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Thermometry

Agreed EURAMET Project N° 927

Comparison of blackbodies for calibration of infrared ear thermometers

"Technical protocol"

(version 5, 2007-11-16)

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1 Introduction

The EURAMET comparison was initiated during the EURAMET TC THERM meeting on 5./6. April 2005 in Vienna. MIRS/FE-LMK was chosen to be the pilot laboratory. The procedures and instructions, which are given in this protocol, should be followed by all participants. The objective of the intercomparison is to determine agreement of blackbodies in calibration of IRETs among European national laboratories.

IRET is an instrument, which measures temperature of a human body. Despite all problems reported in the literature, more and more such thermometers are used not only in common but also in medical practice. Therefore they shall meet certain requirements. Essential requirement is related to accuracy. There are several standards in the world, which describe requirements for IRETs. In EU this is the standard EN 12470-5, which is a harmonised standard and supports the Medical Device Directive (MDD). Other standards are ASTM standard, Designation E 1965 – 98 and the draft of Japan Industrial Standard. The basic requirement for accuracy in EN 12470-5 is that the maximum permissible error of IRET is ±0,2 °C in the range from 35,5 °C to 42,0 °C. The International Organization for Standardization (ISO) is developing a new standard for clinical thermometers, which will include also IRETs. To verify the accuracy of an IRET a suitable blackbody is needed. An example of a blackbody is presented in Annex C of the standard EN 12470-5. Such blackbody in a stirred water bath will be provided for the comparison by the pilot laboratory.

The comparison is intended to be performed in one loop. Therefore the pilot laboratory will provide the bath with the “EN-type” of a blackbody and the transfer IRET. The bath is owned by the manufacturer Kambič Laboratorijska oprema. Expenses related to renting of baths are covered by the pilot laboratory. The IRET and the bath will be calibrated in the pilot laboratory before and after comparison measurements in participating laboratories. The transfer calibration bath is shown in Figure 1. The transfer IRET is shown in Figure 2.

Figure 1: Transfer calibration bath with the EN-type of blackbody

Figure 2: Transfer IRET

The transfer IRET and the transfer bath are relatively robust but in any case transportation and handling should be performed with extreme care. Suitable package is provided so that the transport is possible with the **express courier**. **Each laboratory is responsible and covers expenses for transport of the devices to the following laboratory in the schedule.**

Each participant laboratory will calibrate at least the transfer IRET against the transfer black-body and against a local blackbody. After calibration of transfer IRET (and local IRET, if available) a laboratory will report the results in the Excel spreadsheet, which will be provided by the pilot laboratory. This report will be sent (within 1 month after measurements) to the pilot laboratory by E-mail.

2 Scheme of organization and provisional schedule of comparison

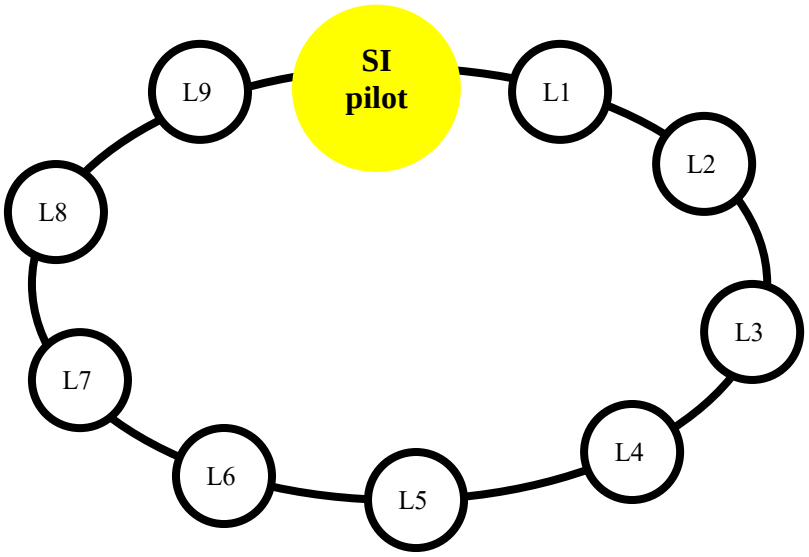

Figure 3: Organization of comparison

For a given laboratory, the time allowed for the measurements (calibration of IRET) is estimated to be less than 2 weeks. The transfer time between two laboratories could be rated up to 2 weeks. According to these estimations comparison will in principle follow the schedule presented in Table 1. It will be organised in the loop as presented in Figure 3.

Table 1: Provisional schedule of comparison

	Start of measurements	Country
SI pilot	1. November 2007	*SI
L1	1. December 2007	**CH
L2	15. January 2008	**TR
L3	15. February 2008	**NO
L4	15. March 2008	***LT
L5	15. April 2008	DK
L6	15. May 2008	DE
L7	15. June 2008	NL
L8	15. July 2008	UK
L9	1. September 2008	FR
SI pilot	1. October 2008	SI

* ATA-carnet form must be filed at customs when **leaving** the country
** ATA-carnet form must be filed at customs when **entering and leaving** the country
*** ATA-carnet form must be filed at customs when **entering** the country

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4 Task of the pilot laboratory

The pilot laboratory provides:

- the transfer bath with the "EN-type" of blackbody and the transfer 4-wire PRT
- the transfer IRET as a transfer thermometer
- ATA carnet for countries outside the EU (Switzerland, Turkey, Norway)

The pilot laboratory will calibrate all circulating thermometers (PRT and IRET) of the comparisons twice (at the beginning and at the end of the comparison), according to the instructions given below.

