BEST PRACTICE GUIDE
USE OF INFRARED EAR THERMOMETERS TO PERFORM TRACEABLE NON-CONTACT

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# USE OF INFRARED EAR THERMOMETERS TO PERFORM TRACEABLE NON-CONTACT MEASUREMENTS OF HUMAN BODY TEMPERATURE

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## 1. Scope

This document applies to clinical thermometers, type infrared ear (tympanic membrane) thermometers[1], for the measurement of human core body temperature in the range from 34 °C to 43 °C.

## 2. Objective

The objective of this document is to give definitive good practice guidance, with realistic uncertainties for the measurement of human core body temperature using ear thermometers.

## 3. Introduction

There are several methods for measuring temperature (and hence human core body temperature). Depending on the type of contact between the thermometer and the object being measured, they can be classified as:

- Contact methods.
- Non-contact methods (methods that use the emitted thermal radiation).

Contact methods are those in which the temperature sensor is in direct contact with an object. For correct operation, the thermometer depends upon the zeroth law of thermodynamics in that thermal equilibrium needs to be achieved between the object and the thermometer. This always takes some time (usually several minutes), which is why contact thermometers used for body temperature measurement often contain built-in predictive algorithms to speed up the measurement process[2].

Non-contact methods exploit the fact that all objects above absolute zero emit thermal radiation. This thermal radiation can be detected and measured by a sensor remote from the emitting surface; that is, there is no direct contact between the thermometer and the object whose temperature is being measured. However, non-contact thermometers are, in general, less accurate[3] than contact thermometers because of the following effects, among others:

[1] Hereafter referred to as "ear thermometers"

[2] These predictive algorithms introduce some additional uncertainty into the measurement process .

[3] In this document three different metrological terms are going to be used [1]:
*measurement accuracy, accuracy of measurement, accuracy:* closeness of agreement between a measured quantity value and a true quantity value of a measurand. The concept 'measurement accuracy' is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.
*measurement error, error of measurement, error*: measured quantity value minus a reference quantity value.
*measurement uncertainty, uncertainty of measurement, uncertainty*: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated. In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand

- The object's capacity to emit thermal radiation (emissivity) and, conversely, the object's capacity to reflect environmental thermal radiation.
- The environment through which the thermal radiation propagates from the object to the thermometer (environmental conditions).
- The thermometer's capacity to collect the emitted thermal radiation, correct for reflected thermal radiation and infer the object's temperature (optical characteristics of the thermometer, detector, lenses, alignment, background temperature etc.).

The purpose of a clinical thermometer is to determine the actual temperature of a particular body site and then relate that measurement to core body temperature. Determining whether a patient is afebrile, febrile, hypothermic and, if trends are being recorded, has a rising or decreasing body temperature are possible outcomes of the measurement.

Core body temperature is generally considered to be the temperature of the blood in the heart and the brain [2]. However, core is more a concept than a practical body site. Pulmonary artery, distal oesophagus, urinary bladder or the tympanic membrane (not the ear canal) are recognized core body temperature sites, so to obtain true core body temperature, insertion of an invasive catheter is required. Such measurements are generally considered too invasive outside of operating rooms or critical care units and are rarely performed outside of such environments. Tympanic *contact* temperature measurements are considered less invasive [3, 4, 5] but the fragility of the tympanic membrane is a major consideration against routine use of this measurement site for contact thermometry.

Alternative temperature measurement body sites (not considered core body temperature sites) that could, with appropriate corrections, represent core temperature are:

- The oral, rectal or axillary sites, traditionally measured by contact thermometers. These sites, however, were choices of convenience rather than being reliable representations of core body temperature. They generally do not represent that quantity and an offset should, in principle, be applied to correct the readings to core body temperature, though this is rarely done.
- The ear canal, with the tympanic membrane at the end, is used routinely for non-contact infrared body temperature measurement. However the measured temperatures may not strictly represent core body temperature because the measured thermal radiation is generally a mixture of thermal radiation emitted from both the tympanic membrane and the lower ear canal. This constraint is not generally considered a major issue because the blood supply of these come from the internal and external carotid artery, respectively, so, in principle, they should have the same temperature. In addition, the ear canal is well insulated from ambient conditions and is located in close proximity to major brain arteries and veins, so its temperature is, in all likelihood, very close to that of the tympanic membrane. This means that the auditory canal, near the tympanic membrane, is likely to have an effective emissivity close to an ideal blackbody cavity. Additionally, it ends only about 3.5 cm from the hypothalamus, which is the body temperature control centre. Nevertheless, despite the suitability of the site for body temperature measurement in principle, in practice there are a number of issues rendering the technique prone to systematic errors, chief among which are:
    - Anatomically, the ear canal is a slightly curved tube about 3.0 cm - 3.5 cm in length (for an adult). This curvature, depending upon the individual, can obscure sight of the deep inner ear canal and tympanic membrane (which is why during the

