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BEST PRACTICE GUIDE: USE OF INFRARED FOREHEAD THERMOMETERS TO PERFORM TRACEABLE NON-CONTACT MEASUREMENTS OF HUMAN BODY TEMPERATURE

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## **BEST PRACTICE GUIDE**

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

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## 1. Scope

This document applies to clinical thermometers, type forehead/skin thermometers, for the measurement of body temperature in the range from 22 °C to 40 °C.

## 2. Objective

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

## 3. Introduction

There are several methods for measuring temperature (and hence human 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<sup>1</sup>.

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<sup>2</sup> than contact thermometers because of the following effects, among others:

- The object's capacity to emit thermal radiation (emissivity) and, conversely, the object's capacity to reflect environmental thermal radiation.

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<sup>1</sup> These predictive algorithms introduce some additional uncertainty into the measurement process

<sup>2</sup> 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 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 reference body site and then relate that measurement to core body temperature. Determining whether a patient is afebrile, febrile, or 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 reference body 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<sup>3</sup>. 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<sup>4</sup>. 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<sup>5</sup>: the output of an infrared thermometer displays the measured temperature with no attempted correction made to body temperature site, for example. in the case of skin/forehead thermometers, no correction for skin emissivity

#### 4. Principle of Measurement by Infrared Forehead Thermometers

A forehead or skin infrared thermometer (IRFT) is a non-contact infrared temperature measurement device that can be used to infer body temperature from a measurement of the subject's skin surface temperature. These thermometers have some advantages compared with contact thermometers:

- short response time;
- there is no contact between the subject and the thermometer (unlike in the case with infrared ear thermometers), which is good from an infection control perspective.

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<sup>3</sup> 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.

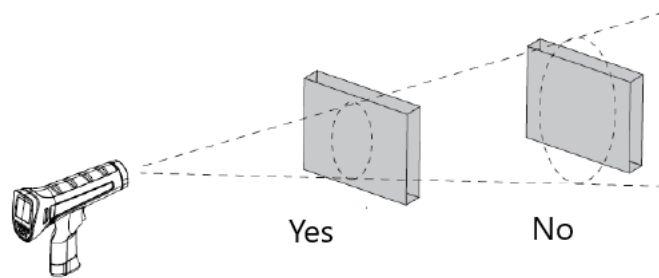
<sup>4</sup> Which is why the standard ASTM E1965-98 (2016) "Standard specification of infrared thermometers for intermittent determination of patient temperature" [7]: "addresses assessing a subject's body internal temperature through measurement of thermal emission from the ear canal and performance requirements for noncontact temperature measurements of skin" To be clear, this standard is explicit that skin thermometers are intended for determining the skin temperature of a patient, they are not intended for evaluating (core) body temperature.

<sup>5</sup> There are many instruments that do not have a direct mode. In the case of infrared forehead thermometers, the manufacturers must supply the corrections applied in order to perform the calibration at the laboratory [7, 8] (see the sections below).

There are two standards<sup>6</sup> that describe the performance of such thermometers: ASTM E 1965-98 (2016) “Standard specification for infrared thermometers for intermittent determination of patient temperature” [7] and 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].

The principle for measuring skin temperature is technically the same as that used by infrared ear thermometers (see [9]). However, there are two significant differences.

- The first relates to the measurement site. For forehead/skin thermometers, the emissivity of the skin and reflected thermal radiation need to be taken into account. This is a significant issue because skin emissivity may vary from site to site on the body and between individuals with values in the range from 0.94 to 0.99 [10, 11, 12]. This is unlike the emissivity of the ear canal, where the emissivity is effectively 1.00 [7]. The background thermal radiance may vary and be poorly controlled (such as measurements in public places or even outside), depending on where the measurements are taken<sup>7</sup>.
- The second relates to the field of view (FOV) of the instrument (see section 7.2.1). For both, ear and forehead/skin thermometers, the FOV is usually quite wide, but in the case of ear thermometers, they are designed to be inserted into the ear canal and the FOV is completely filled. This is different for forehead/skin thermometers, where, unless care is taken, the region of interest is likely to fill only a portion of the FOV. To prevent spuriously low readings, and to even approximately measure forehead/skin temperatures, both the instrument design and the measurement distance (supplied by the manufacturer) should ensure that the measured thermal radiation is collected from the skin surface of interest, avoiding, as far as practicable, any stray thermal radiation from other unrelated parts of the body – for example, hair or external objects having different surface temperatures, which could be sources of spurious reflected or emitted thermal radiation (see Figure 1).