5 Requirements to be fulfilled by participating laboratories

1. All participating laboratories shall have their own blackbody, which is capable of operation in the range from 35,5 °C to 42 °C and is used for calibration of IRETs.

2. All participating laboratories shall be able to measure a resistance of the 4-wire PRT, which will be provided in the calibration bath with the blackbody to determine its temperature. The measuring current shall be 1 mA.

3. Additionally the participating laboratories may also have their own IRET, which will be calibrated against the transfer blackbody and against a local blackbody.

6 Detailed instructions for participating laboratories

6.1 Description of package and the transfer bath with the blackbody

Upon receiving the bath with the blackbody and the IRET, the laboratory shall inspect received items for damage. The report of initial inspection shall be recorded in the form "PACKAGE RECEIVED", which is a part of this protocol and sent either by a fax or E-mail to the pilot laboratory. If there is any damage observed, the pilot laboratory shall be contacted to receive instructions on how to proceed.

If no damage is reported to the pilot laboratory, the laboratory shall leave the equipment for one day in the laboratory conditions. The transfer bath with the blackbody (in the following text transfer BB) should be positioned on a level surface, like in Figure 4.

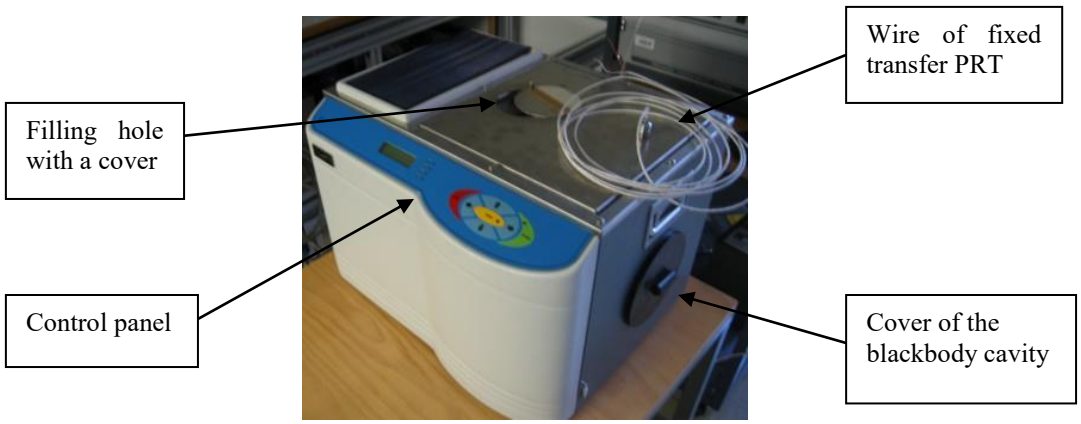

Figure 4: Transfer bath with the blackbody positioned on a level surface

The transfer bath with the blackbody should be placed away from any direct air flow so that the blackbody is not affected by it. Transfer BB consist of the blackbody of "EN-type" made of copper, the transfer PRT of nominal resistance 100 Ω, which is fixed and it can not be removed from the transfer bath, internal temperature sensor, two electric heaters of 100 W and 800 W power, the stirring system, the hole with mesh to prevent entry of other objects to the bath and the control panel to control the bath regulation (set point temperature, start and stop,..).

Diameter of the aperture of the transfer blackbody cavity is 20 mm. Figure 5 shows technical drawing of the transfer blackbody cavity and the position of transfer PRT.

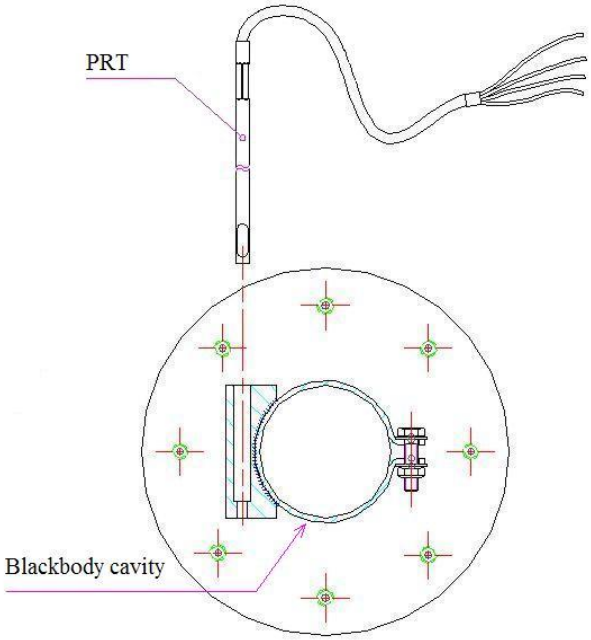

Figure 5: Position of the transfer PRT in the transfer BB

6.2 Preparation of transfer bath with the blackbody for use

After the transfer BB has been positioned, it has to be filled with distilled or demineralized water. Before filling the bath with water, the drain valve of bath has to be checked and closed (the operation of filling water is described in the next page). Figure 6 shows closed drain valve, two connections for cooling water, main switch and power cable of the bath. Power cable shall have appropriate connection for the socket. Originally it is equipped with the EU standard plug. Wherever necessary (UK for example), please use an appropriate adaptor or cable.