measurement, steps need to be taken to straighten the ear canal —the technique of "ear tugging"— though this is not widely used in practice).

- More prosaically, wax or fluid in the ear canal can partially or completely obscure the tympanic membrane and inner ear canal, leading to large errors of measurement.

- Skin temperature measurements are made in an attempt to determine the surface temperature of the human body. However, the measured temperature significantly depends on the skin blood perfusion and, in particular, the environmental conditions[4]. Moreover, skin temperature may vary with abnormal transpiration (sweating), which occurs as a consequence of some health conditions or medical treatments. Therefore, in most measurement situations, such as screening in public places or outside, skin temperature cannot be reliably correlated with the internal body temperature[5]. This means that it is difficult in most public health settings to reliably determine body temperature with such devices. However, although the measured temperature is very likely to be significantly offset from core body temperature (for instance, depending on the part of the facial skin measured [6]), skin temperature measurement can, with care, in suitable environments and with well-designed and manufactured devices, be used to determine temperature trends. More work is required to determine whether such devices can, in said conditions, reliably determine core body temperature.

Infrared clinical thermometers of either type often have two modes adjusted/unadjusted (or indirect/direct):

- Adjusted (indirect) mode: the output of an infrared thermometer gives a temperature with an attempted correction to a particular body site (that is, oral, rectal, core…)
- Unadjusted (direct) mode[6]: the output of an infrared thermometer displays the measured temperature with no attempted correction made to body temperature site or for example, in the case of skin/forehead thermometers, no correction for skin emissivity.

## 4. Principle of Measurement by Infrared Ear Thermometers

Infrared ear thermometers (IRETs) were introduced into the market as clinical thermometers in the early 1990s. They have some advantages compared with contact thermometers:

- short response time
- the temperature of the tympanic membrane is close to core body temperature due to its proximity to the hypothalamus
- minimally invasive

[4] There could be other parameters that affect temperature; for example, the age of the subject or medical conditions that contribute to poor skin blood perfusion.

[5] Which is why the standard ASTM E1965-98 (2016) "Standard specification of infrared thermometers for intermittent determination of patient temperature" [7]: "addresses assessing a subject's body internal temperature through measurement of thermal emission from the ear canal and performance requirements for noncontact temperature measurements of skin". To be clear, this standard is explicit that forehead thermometers are intended for determining the skin temperature of a patient; they are not intended for evaluating (core) body temperature. The equivalent ISO standard ISO 80601-2-56:2017 [8] does allow for clinical validation of forehead thermometers but this is not done over a range of environmental conditions usually only in controlled room environments of around 23 $^{o}$C.

[6] There are many instruments that do not have a direct mode. In the case of infrared ear thermometers, this is not critical because they measure a blackbody with emissivity near 1 (see the sections below).

The standards that describe and formalize temperature measurements performed with these IRETs are:

- ISO 80601-2-56:2017 “Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement” [8].
- ASTM E 1965-98 (2016) “Standard specification for infrared thermometers for intermittent determination of patient temperature” [7].
- JIST 4207 “Infrared ear thermometers” [9].

IRETs measure human body temperature using the infrared radiation (IR) emitted by the tympanic membrane and the lower ear canal, which is assumed to be a blackbody with relatively high emissivity[7,8]. An IRET is an electronic device having an infra-red detector with a sensor in which IR radiation is collected from the field of view of the detector and is converted into an electrical signal for calculation of the temperature of the subject. In practice, the essential elements of the measuring system may have many configurations, and there may be additions to enhance accuracy and add features required for the practical use of the device.