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<sup>6</sup> The ISO-80601-2-56 (2017) standard covers all types of clinical thermometers: contact and non contact. It is very general and it doesn't describe the performance of forehead thermometers explicitly. The ASTM E1965-98 (2016) standard is more explicit and states that forehead/skin thermometers are intended for determining the skin temperature of a patient — they are not intended for evaluating (core) body temperature.

<sup>7</sup> IRFTs try to compensate for ambient conditions by attempting to measure ambient temperature independently. This, however, is difficult to do as the device may be warmed by the operator's hand and internal electronics so the measured internal temperature may not represent ambient. It also takes some time for a thermometer to even approximately acclimatise to ambient conditions. So, for example, if the thermometer was taken outside of a controlled environment and a measurement made, the ambient could vary from below 0 °C to above 30 °C, which would have a significant impact on the measured skin temperature (quite apart from the fact that, for example, the forehead would be significantly radiating away heat in cold conditions and so would be very significantly cooler than core body temperature).

**Figure 1.** The field of view of the thermometer limits the distance to the object to be measured.

Two types of thermometer for measuring forehead skin temperature are available on the market:

- The so-called temporal artery thermometer is placed touching the temple and it has a cup shape at the end. Generally, it is moved over the skin surface from the centre of the forehead towards the ear and the maximum temperature is recorded.
- The more general forehead thermometer measures at just one point at a distance of several centimetres from the skin.

The following sections apply to both, as well as to more general skin thermometers.

## 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 determine 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, before the thermometer is used, its accuracy as a clinical thermometer needs to be verified in two steps<sup>8</sup> [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 IRFT 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 particular reference body site temperature. The clinical accuracy is validated in the adjusted mode with a sufficiently large group of human subjects [8]. It must be noted here that this process is only likely to be even approximately successful in the case of IRFT due to the strong influence of skin emissivity and background thermal radiation. Very carefully controlled environmental conditions, with well thermalized subjects, will be needed to determine even approximate adjustments to clinically recognised temperature measurement sites.

## 6. Basic Operating Instructions

Here we summarise the best practice that needs to be followed to obtain the best performance from infrared forehead thermometers for body temperature measurement. This advice comes from: a) the 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 and ASTM E1965-98 detail the content of the user's instructions for infrared clinical non-contact thermometers. These should include information about the specific

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<sup>8</sup> Clinical validation for IRFTs is described only in [6]. [7], 5.5.1.1, states that clinical accuracy requirements are not applicable to skin thermometers.



use of the equipment (placement, distance, 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. close to the forehead for an IRFT)
- The body reference site that the IRFT is attempting to infer (e.g., core or oral).
- Measurement duration and time between measurements.
- Measurement range.
- Clinical accuracy: the uncertainty the IRFT aims to attain during routine clinical use.
- Whether it is necessary to use a protective cover on the sensing head of the thermometer (for IRFTs, this only applies to temporal artery thermometers): 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 an IRFT. These are summarized as follows:

Instrument precautions:

- The thermometer should be placed at the correct distance from the skin (typically a few centimetres) – the size of the target being measured should be at least twice the manufacturer's specified FOV. The manufacturer should indicate the distance range in the thermometer instructions.
- The thermometer should thermalize for about 15 min before being used.
- Do not hold the thermometer in the hand during the measurement for a long time.
- they may give unreliable measurement results when they
- To achieve the lowest possible uncertainty for consecutive measurements, wait a minimum of 30 seconds between two measurements.
- 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 and 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.
- The thermometer must not be used in inappropriate conditions (air conditioner drafts, dusty environments, in the presence of parasitic heat sources or thermal radiation sources). The presence of any of these may well lead to significantly erroneous measurements.