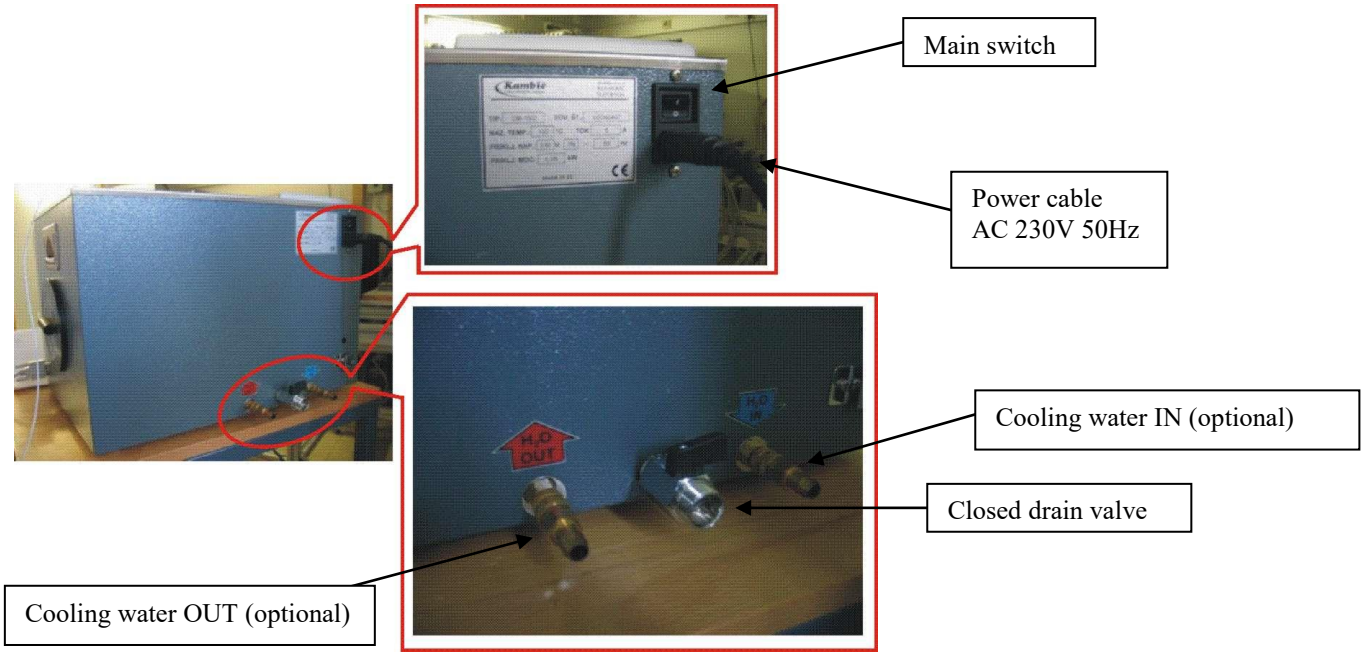

Figure 6: Back side of the transfer BB

Figure 7 shows the hole with a mesh through which the bath is filled. First of all the cover of filling hole has to be opened and then water is poured into the bath through this hole. The volume of water filled is about 15,2 liters and it should be either demineralised or distilled.

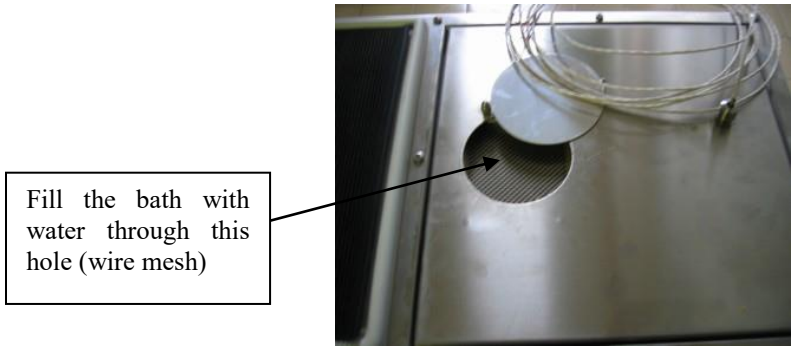

Figure 7: Filling hole with mesh

Water shall reach at least wire mesh or it should be 1 mm above the mesh. If it is higher than 1 mm above the mesh, it has to be removed through the drain valve. The water level in bath will increase after the bath and stirring system is switched on.

Measurements of transfer IRET and eventual local IRET should be performed against the transfer bath with “EN-type” of blackbody and local bath with blackbody at the following set of temperatures 35,5 °C, 38,0 °C and 41,0 °C. It is important to start measurements with a set temperature of the bath at temperature 35,5 °C and then continue with 38,0 °C and 41,0 °C and not vice versa, because the bath cools down very slowly. If cooling down is needed, the fastest way is to switch off the regulation of bath temperature (described further). When the regulation is switched off heaters and stirrer don’t work. Stirrer motor contributes to heating the bath water, when the stirrer is running.

