shall comply with **EN 1041**. If symbol are used, they shall be in accordance with **EN 980**.**8.2 Marking**In addition to the marking required by 8.1, the IR ear thermometer shall be marked with at least the following information:**a)** whether protective probe covers are required**b)** the symbol “°C” adjacent to the numerical, if not indicated at the display**c)** body site, i.e., ear**d)** the estimated mode(s) if applicable. e.g. estimated core, estimated rectal, estimated oral, adjacent to the numerical value, if not indicated at the display**e)** year and month of manufacturer, and of first calibration if different | **8 Marking****8.1 Marking on thermometer**In addition to compliance with **JIS T0601-1**, the thermometer shall bear the following items at the legible place of the exterior. However, if the making space is too narrow to indicate all the items, it is allowable to limit them to a), d), g), h) and j) and to indicate other items on a container, in instructions manual instruction, or on an inner package.**a)** name**b)**In case of the product using the probe cover, and if the thermometer has no function of detecting the attachment of the probe cover, its necessity**c**) Region to be measured (ear etc.)**d)** The symbol “°C” near the temperature value indicated (The symbol may be indicated electronically together with the numerical value.)**e)** Type and degree of protection against electrical shock**f)** Rated power supply voltage(V)**g)** Type of battery(However, it may be indicated at the battery container.)**h)** Name of manufacturer**i)** Location of manufacturer**j)** Manufacturing serial number or manufacturing lot number |

**4. Future affairs**

* 1. Which of the following activities on infrared ear thermometers do you suggest that APLMF should provide in the future? (More than one selection is permissible.)
* Training
* Seminar
* Presentation
* Others (please specify below)

Response / Comments:

* 1. How many people from your economy would participate in these activities?
* Training \_\_\_\_\_\_ person(s)
* Seminar \_\_\_\_\_\_ person(s)
* Presentation \_\_\_\_\_\_ person(s)
* Others \_\_\_\_\_\_ person(s)

Response / Comments:

* 1. Please recommend expert(s) as lecturers for the above activities.

Response / Comments:

* 1. What do you think the Working Group on Medical Measurements should work on in the future?

Response / Comments:

* 1. Other Response / Comments: any Response / Comments you may add to this survey would be appreciated.

Response / Comments:

Thank you very much for your efforts in completing this survey.