- For temporal artery devices, the covers supplied with the thermometer should be used for the measurement. Take care that the cover is properly placed and doesn't block the field of view of the thermometer. If disposable covers are not prescribed, the cleanliness of the optics must be strictly observed.

Patient precautions:

- Make sure that the vascular system on the forehead or in the area of the temporal artery is not affected by sclerotic changes (insufficient blood supply to the measuring area).
- The skin should be clean, with a clear view of the target area; there should be no sweat, face creams, makeup or other barrier, hat, hair or other material obstruction. Glasses frames, some types of tattoos, piercing or other metal objects may distort the thermal conditions of the measured area; if that is the case, it will be necessary to choose a more suitable method of measurement.
- Do not measure temperature immediately after showering, swimming, etc., when the forehead is wet.
- Do not measure the forehead temperature immediately after the patient removes a head/forehead covering – wait at least 10 min before measurement.
- Do not measure the forehead temperature immediately after the patient comes into the measurement environment from outside ambient (e.g., if it is cold outside, the forehead is likely to have a significantly depressed temperature) – wait at least 10 min before measurement.
- If repeated measurements are required for determination of temperature trends always measure at the same place, otherwise it is possible that the measured values may be at variance.
- Do not measure the temperature of an infant during breastfeeding or immediately after breastfeeding.
- If there are doubts about 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.

It is recognised that IRFTs are preferred by medics and for use in public health settings to detect febrile subjects since close contact is not necessary. However, all the precautions listed above should be carefully followed and, as it will be shown in section 6, some can still have a significant influence on the uncertainty of measurement.

## 7. Measurement Influence Quantities and Associated Uncertainties

The accuracy of an IRFT depends on its ability to determine the temperature of the skin, the accuracy of the thermometer itself, its ability to infer the temperature of other clinically recognised body sites from the measurement and the uncertainty in use.

### 7.1. Ability to determine the core body temperature

In a recent publication [13], after collecting and studying different publications, it was concluded that clinical studies (in which measurements were compared with core temperature references) **do not support the use of forehead thermometers in a clinical setting** for identifying febrile individuals and

IRFTs' ability to measure body temperature was, in general, considered to be outside the clinically acceptable limits.

When the measurement situation is considered, this finding is not surprising: skin temperature depends greatly on both the skin blood perfusion and the environmental conditions. Because of these factors, and on the basis of published evidence to date, it doesn't seem likely that skin temperature can be reliably correlated with core body temperature.

In practice more studies are needed to evaluate if it is possible under any circumstances to use IRFTs to reliably determine body temperature<sup>9</sup>.

## 7.2. Performance of the IRFT

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 IRFTs, then additional factors are considered specifically for IRFTs.

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

The standard IEC TS 62492-1:2008 “Industrial process control devices – Radiation thermometers (i. e. non-contact IR) – Part 1: Technical data for radiation thermometers” [14] 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” [15] describes how to measure these parameters. The metrological parameters that affect the accuracy of such IR thermometers are:

- **Noise equivalent temperature difference (NETD):** how the electrical noise from within the instrument affects the temperature indication – for an IRFT this is generally lower than the resolution of 0.1 °C.
- **Measuring distance:** the measuring distance should be within the manufacturer's specified range, depending on the field of view of the thermometer. In any event, it should be constrained to ensure that the target diameter is at least twice the diameter of the field of view (FOV) specified by the manufacturer.
- **Field of view (FOV, target area, measurement field):** flat area (usually circular) of the measured object from which the radiation thermometer receives radiation.
- **Size of source effect (SSE):** quantifies how much the temperature reading of the radiation thermometer changes when changing the size of the radiating area of the observed source. Usually it is expressed as a percentage of the signal coming from the target. SSE is caused by scattering and diffraction within the optical system of the measuring instrument. This can be a significant source of uncertainty for IRFTs.
- **Emissivity:** 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 IRFTs, the emissivity of the skin can be considered to be between 0.94 and 0.99, so the thermometers should be adjusted for this emissivity. Any departure of the assumed emissivity from the true value of the emissivity of the skin being measured is an uncertainty source. The uncertainty

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<sup>9</sup> Note that it may be possible to monitor temperature trends with some devices of this type if used in a carefully controlled environment .

is far from negligible (on the order of a few tenths of a degree Celsius) and is a function of the ambient temperature – the further away the skin is from ambient temperature, the higher the uncertainty.