It is possible to cool down the bath temperature with cooling water using connections in Figure 6. During the bath operation, the cooling water can be used, but it is not recommended. If it is used, the water flow should be moderate and led (light-emitting diode) L1 (see Figure 8) should be pulsing with approximately 50% duty cycle. When led L1 is switched on it means that the 100 W electric heater is on. Led L2 (800 W electric heater) should be switched off after the bath reaches stable temperature. In the case when both leds are switched off, the water flow should be increased. In the case when both leds are switched on or L2 is pulsing the water flow should be decreased.

The transfer PRT is mounted in such way that it is in a contact with the blackbody cavity (see Figure 5) and directly measures temperature of the blackbody. The transfer PRT shall be connected to a resistance measuring system (bridge or multimeter).

6.3 Instructions for use of the transfer bath with the blackbody

To start the operation of transfer BB, turn on main the power switch (see Figure 6). On LCD will be displayed current temperature of the water in bath, date and time (see Figure 9). Current temperature is read by internal temperature sensor which is needed for bath regulation. Figure 8 shows bath control panel.

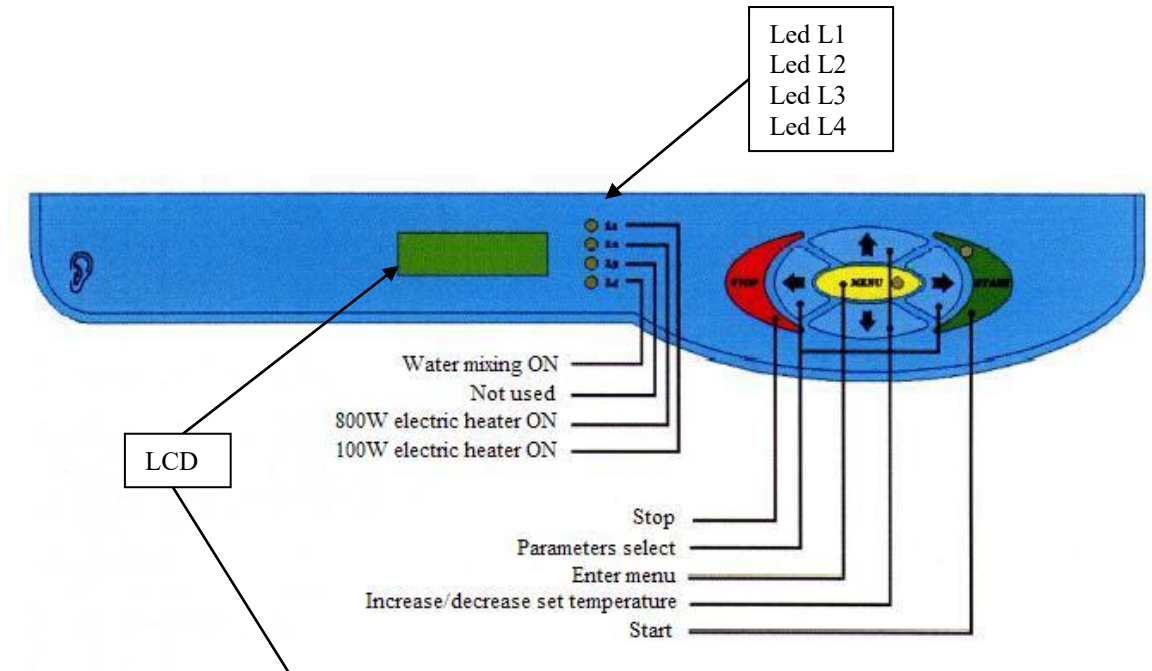

Figure 8: Control panel of the bath

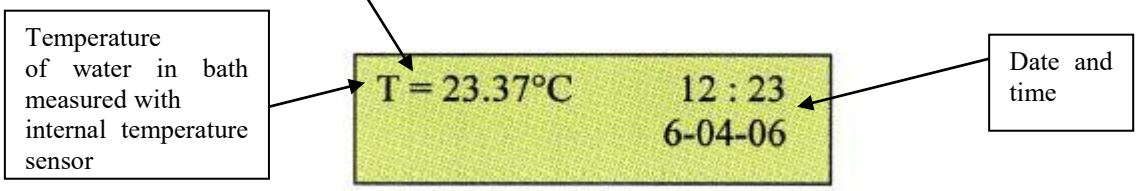

Figure 9: Temperature of water in bath, date and time

Before starting the transfer BB regulation it should be set to desired temperature of a black-body (bath). First temperature to be set is 35,5 °C. On the control panel of the bath, button "**MENU**" has to be pressed. The yellow led in button "**MENU**" will turn on. On LCD will be displayed previous set temperature (for example 35,0 °C or something else, probably 35,5 °C, 38,0 °C or 41,0 °C):