While contact thermometers rely on conductive heat transfer, IR thermometers in general, and IRETs in particular, seek to utilise emitted electromagnetic (thermal) radiation. The magnitude and the spectral distribution of the emitted thermal radiation are functions of the temperature and emissivity of the tympanic membrane and lower ear canal configuration. The spectral density of the radiation is governed by Planck’s law and theoretically comprises an infinitely wide spectrum. However, due to the shape of the blackbody spectral density curve and the filtering of the device’s optical components, the measurement bandwidth of an IRET is generally limited to the range from around 3 μm to at most 30 μm (typically 8 - 14 μm), that is generally situated in the near to mid infrared spectral range.

## 5. Clinical Validation

Each reference body site will have a different temperature according to the balance between heat production, transfer and loss. That means that laboratory verification of a clinical thermometer performance is not sufficient to ascertain its effectiveness in determining core body temperature, partly because of the external factors (patient and environment) mentioned above and partly because of the thermometer’s internal adjustment algorithm, where an offset is applied to obtain the indicated core body temperature (or other body temperature measurement sites). So, the accuracy of a clinical thermometer needs to be verified in two steps [8]:

- By comparing its indicated temperature (in unadjusted or direct mode) with that of a reference thermometer that is traceable to national standards of temperature. For a clinical thermometer, measurement accuracy can be correctly determined under laboratory conditions through the process of calibration. For IRET the calibration is performed against a blackbody reference source designed for this specific purpose.
- By using statistical methods that compare the indicated temperature (in adjusted mode) with that of a reference clinical thermometer that has a specified clinical accuracy to represent a

[7] This is thought to be a reasonable assumption provided the ear canal is unobstructed by wax or fluid

[8] Emissivity is an indicator of how well an object emits electromagnetic radiation from its surface. It is expressed using a dimensionless value with a range from 0 to 1. An ideal blackbody has an emissivity of 1 and, by definition, is a perfect emitter of thermal radiation. In reality, objects are never perfect; therefore, the emissivity of the surface, in the waveband of measurement, needs to be taken into account in any practical measurement.

particular reference body site temperature. The clinical accuracy is validated in the adjusted mode with a sufficiently large group of human subjects [8].

## 6. Basic Operating Instructions

Here we summarise the best practice that needs to be followed to obtain the best performance from IRETs for body temperature measurement. This advice comes from: a) the three main standards governing infrared clinical thermometers; b) the experience and practice members of this group; and c) experience and practice of clinicians.

The standards ISO 80601-2-56:2017, ASTM E1965-98 (2016) and JIST T4207 detail the content of the user's instructions for IRETs and other clinical thermometers. The user's instructions should have information about the specific use of the equipment (placement, batteries, switching on/off, cleaning, displaying modes, etc.). The most important content related to practical use is:

- Measurement site (where the clinical thermometer is placed during the measurement, i.e. the ear for an IRET).
- The body reference site that the IRET is attempting to infer (e.g. core or oral).
- Measurement duration and time between measurements.
- Measurement range.
- Clinical accuracy: the uncertainty the IRET aims to attain during routine clinical use.
- Whether it is necessary to use a protective cover on the sensing head of the thermometer: instructions about thermometer use with and without cover.
- Information about whether the thermometer measures in direct mode or in adjusted mode.
- Battery information.
- Information about maintenance and calibration.

There are a number of principles that should be followed (in addition to the manufacturer's instructions) in order to reduce measurement uncertainty with the IRET. These are summarized as follows:

Instrument precautions:

- The thermometer should be aligned as best as possible within the ear canal (the measurement head is not obstructed and no gap is present around it).
- Dirt, fluid or ear wax should be removed from the ear canal before the measurement.
- The sensing head should be aimed directly at the tympanic membrane, not at the ear canal. This generally necessitates "ear tugging" during measurement to attempt to straighten the ear canal and give a better view of the tympanic membrane and lower ear canal.
- The probe covers supplied with the thermometer should always be used for the measurement. Care must be taken that the cover is properly placed and doesn't block the field of view of the thermometer.
- Disposable covers are to be used once only. However, in emergency situations, when disposable covers are not available then to avoid both unreliable measurement and cross infection it is essential that the sensing head is kept completely clean and sterile. After cleaning the sensing head with wipes soaked in alcohol, wait 10 minutes before making further measurements so that the thermometer returns to thermal equilibrium and sterility has been achieved.