- **Temperature parameter:** parameter that gives an additional uncertainty in the measured temperature value depending on the deviation of the temperature of the IRFT from the value for which the technical data is valid after warm-up time and under stable ambient conditions.
- **Humidity parameter:** parameter that gives an 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 or 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 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, which describes the test methods, in order to assign an uncertainty to the thermometer when operating in near ideal (laboratory) conditions.

For an IRFT the maximum permissible error (MPE) stated in ASTM E1965 – 98 for infrared clinical thermometers is 0.3 °C. All the parameters listed above should have been included in order to evaluate realistic values for the MPE<sup>10</sup>.

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

#### *Laboratory tests against blackbody references*

The ISO 80601-2-56:2017 and the ASTM E1965 – 98 standards include some requirements for the calibration of IRFTs to verify that the uncertainty is below the MPE in the standard. If a cover is required, the calibration should be performed using the cover supplied with the IRFT. **The calibration should be performed with the thermometer indication in direct mode**<sup>5</sup>.

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

- Use of a blackbody cavity with emissivity near to 1, specially designed for the purpose (EN 12470-5 (2003) [16], ASTM E1965 – 98 [7] and JIS T 4207: 2005 [17]), immersed in an isothermal enclosure with a volume of at least 5 litres.
- The isothermal enclosure should have a temperature stability not larger than  $\pm 0.02$  °C and a homogeneity of  $\pm 0.01$  °C.
- Use of calibrated reference thermometers, with metrological traceability, and with an expanded calibration uncertainty ( $k = 2$ ) below 0.02 °C.

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<sup>10</sup> IRFTs should be labelled with a regional quality marking (e.g., CE marking in Europe) to advise users that its conformity has been checked properly and has an authorised certificate of conformity.

- The expanded uncertainty of the reference radiance temperature of the blackbody calibrator should be less than 0.07 °C<sup>11</sup>

The requirements of ASTM E1965 – 98 for test equipment are:

- Use of a special blackbody cavity provided in Annex A1 of the standard (and suitable for calibrating an IRFT — that is, with a sufficiently large aperture size<sup>12</sup>), inserted into an isothermal liquid enclosure with a volume of at least 2 L.
- The isothermal enclosure should have a temperature stability not larger than  $\pm 0.03$  °C.
- The temperature of the isothermal enclosure should be determined using a traceably calibrated reference thermometer, with an expanded calibration uncertainty ( $k = 2$ ) below 0.03 °C positioned in the liquid close to the blackbody cavity.

*Additional tests to confirm performance with human subjects*

In addition to the validation/calibration in a laboratory as described above, a clinical validation is needed to meet the MPE [8]. Clinical accuracy tests are intended for evaluation of the accuracy of built-in instrumentational or combined site offsets, or both, and performance of a forehead/skin thermometer in attempting to represent the temperature of clinically recognised body temperature measurement sites of actual subjects.

It is important that the laboratory and clinical accuracy tests are carried out rigorously to ensure the thermometer meets the required performance specifications. A comparison of different IRFTs has been reported in [18]. Nine thermometers (three types) were measured and compared with national standards and the results show that at least five of them fell far outside the accuracy range stated by their manufacturers as well as that required by the ASTM standard. These measurements, in combination with the recent review given in [13], indicate that for the IRFTs tested, few, if any, were suitable for body temperature measurement.

### 7.3. IRFT uncertainty in clinical use

IRFTs are prone to particular sources of uncertainty that should be considered when they are used. These are listed below and estimates of their values are given in the Table 1:

- **Resolution**<sup>13</sup>: every time a measurement is made, the resolution of the thermometer should be considered. The resolution of an IRFT is usually 0.1 °C.
- **Repeatability**<sup>13</sup>: the standard deviation of the measurements, if more than one reading is taken, otherwise the resolution value should be used.
- **Size of source effect (SSE)/distance effect**: the measured temperature of a target at constant temperature varies depending on the size of the target. Due to this, IRFTs should be used as

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<sup>11</sup> 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.