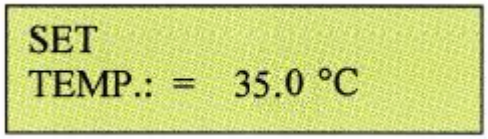

Figure 10: Set temperature

Then up or down buttons have to be used. Set temperature value to 35,5 °C and enter it with "**MENU**" button, the yellow led will turn off. On LCD will be displayed:

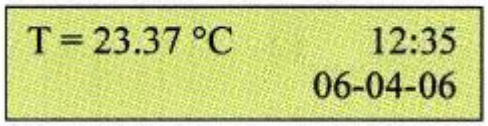

Figure 11: Temperature of water in bath, date and time

To initiate bath regulation the "**START**" button has to be pressed. After the "**START**" button has been pressed, electric heaters and stirrer motor will automatically turn on and the bath water will begin circulating and heating. On LCD will be displayed:

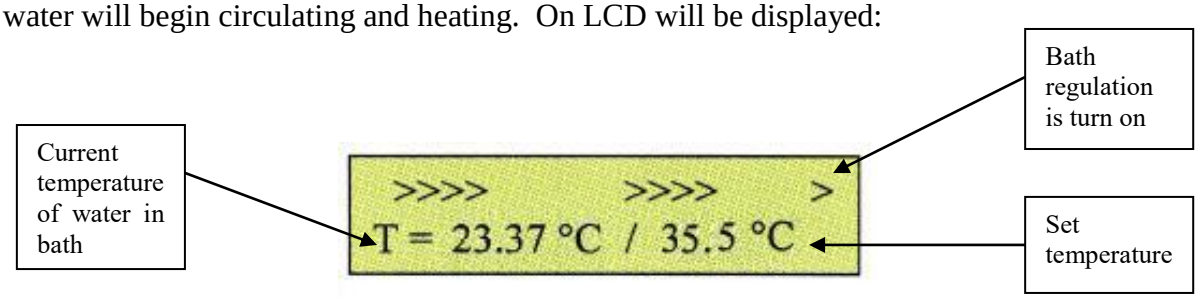

Figure 12: Regulation of water temperature in bath

It should be checked that the water is circulating properly and that the stirrer is running smoothly and relatively silently. During the regulation it is possible to change a set temperature simply by pressing the "**MENU**" button. On LCD will be displayed like in Figure 10. Simply change *set temperature* value by pressing up or down buttons. Set temperature will be automatically accepted when the button up (increase) or down (decrease) is pressed. For exit the set temperature menu the "**MENU**" button has to be pressed.

The bath regulation could be stopped any time. To stop regulation, the "**STOP**" button has to be pressed and held for 3 seconds. On LCD will be displayed:

Figure 13: Regulation of bath was stopped

Before turning off the main power switch, the state of LCD should be like in Figure 9. The "**MENU**" button has to be pressed two times.

After the first set point 35,5 °C (the second is 38,0 °C and the third is 41,0 °C) has been set and regulation has been started the cover of blackbody cavity has to be opened (see Figure 14). Before taking measurements wait for the bath to stabilize. This is possible by measuring a resistance of the transfer PRT, which is mounted in the bath. It is in a contact with the black-body cavity. During measurements with IRET **the cavity has to remain open** to keep temperature stability of the blackbody and the filling hole should remain open too (it is easier to control the water level in bath and keep temperature stability).

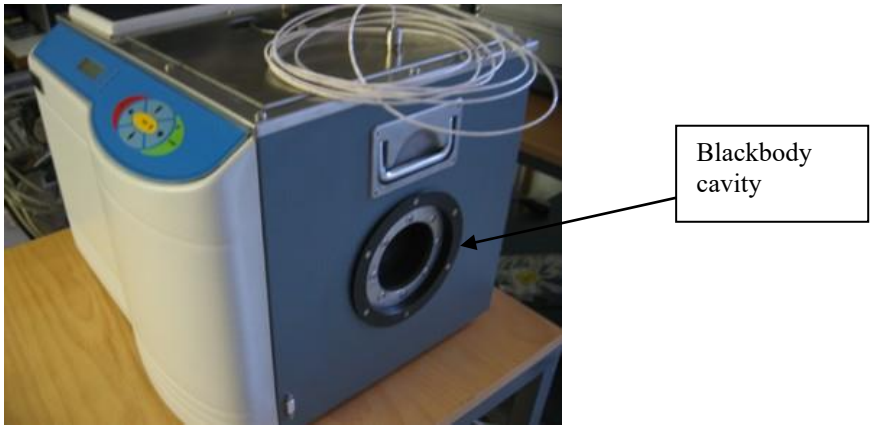

Figure 14: Opened blackbody cavity

6.4 Description of transfer IRET with instructions for use

The transfer IRET has two modes of operation. These are normal and calibration mode. It has to be set in calibration mode. In the calibration mode "CAL mode" it is possible to display temperature with a resolution of a hundredth of degree celsius (0,01 °C) and the instrumental emissivity is set to one (which is not possible in the normal mode). To enter the "CAL mode" the following steps should be performed:

- Wait until the thermometer is in standby mode (it switches off)
- Press and hold the On/Mem button (see Figure 15)
- Then as soon as possible press and hold down the Activation button
- When the "CAL" will be displayed and flashing, release all buttons (see Figure 16)

IRET is now ready to take measurements.