- To achieve the highest possible accuracy for consecutive measurements, wait a minimum of 30 seconds between two measurements, removing the thermometer from the ear in between measurements
- Do not hold the thermometer in the hand during the measurement for a long time.
- After replacing the battery, wait for the thermometer to achieve operational stability, usually at least 10 minutes.
- The performance of the device should be checked against a known traceable temperature reference if at any time the thermometer has experienced:
    - operating temperatures outside its working and/or storage temperatures:
    - strong shocks or falls;
    - strong sunlight;
    - direct contact with water, if it is not well insulated;
    - humidity levels more extreme than specified for normal operation by the manufacturer;
    - strong electromagnetic fields (e.g. MRI devices).
- The performance of the device should be checked against a known traceable temperature reference after a certain period of routine use. This period is usually specified by the manufacturer and is an essential step to ensure ongoing reliable thermometer performance.
- Do not use the thermometer in inappropriate conditions (strong air conditioning, dust, parasitic heat sources or in the presence of thermal radiation sources such as sunlight).

Patient precautions:

- The patient should not drink, eat or engage in sports activities immediately before or during the measurement.
- The measured values may be different in each ear. Therefore for determining patient temperature trends, always measure the temperature in the same ear.
- Do not measure the temperature of a patient who has been lying with their ear on a pillow; the temperature measured shortly afterwards may be elevated in that ear.
- Measurements must not be made in an ear, showing an inflammatory disease, after an ear injury (e.g. damage to the tympanic membrane) or during the post-operative treatment phase. In addition, the ear temperature cannot be measured if medication has been applied to the ear.
- Do not measure the temperature of an infant during or immediately after breastfeeding.
- If there are doubts about the measured temperature (e. g., it does not correspond to how the patient feels), wait for several minutes then repeat the measurement. Alternatively, use an independent clinical method.

## 7. Measurement Influence Quantities and Associated Uncertainties

This section discusses the overall temperature uncertainty achievable by an IRET. This uncertainty depends upon three main factors: the IRET's ability to determine core body temperature, the performance of the thermometer itself and the uncertainty introduced into the measurement when in clinical use. These are discussed in turn below.

## 7.1. Ability to determine the core body temperature

The ear canal temperature, as measured by an IRET, is expected to be relatively close to the temperature of the tympanic membrane, which in turn is anticipated to be close to core body temperature. Potential sources of uncertainty are:

- Inflammations, which have been observed to cause an increase of the measured temperature by about 0.1 °C [10].
- The effects of ear wax that occludes the ear canal have been observed to reduce measured temperatures between 0.1 °C and 0.3 °C [11, 12]. Note, though that in case of an ear that has fluid or significant accumulation of ear wax, these figures could be significantly higher.

Measuring the temperature of an ear with an inflammation or that has an accumulation of ear wax should be avoided.

The emissivity of the ear canal has been generally assumed to be approximately 1.0 (see [7]) and it is currently thought that this assumption is an insignificant source of uncertainty.

## 7.2. Performance of the IRET

In general, all infrared (IR) thermometers work in the same way. The first part of this section describes the uncertainties that all IR thermometers are subject to, given in the context of IRETs, then additional factors are considered specifically for IRETs.

### 7.2.1. General IR thermometer specifications – in the context of assessing IRET performance

The standard IEC TS 62492-1:2008 "Industrial process control devices – Radiation (i. e. non-contact/IR) thermometers – Part 1: Technical data for radiation thermometers" [13] describes the metrological data used to describe the characteristics of a radiation thermometer and standard IEC TS 62492-2:2013 "Industrial process control devices – Radiation thermometers – Part 2: Determination of the technical data for radiation thermometers" [14] describes how to measure these parameters. The metrological parameters that affect the accuracy of IR thermometers are:

- **Noise equivalent temperature difference (NETD)**: how the electrical noise from within the instrument affects the temperature indication – for an IRET, this is generally lower than the resolution of 0.1 $^{o}$C.
- **Measuring distance**: in the case of IRETs, this effect is not significant because the distance between the end of the sensing head and the target is nominally zero.
- **Field of view** (target area, measurement field): flat area (usually circular) of the measured object from which the radiation thermometer receives radiation. In the case of IRETs, the effect of underfilling the field of view is negligible because the field of view is completely filled as the sensing head is placed within the entrance of the ear canal.
- **Size of source effect (SSE)**: difference in the temperature reading of the radiation thermometer when changing the size of the radiating area of the observed source. In the case of IRETs, this effect is negligible because the blackbody can be considered infinite in size, the sensing head being placed within the entrance of the ear canal.
- **Emissivity**[8]: the emissivity of a surface is the ratio of the radiation emitted from this surface to the radiation emitted from a blackbody at the same temperature. In the case of IRETs, the

emissivity of the ear canal is generally assumed to be 1.0, so the thermometer generally calculates the indicated temperature based on this assumption. In practice, any departure from an emissivity of 1.0 will be a source of uncertainty.