<sup>12</sup> It is possible to use a different design of the one in this Annex; however, the emissivity of such a blackbody should be known in comparison with this and used to correct the measured temperatures. If it is possible, the blackbody used for the calibration of IRFTs should have a similar size to a human forehead (approximately  $\phi$  50 mm). This can reduce the uncertainty due to the SSE corrections (see section 7.3 below).

<sup>13</sup> Either the standard deviation of repeat readings or the resolution uncertainty should be included, whichever is greater.

close as possible to the skin surface to achieve a minimum spot size from which a measurement is taken. In [18], when maintaining a fixed distance to the target (5 mm) in order to receive 98% of the radiation coming from the target, a minimum target size between 11 mm and 19 mm was required. These areas are larger than desirable in clinical practice. As an example, from a Czech study of several IRFTs [19], when measuring different target sizes, the difference of the average displayed temperature value was 0.2 °C. **In general IRFTs have relatively poor SSE characteristics and are used over a range of distances. If the manufacturer's stated distance of use is not followed uncertainties of several degrees Celsius are easily possible.**

The distance to the target is related to the SSE because increasing the distance reduces the solid angle subtended by a fixed diameter target. Consequently, as the distance to the target is increased, the temperature reading deviates increasingly from the true target temperature (in temperate climates this means that the IRFT will almost always read lower than the true value). The results in [18] show that the magnitude of the distance effect combined with the SSE can be very large, causing a change in the temperature reading of 8 °C (for one of the thermometer types tested) when moving the thermometer from 4 mm to 7 mm away from a 15 mm diameter source at a constant temperature of 32 °C. Hence, an IRFT touching the temple would be more repeatable than one placed at a distance – but of course this negates the benefit of the method being non-contact.

- **Ambient conditions:** related with the distance effect, ambient thermal radiation, solar radiation, air conditioning, wind, etc. To determine the effect of ambient conditions, we start from [20]. The influence of ambient thermal radiation increases as the target temperature is increasingly different from ambient temperature. The requirement to measure the temperature from a very small distance from the forehead partially compensates for the influence of the surrounding sources. For some higher-quality thermometers, the manufacturer states that the measured values are internally compensated for the ambient temperature (the ambient temperature is measured by an independent sensor built into the thermometer). If we assume that the influence of the environment is compensated for, we can estimate a maximum variation of  $\pm 0.1$  °C. If the thermometer is not compensated, the effect of ambient thermal radiation, in accordance with [20], is estimated to cause errors from 0.3 °C to 0.4 °C (assuming an emissivity uncertainty of 0.005). Note also, the ambient conditions can have a significant physiological effect on the subject's forehead temperature – perhaps lowering its temperature by several degrees Celsius if it has been exposed to cold weather immediately before measurement.
- **Emissivity:** this is a complex issue because, in general, the thermometer compensates for skin emissivity with an assumed value, and it may also attempt to correct for the background thermal radiation with an internal thermometer. The determination of skin emissivity was the aim of various clinical studies and values ranging from 0.94 to 0.99 were determined [10, 11, 12]. The total uncertainty of this determination is reported to be in the range of approximately (0.002 to 0.005); i.e., 0.2% to 0.5% of the emissivity value (maximum values). This gives rise to a number of uncertainty contributions (see annex 2): if we consider  $\varepsilon = 0.98 \pm 0.02$  ( $u(\varepsilon) = 0.02/\sqrt{3} = 0.012$ ) and  $t_{\text{amb}} = 20$  °C  $\pm 2$  °C ( $u(t_{\text{amb}}) = 2/\sqrt{3} = 1.2$  °C), the standard uncertainty for a measured temperature of 37 °C is 0.2 °C for a typical thermometer working in 8  $\mu\text{m}$  – 14  $\mu\text{m}$  (see annex 1 and 2).