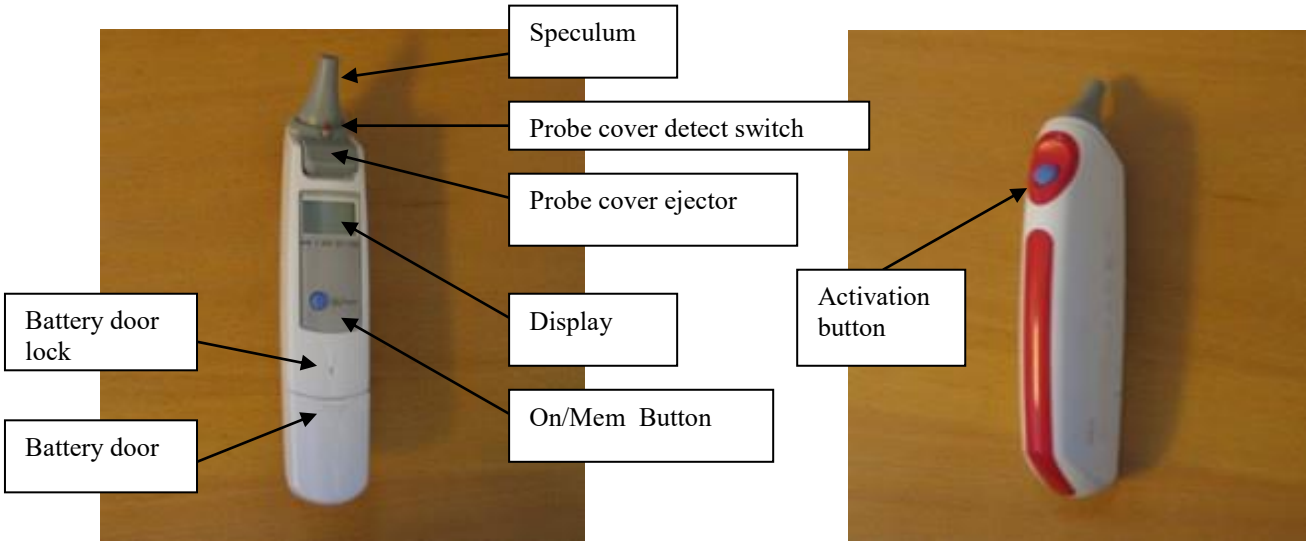

Figure 15: Transfer IRET; front and back view

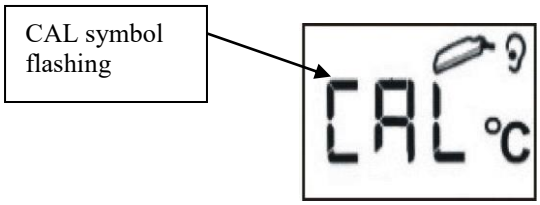

Figure 16: Display – calibration mode

To measure temperature of the blackbody the IRET has to be positioned like in Figure 17. It has to be placed as deep as possible in the blackbody cavity, but not touching the edges of the cavity.

- Then press and hold the Activation button until the beep is heard (temperature has been read).
- After having performed a temperature reading, take the IRET out of the blackbody cavity, turn it around to read the LCD and then press the On/Mem button. As long as this button is pressed the internal sensor temperature will be indicated on display.
- Release the On/Mem button. The display will switch to an indication, where three figures without decimal point and without the unit indication are displayed. The meaning of the figures are :

  First digit: last part of the integer part of the measured temperature
  Second digit: tenth of degree of the measured temperature
  Third digit: hundredth of degree of the measured temperature

For example: If the set point temperature of bath is 35.5 °C and the numbers indicated on display are 551, it means that the measured temperature is 3**5.51** °C.

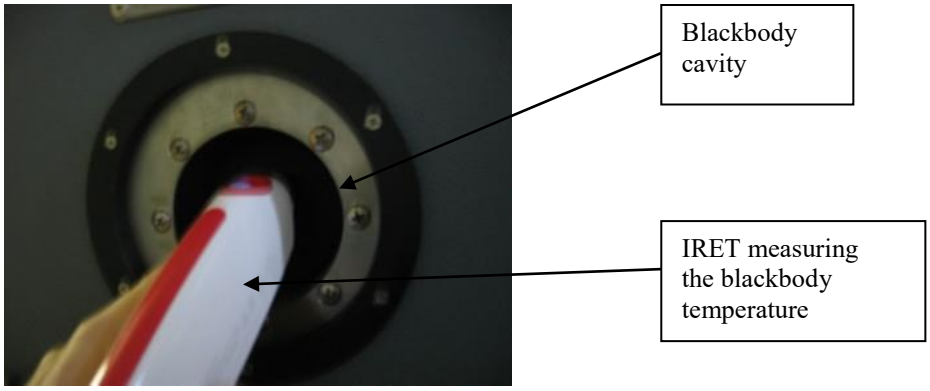

Figure 17: Measuring temperature of the blackbody

- After the first reading has been taken, repeat the procedure for other readings (place the IRET like in Figure 17, then press and hold the Activation button…),third...
- The calibration mode "CAL mode" will be canceled automatically, when the thermometer enters, the standby mode (it switches off).
- The IRET switches off automatically.