- **Temperature parameter**: parameter that gives an additional uncertainty in the measured temperature value depending on the deviation of the temperature of the IRET from the value for which the technical data is valid after warm-up time and under stable ambient conditions.
- **Humidity parameter**: parameter that gives the additional uncertainty in the measured temperature value depending on the relative air humidity at a defined ambient temperature.
- **Long-term stability**: reproducibility of the measurements repeated over a long time period (this could be days, weeks, months)
- **Short-term stability**: reproducibility of the measurements repeated over a short time period (several hours)
- **Response time**: time interval between the instant of an abrupt change in the value of the input parameter (object temperature) and the instant after which the measured value on the IR thermometer remains within a specified limit of its final value.
- **Warm-up time**: time period needed after switching on the IR thermometer for it to operate according to its specifications.

These parameters should be determined by the manufacturer according to IEC TS 62492-2:2013 Part 2 in order to assign an uncertainty value for the thermometer when operating in near ideal (laboratory) conditions.

For an IRET, the maximum permissible error (MPE) specified in ISO 80601-2-56:2017 is 0.3 °C in the range from 34 °C to 43 °C. In the case of the ASTM E1965 – 98 (2016), the MPE is 0.2 °C from 36 °C to 39 °C and 0.3 °C at temperatures less than 36 °C and greater than 39 °C. In the case of JIS T4207, the MPE is 0.2 °C from 35.5 °C to 42 °C, at normal ambient conditions. All the parameters listed above should have been included in order to evaluate realistic values for the MPEs[9].

### 7.2.2. Additional considerations regarding uncertainty assignment to IRETs

*Laboratory tests against blackbody references*

The ISO and ASTM standards include some requirements for the calibration of IRETs to verify that the uncertainty of the thermometer is at or below the MPE in the standard. The calibration should be performed using the sensing head cover supplied by the manufacturer and should be performed with the thermometer indication in direct mode[10].

In the case of the ISO 80601-2-56:2017 standard, the following requirements are necessary to IRETs:

- Use of a blackbody cavity with emissivity near to 1 specially designed for the purpose of calibrating IRETs (EN 12470-5 (2003) [15], ASTM E1965 – 98 (2016) or JIS T 4207: 2005) immersed in an isothermal enclosure with a volume of at least 5 litres.

[9] Thermometers should be labelled with a regional marking (i. e. CE marking at Europe) to advise users that its conformity has been checked properly against appropriate standards.

[10] It should be noted that this calibration should be done with the thermometer indicating in direct mode. Sometimes this is not possible because of manufacturing constraints [16], although in the IRET's case, the difference from the indirect mode would not be significant because the emissivity is considered to be 1.0, the same as for a perfect blackbody.

- The isothermal enclosure should have a temperature stability not larger than ± 0.02 °C and a homogeneity of ± 0.01 °C.
- Use of calibrated reference thermometers, with metrological traceability, and with an expanded calibration uncertainty ($k$ = 2) below 0.02 °C.
- The expanded uncertainty of the reference radiance temperature of the blackbody calibrator should be less than 0.07 °C[11]

In the case of the ASTM E1965 – 98 standard, the requirements are:

- Use of a special blackbody cavity provided in Annex A1 of the standard, immersed in an isothermal enclosure with a volume of at least 2 litres.
- The isothermal enclosure should have a temperature stability not larger than ± 0.03 °C.
- Use of calibrated reference thermometers, with metrological traceability and with an expanded calibration uncertainty ($k$ = 2) below 0.03 °C, positioned in the liquid close to the blackbody cavity.

Infrared ear thermometers have been widely studied by European National Metrology Institutes and an international laboratory comparisons have been performed [16, 17]. The results of these comparisons confirmed that the IRETs used in the study met the accuracy specified by the standards mentioned above.