Some IRETs might exhibit higher readings of temperature due to their heating by hand. That will be observed by the temperature curve of subsequent readings during the measurement.

Measurements with the transfer IRET should be performed against the transfer bath with the "EN-type" of blackbody and against the local bath with the blackbody.

6.5 Measurements

After stabilization of the temperature in both the transfer bath and the local bath, **the first** series of measurements has to be taken. In the first series the transfer IRET is **without attached probe cover.** Probe covers are shown in Figure 18. In the calibration mode the transfer IRET allows measuring even, if there is no probe cover installed. The transfer IRET automatically detects that a probe cover is not attached (symbol of probe cover is displayed flashing). Readings with the transfer IRET, which is set to the calibration mode - "CAL mode", have to be taken directly alternating between the transfer BB and local BB. The first cycle of measurements has to be taken with the transfer IRET against the transfer BB plus the reading of the transfer PRT resistance, and immediately after that against the local BB plus the reading of temperature of the local BB, determined by the local calibrated thermometer. This cycle has to be repeated 20 times. Thus in the first series 80 measurements have to be taken.

In **the second** series of measurements the procedure remains the same, the only difference is that the IRET is used **with attached probe cover** which is marked as "1**"**.

Figure 18: Three probe covers

All readings have to be taken in approximately 20 second interval. If the probe cover is damaged (top of the cover is torn, problems with attaching, ...) for any reason, the laboratory has to clearly mark the measurement results made by the consecutive reserve probe cover, which is marked as “2” or “3”. Series of measurements with a probe cover will enable us to determine the influence of a probe cover. Figure 19 shows how to attach or detach a probe cover.

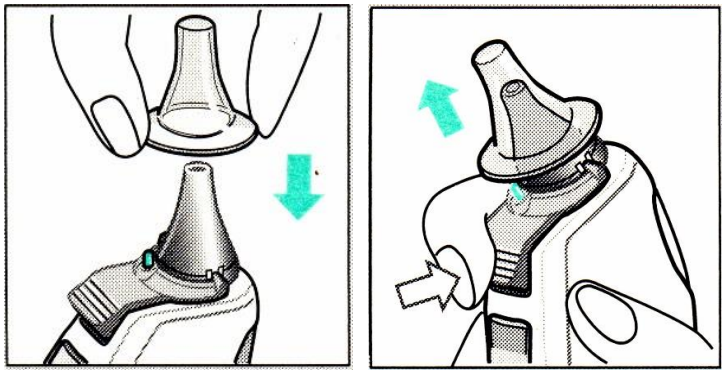

Figure 19: Attaching/detaching probe cover

If the laboratory has its own IRET, measurements of the local IRET should be performed against the transfer bath with the “EN-type” of blackbody and against the local bath with the blackbody in the same way as with the transfer IRET. This means that you should try to perform measurements with the local IRET without the probe cover even, if it is not designed for such application.

If possible, the local IRET shall also be measured in the calibration mode. If the calibration mode is not available, record the operation mode of IRET as it is used during comparison. Also the local IRET shall have a dedicated probe cover for the measurements with suitable marking and reserve probe cover. If a reserve probe cover has to be used, the laboratory has to clearly mark the related measurement results. If possible, the laboratory shall perform also one set of measurements with the local IRET without the probe cover.

After completion of comparison measurements, bath regulation has to be stopped. To stop bath regulation it should be pressed and held the “**STOP**” button for 3 seconds and then

"**MENU**" button has to be pressed two times to enter LCD like in Figure 9. After that the main switch should be turned off.

After 5 to 7 days repeat the complete set of measurements once again. With the second set of measurements we will try to estimate a short-term stability of IRETs.

6.6 Preparing the package for transport to the following laboratory

Before packing the bath again the water of the blackbody bath has to be completely poured out through the drain valve. At the end of measurements, please pack the bath and the IRET securely to the original package and organize the transport to the next participant. When you send the package, please send also a signed form "PACKAGE SHIPPED" to the coordinator.

The procedures required by the Department of Customs of various countries shall be strictly obeyed when the devices are shipped outside the EU. In these cases, the ATA Carnet forms shall be carefully and accurately completed. **It is the responsibility of the laboratory organising the transfer to the next laboratory to present the ATA Carnet to Customs, when leaving the country and upon arrival in the country of destination.** Usually only express courier (e.g. DHL) performs appropriate customs procedure. Nevertheless, any courier must be informed about the ATA carnet forms and procedure, if the transport goes outside or back to the EU and between countries, which are not members of the EU. The pilot laboratory will provide suitable ATA carnet forms for participants outside EU. The ATA carnet forms will accompany the package.

If the devices have not been received in due time the pilot laboratory shall be immediately informed. As a result the delayed laboratory may be excluded from the comparison, or the timetable may be revised accordingly.

7 Reporting the results

The participating laboratories shall fill the Excel spreadsheet provided by the pilot laboratory. The spreadsheet will be sent to a participating laboratory via E-mail after a participating laboratory confirms a receipt of the package.
The file named "EURAMET 927 XX first set.xls" contains four spreadsheets. A laboratory fills the "Instrument details" spreadsheet first. Other three spreadsheets are prepared for filling the measurement results, separately for each set temperature. Please, rename the file and replace XX with your country code. For the second set of measurements, rename the file to "EURAMET 927 XX second set.xls".

Details of instrumentation of a participating laboratory, which has to be reported to the pilot laboratory

<u>Blackbody details</u>
Manufacturer, model and serial number
Heating power (AC or DC)
Temperature uniformity along the blackbody cavity measured with at least two thermometers.
Temperature stability at 41 °C over 1 hour presented as a graph and standard deviation of the sample (not standard deviation of mean).
Emissivity and its uncertainty (either calculation or estimation) with brief explanation, how it was determined.

Local IRET details
Manufacturer, model and serial number
Available operating modes
Resolution
Additional data, if available (e.g. spectral response, field of view, etc.)

Local reference (contact) thermometer details
Manufacturer, model and serial number
Uncertainty
Drift

Details of instrument for measuring the resistance
Bridge (AC or DC) or other instrument
Manufacturer, model and serial number
Frequency (if applicable)
Bandwidth (if applicable)
Accuracy (ppm)

Reference resistor (if applicable)
Manufacturer, model and serial number
Temperature coefficient of the reference resistor (Ω/°C)
Uncertainty and drift (ppm)
Maintained: air, temperature stabilized oven, temperature stabilized (water, oil) bath
Temperature of maintenance (°C)
Temperature stability of the air, oven or bath (°C)

Uncertainty budget in calibration of an IRET consists of the following uncertainty contributions at least:

Type A
- standard deviation of a sample of IRET measurements at each temperature point

Type B
- uncertainty of a blackbody radiator (stability measured as a standard deviation of a transfer PRTs during the measurement of IRETs and uniformity of temperature along the blackbody cavity). Uniformity for transfer blackbody will be given by the pilot laboratory.
- uncertainty of the transfer PRT (including drift). Uncertainty for the transfer PRT will be given by the pilot laboratory.
- uncertainty of a measuring instrument for resistance (if the resistance bridge is used laboratory has to state also uncertainty of a reference resistor used in combination with the bridge, and drift of the reference resistor).
- uncertainty of an IRET resolution.
- any other uncertainty component given and described by a participating laboratory

8 Customs declaration

TO WHOM IT MAY CONCERN

EURAMET Comparison (EURAMET Project N° 927)

EURAMET is an organisation representing the National Measurement / Standards Laboratories of a large number of countries/territories in the European region. Its broad objective is to improve the measurement capabilities in the European region by sharing facilities and experience in metrology.

As a part of major intercomparison program, EURAMET is conducting a comparison of blackbodies for calibration of infrared ear thermometers in the temperature range from 35 °C to 42 °C involving the participants as given in the Laboratory Schedule.

The project is co-ordinated by:

Dr. Igor Pušnik
University of Ljubljana
Faculty of Electrical Engineering
Laboratory of Metrology and Quality
Tržaška 25
SI-1000 Ljubljana
Slovenia
Phone: +386 1 4768 224
Fax: +386 1 4264 633
E-mail: igor.pusnik@fe.uni-lj.si

The following artefacts are circulated among the participants for calibration:
water bath with the blackbody: Kambič laboratorijska oprema, OB 15/2, N° 06042407
transfer infrared ear thermometer: Braun, Thermoscan 6012, N° 10107030058

The purchase/manufacturing cost of the artefacts was 6000 EUR. However it has no commercial value (it is not for sale). It is meant solely for the calibration of national standards and will be re-exported immediately after the calibration is completed (see enclosed Laboratory Schedule).

We request that the device is not handled or removed from the container/package. If a Customs inspection is required, then please contact the relevant person listed in the attached schedule so that he/she can be present and help you unpack it.

Please send to:
Igor Pušnik
MIRS/FE-LMK
Fax: +386 1 4264 633
E-mail: igor.pusnik@fe.uni-lj.si

PACKAGE RECEIVED

EURAMET Comparison (Project N° 927)

Name of participating laboratory:

The_____ and their ATA Carnet were
(serial number of IRET and blackbody)

received at _____
(name of laboratory)

on _____
(date)

The condition when it was received was:

☐ in good physical and working order

☐ damaged *(explain)*

Signature

Please send to:
Igor Pušnik
MIRS/FE-LMK
Fax: +386 1 4264 633
E-mail: igor.pusnik@fe.uni-lj.si

PACKAGE SHIPPED

EURAMET Comparison (Project N° 927)

Name of participating laboratory:

The_____ and their ATA Carnet were
(serial number of IRET and blackbody)

sent to _____
(name of laboratory)

on _____
(date)

Signature

PROTOCOL APPROVAL

EURAMET Comparison (Project N° 927)

This approval concerns only the protocol of the measurement.

We need a formal approval from any participant to the final protocol of EURAMET Project N° 927.

Name of participating laboratory:

☐ We approve the Protocol (version 2007-11-15) and we agree to participate in the EURAMET comparison (Project N° 927)

☐ We do not approve the Protocol (version 2007-11-15) and we will not be participating in the EURAMET comparison (Project N° 927)

Date _____

Name _____

Responsibility _____

Signature _____