*Additional tests to confirm performance with human subjects*

In addition to the validation/calibration in a laboratory a clinical validation is needed to meet the MPE. Clinical accuracy tests are intended for evaluation of the accuracy of built-in instrumentational or combined site offsets, or both, and performance of an IRET in assessing core body temperatures of actual subjects. Details of performing the clinical validation are given in the above ISO and ASTM standards but IRET performance should be demonstrably within the MPE even after clinical validation.

## 7.3. IRET uncertainty in clinical use

Some of these sources of uncertainty could potentially be the largest in the uncertainty estimation in the use of IRET. Individual components are:

- **Resolution**[12]**:** every time a measurement is made, the resolution of the thermometer should be considered. The resolution of an IRET is usually 0.1 °C
- **Repeatability**[12]**:** the standard deviation of the measurements, if more than one reading is taken
- **Misalignment:** the IRET should in principle measure the tympanic membrane temperature. This temperature is different from the average ear canal temperature. Because the IRET, in general, has a very large viewing angle (some even larger than 90$^{o}$), it inevitably measures also some portion of the ear canal beside the tympanic membrane. Depending on the

[11] This uncertainty includes the components coming from the contact reference thermometer, the liquid bath and the emissivity of the blackbody inserted into the liquid bath. If the references EN 12470-5, ASTM E1965 – 98 or JIST IRET are followed the blackbody emissivity can be considered to be approximately 1.0

[12] Either the standard deviation of repeat readings or the resolution uncertainty should be included, whichever is greater.

positioning of the thermometer relative to the ear canal, this contribution could be smaller or larger. Differences of up to 0.2 °C with changes of alignment have been reported in [18].

- **Obstruction in the ear canal**: the effect of ear wax occluding the ear canal is between 0.1 °C and 0.3 °C [11, 12]. In addition the observed effect of inflammation has been 0.1 °C, though this was not a comprehensive study and the possible effect may well be more [10].
- **Ambient conditions (effect on ear)**: ambient temperature can also affect the temperature of the ear canal walls, but this effect can be considered negligible compared with the others listed here.
- **Ambient conditions (effect on thermometer)**: if the IRET is operated outside of the range of operation specified by the manufacturer, this will lead to additional sources of uncertainty.
- **Influence of the probe cover (the variation between different probe covers):** this can result in a lower amount of thermal radiation reaching the detector due to the inter-probe cover transmission variability. Values between 0.1 °C and 0.2 °C are reported in [18] for this effect.
- **Heating of the thermometer when held in the hand and by the heat flux from the body**: depending on the design of the thermometer, there can be a difference of up to 0.4 °C in the ear thermometer reading [18, 19].
- **Drift**: a periodic traceable calibration is always needed to maintain the accuracy of the thermometer. The manufacturer should give information about the calibration period[13] but frequency of use should also guide the calibration interval. The IRET performance could be significantly in error if it has experienced a shock of some kind, such as temperature excursions outside its normal range of use, or a physical shock, such as dropping on the floor and should be checked before re-entering service.

*Uncertainty budget*

In Table 1 a typical uncertainty budget is shown (see annex for more detailed information). **It does not include the ability of the thermometer to measure core body temperature**; this source of uncertainty depends on how reliably the determination of the difference between core body temperature and tympanic membrane temperature has been made, and its subsequent incorporation into the correction algorithm of the IRET by the manufacturer. In principle this should be a small correction as tympanic membrane temperatures are thought to be closely aligned with core body temperature.

[13] For instance, one of the requirements that the manufacturer should have met in order to get a CE marking with the European Council Directive 93/42/EEC of 14 June 1993 for medical devices (IIa class medical devices) is: "where appropriate, the manufacturer should include in the instruction manual indications about the safe use of the device, including the need of periodical calibrations and/or verifications, in order to ensure the reliability of the measurements performed".

**Table 1.** Typical uncertainty budget for an IRET. The total uncertainty is rounded and given to the same number of decimal places as the usual resolution in this type of thermometers (0.1 °C).

| **Uncertainty component**[14] | **Value (maximum error) °C** | **Value (standard uncertainty) °C** |
|---|---|---|
| **Standardization/initial calibration** | | |
| ASTM E1965 – 98 (2016)<br><br>ISO 80601-2-56:2017 | ± 0.3 | 0.3 /√3 |
| **In use** | | |
| Repeatability | 0.2 (*) | 0.2 /√12 |
| Misalignment | 0.2 | 0.2 /√12 |
| Obstruction in the ear canal | 0.3 | 0.3 /√12 |
| Influence of the cover | 0.2 | 0.2 /√12 |
| Heating of the thermometer when held in the hand and by the body heat flux | 0.4 | 0.4 /√12 |
| Drift (at least the calibration uncertainty) | ± 0.3 (**) | 0.3 /√3 |
| **Expanded Uncertainty (*k* = 2) [≅ 95% confidence interval]** | | **0.5 °C** |

(*) 10 measurements performed, with a maximum variation of twice the resolution.

(**) A drift equal to the MPE has been considered.

## 8. REFERENCES


[1] "International vocabulary of metrology. Basic and general concepts and associated terms (VIM)". JCGM 200:2008.

[2] Brengelmann G. L., "Dilemma of body temperature measurement" Shiraki, Keizo and Yousef, M.K. Ed. *"Man in stressful environments: thermal and work physiology"* Charles C. Thomas, Springfield, IL, 1987, pp 5-22.

[3] Benzinger M., "Tympanic thermometry in anaesthesia and surgery", *JAMA*, 209, 1969, pp 1207-11.

[4] Webb G. E., "Comparison of esophageal and tympanic temperature monitoring during cardiopulmorary bypass" *Anaesthesia and Analgesia*, 52, 1973, pp 729-33.


[14] The effects of ambient conditions are considered negligible if the IRET is operated within the manufacturers stated operating conditions. The contribution due to the correction to core body temperature has been neglected and the assertion that the ear canal plus tympanic membrane combination has an emissivity of 1.0 has been assumed to be nominally correct in this uncertainty analysis.

[5] Brinnel H. and Cabanac M. T. “Tympanic temperature is a core temperature in humans” *J. Therm. Bio.* (UK) 14, 1969, pp 47 – 53.

[6] Y. Zhou et al “Clinical evaluation of fever screening thermography: impact of consensus guidelines and facial measurement location” *J. of Biom. Opt*., 25(9), 097002, 2020.

[7] ASTM E1965 – 98 (2016) “Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature”.

[8] ISO 80601-2-56:2017 “Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement”.

[9] JIS T 4207: 2005(E) “Infrared ear thermometers”.

[9] Terndrup T. E. and Wong A., “Influence on otitis media on the correlation between rectal and auditory canal temperatures” *Am. J. Dis. Child.,* 145, 1991, pp 75-78.

[10] Hasel K. L. and Erickson R. S., “Effect on cerumen on infrared ear temperature measurement”, *Journal of Gerontological Nursing*, 21, 12, 1995, pp 6-14.

[11] Dozena D., Lunt M. and Tanberg D., “Cerumen occlusion lowers infrared tympanic membrane temperature measurement”, *Acad. Emerg. Med.* 2, 1995, pp 17-19.

[12] Fraden J., “Medical infrared thermometry: Review of modern techniques” *Temperature Its Measurement and Control in Science and Industry*, 6, part 2, Am. Inst. Of Physics, New York, 1992, pp 825 – 830.

[13] IEC TS 62492-1:2008 “Industrial process control devices - Radiation thermometers - Part 1: Technical data for radiation thermometers”.

[14] IEC TS 62492-2:2013 “Industrial process control devices - Radiation thermometers - Part 2: Determination of the technical data for radiation thermometers”.

[15] EN 12470-5:2003 “Clinical thermometers. Part 5: Performance of infrared ear thermometers (with maximum device)”, inactive.

[16] Pušnik I., et al. “Comparison of blackbodies for calibration of infrared ear thermometers”. *International journal of thermophysics*, vol. 32, no. 1/2, pp. 127-138, 2011.

[17] Ishii J., Fukuzaki T., McEvoy H.C., Simpson R., Machin G., Hartmann J., Gutschwager B. & Hollandt J., “A comparison of the blackbody cavities for infrared ear thermometers of NMIJ, NPL and PTB”, In: Tempmeko 04, The 9th International Symposium on Temperature and Thermal Measurements in Industry and Science, Zagreb, Croatia, Editor in Chief Davor Zvizdic, Published: LPM/FSB, p. 1093-1098 (2005).

[18] Pušnik I. and Drnovšek J. “Infrared ear thermometers. Parameters influencing their reading and accuracy”. *Physiol. Meas.* 26, 2005, pp 1075–1084.

[19] Simpson, R., Machin, G., McEvoy, H.C. & Rusby R.L., “Traceability and calibration in Temperature Measurement: A clinical necessity”, *J Med. Eng. & Technol.* **30**, p. 212-217 (2006) https://doi.org/10.1080/03091900600711530.

[20] “Guide to the Expression of Uncertainty in Measurement (GUM)” JCGM 100:2008.

## ANNEX. Mathematical model and uncertainty calculation

This annex gives details on how the uncertainty values in Table 1 were estimated.

During the measurement, 10 readings of an IRET, the maximum variation observed was twice the resolution. The final measured value is determined as the arithmetic mean ($t_{mean}$) and the standard deviation of the average measurement value is determined (0.06 °C). The resolution of the IRET used for the measurements was 0.1 ° C lower than the repeatability, so only repeatability has been considered in the uncertainty budget. It complies with the ISO 80601-2-56 with a MPE of 0.3 °C and it has not been recalibrated. A maximum drift equal to the MPE is considered in one year. (In the case that the thermometer has been recalibrated, the uncertainty of the calibration, plus the correction if it is not applied, should be considered instead of the MPE, and the drift can be calculated as the differences between successive calibrations).

The value of the measured temperature, $t_x$, can be estimated using the following relationship:

$$t_x = t_{mean} + \delta t_{std} + \delta t_{mis} + \delta t_{obst} + \delta t_{cover} + \delta t_{heat} + \delta t_{drift} \quad (1)$$

where:

$t_{mean:}$ arithmetic mean of the measurements performed;

$\delta t_{std}$: correction due to the repeatability of the thermometer;

$\delta t_{mis}$: correction due to the misalignment;

$\delta t_{dirt}$: correction due to possible obstruction in the ear canal;

$\delta t_{cover}$: correction due to the influence of the cover;

$\delta t_{heat}$: correction due to the influence of heating when holding the thermometer in the hand and by the heat flux of the source;

$\delta t_{drift}$: correction due to the drift of the thermometer.

All the corrections in (1) are usually unknown and can be considered to be zero, taking them into account only as uncertainty components. Using the law of propagation of uncertainties [20] in (1) and assuming independence of the variables, we get $u(t_x)$:

$$u^2(t_x) = u^2(t_{mean}) + u^2(\delta t_{std}) + u^2(\delta t_{mis}) + u^2(\delta t_{obst}) + u^2(\delta t_{cover}) + u^2(\delta t_{heat}) + u^2(\delta t_{drift}) \quad (2)$$

where:

$u(t_{mean})$ is the uncertainty due to the MPE, ± 0.3 °C considered as a maximum error, so using a rectangular distribution we calculate $0.6/\sqrt{12} = 0.3/\sqrt{3}$ as standard uncertainty;

$u(\delta t_{std})$ is the uncertainty due to the repeatability, in this case the standard deviation of the measurements, 0.06 °C;

$u(\delta t_{mis})$ is the uncertainty due to the misalignment, 0.2 °C considered as a maximum error, so using a rectangular distribution we calculate $0.2/\sqrt{12}$ as the standard uncertainty;

$u(\delta t_{obst})$ is the uncertainty due to the dirt in the ear canal, 0.3 °C considered as a maximum error, so using a rectangular distribution we calculate $0.3/\sqrt{12}$ as the standard uncertainty;

$u(\delta t_{cover})$ is the uncertainty due to the influence of the cover, 0.2 °C considered as a maximum error, so using a rectangular distribution we calculate $0.2/\sqrt{12}$ as the standard uncertainty;

$u(\delta t_{heat})$ is the uncertainty due to the influence of heating when holding the thermometer in the hand and by the heat flux of the source, 0.4 °C considered as a maximum error, so using a rectangular distribution we calculate $0.4/\sqrt{12}$ as the standard uncertainty;

$u(\delta t_{drift})$ is the uncertainty due to the drift, ±0.3 °C considered as a maximum error, so using a rectangular distribution we calculate $0.6/\sqrt{12} = 0.3/\sqrt{3}$ as the standard uncertainty.

Table 1 in section 7.3 shows the uncertainty budget with the final calculation.