There would be an additional component for thermal equilibration of skin – for best practice, the skin should be left to equilibrate for 10 to 15 minutes before measurement, and then the effect should be small.

- **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 non-ideal transmission of the probe cover. There are no published studies for IRFTs (temporal artery), so we use the results of infrared ear thermometers (IRETs) as a minimum value (0.2 °C) [21]. The value is zero where no cover is used.
- **Heating of the thermometer when held in the hand and by the heat flux of the source:** depending on the design of the thermometer (whether or not it has internal regulation of the sensor temperature). There are no studies for IRFTs, so we use the results of IRETs as a minimum value (0.4 °C) [21].
- **Thermal homogeneity of the measured area:** as an example, from a Czech study [19] the temperature was measured after complete stabilization of the IRFT, the patient was at rest for at least 30 minutes, his forehead was not exposed to any airflow or other disturbances and was not covered with sweat, and the blood supply to his forehead was not affected by any sclerotic process. As a result, the largest temperature range on the forehead skin corresponded to 0.2 °C (determined from the average temperatures measured at different points of the forehead between the temples). This is very likely to be an underestimate in actual clinical practice, where patient temperature is generally measured within a few minutes of arriving in the assessment room, or the range can be even more if the IRFT is used in a public setting or outside, where offsets of several degrees have been anecdotally reported.
- **Drift:** a periodic traceable calibration is always needed to maintain the accuracy of the thermometer. The manufacturer should give information about the calibration period<sup>14</sup>, but frequency of use should also guide the calibration interval. The IRFT 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, an example of uncertainty budget is given (see annex for a more detailed information), when all the precautions listed in section 6 have been taken. **It does not include the uncertainty in the capability of the thermometer to estimate core or other body temperature sites**, which could well be significant as there are currently no traceable studies published on the evaluation of core (or other) body temperature sites and forehead/skin temperature. Also, it is assumed that the thermometer has a direct mode, which permits its calibration using a blackbody (see section 7).

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<sup>14</sup> For instance, one of the requirements that the manufacturer should have justified 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 instructions 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.** An example uncertainty budget for an IRFT. The total uncertainty is rounded and given to the same number of decimal places as the usual resolution in this type of thermometer (0.1 °C). The influence of the cover has not been considered because it is only used in some very specialist devices (and, in any case, this component is only 0.2 °C, so the overall budget wouldn't be affected). It must be stressed that this is the best estimate of uncertainty – if such thermometers are used in public settings the uncertainty could be considerable larger – even more than double.

Uncertainty component	Value (maximum error) °C	Value (standard uncertainty) °C
<b>Standardization/initial calibration</b>		
ASTM E1965 – 98 ISO 80601-2-56:2017	± 0.3	0.3 /√3
<b>In use</b>		
Repeatability	0.2 (*)	0.2 /√12
Size of source effect (SSE)/distance effect	1.0 (**)	1.0 /√12
Ambient conditions	± 0.1	0.1 /√3
Emissivity	0.2	0.2
Heating of the thermometer when held in the hand and by the source heat flux	0.4	0.4 /√12
Homogeneity of the measured area	0.2	0.2 /√12
Drift (at least the calibration uncertainty)	± 0.3 °C (***)	0.3 /√3
<b>Expanded Uncertainty (k=2) [~95% confidence interval]</b>		<b>0.9 °C</b>

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

(\*\*) From [18], the best value obtained for IRFT B, Figure 6.

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

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## ANNEX 1. 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 IRFT were taken and the maximum variation was twice the resolution. The final measured value is determined as the arithmetic mean ( $t_{\text{mean}}$ ), and the standard deviation of the average measurement value is determined (0.06 °C). The resolution of the IRFT used is 0.1 °C, lower than the repeatability, so only repeatability has been considered in the uncertainty budget. It complies with the ASTM E1965 – 98 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 IRFT 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:

$$t_x = t_{\text{mean}} + \delta t_{\text{std}} + \delta t_{\text{amb}} + \delta t_{\text{SSE}} + \delta t_{\text{cover}} + \delta t_{\text{heat}} + \delta t_{\text{e}} + \delta t_{\text{hom}} + \delta t_{\text{drift}} \quad (1)$$

where:

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

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

$\delta t_{\text{amb}}$ : correction due to the influence of the ambient conditions;

$\delta t_{\text{SSE}}$ : correction due to the SSE and the distance effect;

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

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

$\delta t_{\text{e}}$ : correction due to the influence of skin emissivity;

$\delta t_{\text{hom}}$ : correction due to the homogeneity of the surface being measured;

$\delta t_{\text{drift}}$ : 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 [22] in (1) and assuming independence of the variables, we get  $u(t_x)$ :

$$u^2(t_x) = u^2(t_{\text{mean}}) + u^2(\delta t_{\text{std}}) + u^2(\delta t_{\text{amb}}) + u^2(\delta t_{\text{SSE}}) + u^2(\delta t_{\text{cover}}) + u^2(\delta t_{\text{heat}}) + u^2(\delta t_{\text{e}}) + u^2(\delta t_{\text{hom}}) + u^2(\delta t_{\text{drift}}) \quad (2)$$

where:

$u(t_{\text{mean}})$  is the uncertainty due to the MPE,  $\pm 0.3$  °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;

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

$u(\delta t_{amb})$  is the uncertainty due to the influence of the ambient conditions,  $\pm 0.1$  °C considered as a maximum error, so using a rectangular distribution we calculate  $0.2/\sqrt{12} = 0.1/\sqrt{3}$  as the standard uncertainty;

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

$u(\delta t_{cover})$  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;

$u(\delta t_{\epsilon})$ : is the uncertainty due to the emissivity of the skin, using equations in annex 2, with  $\epsilon = 0.98 \pm 0.02$  ( $u(\epsilon) = 0.02/\sqrt{3} = 0.012$ ) and  $t_{amb} = 20$  °C  $\pm 2$  °C ( $u(t_{amb}) = 2/\sqrt{3} = 1.2$  °C), the standard uncertainty for a measured temperature of 37 °C is 0.2 °C for a typical thermometer working in 8  $\mu\text{m}$  – 14  $\mu\text{m}$ ;

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

$u(\delta t_{drift})$  is the uncertainty due to the drift,  $\pm 0.3$  °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.

## ANNEX 2. Emissivity calculations

An assumption is made that the temperature,  $T_{\text{meas}}$ , displayed on the readout of the forehead thermometer is given by [1]

$$S(T_{\text{meas}}) = \frac{S_{\text{meas}}}{\varepsilon_{\text{instr}}} + S(T_{\text{det}}), \quad (1)$$

where  $S(T)$  is the signal–temperature response function of the thermometer (approximated by the Sakuma–Hattori equation),  $\varepsilon_{\text{instr}}$  is the instrumental emissivity setting on the thermometer,  $T_{\text{det}}$  is the internal temperature of the detector, and  $S_{\text{meas}}$  corresponds to the net radiation at the detector. The latter is given by [23]

$$S_{\text{meas}} = \varepsilon S(T) + (1 - \varepsilon)S(T_{\text{amb}}) - S(T_{\text{det}}), \quad (2)$$

where  $\varepsilon$  is the emissivity of the target (the forehead),  $T$  is the true temperature of the target, and  $T_{\text{amb}}$  is the ambient temperature. Equation (2) corresponds to the difference between the radiation falling on the detector (the first two terms) and that emitted by the detector itself (the third term).

Substituting equation (2) into equation (1) gives

$$\begin{aligned} S(T_{\text{meas}}) &= \frac{\varepsilon S(T) + (1 - \varepsilon)S(T_{\text{amb}}) - (1 - \varepsilon_{\text{instr}})S(T_{\text{det}})}{\varepsilon_{\text{instr}}} \\ &= S(T) + \frac{(1 - \varepsilon_{\text{instr}})}{\varepsilon_{\text{instr}}} [S(T_{\text{amb}}) - S(T_{\text{det}})] + \frac{(\varepsilon - \varepsilon_{\text{instr}})}{\varepsilon_{\text{instr}}} [S(T) - S(T_{\text{amb}})]. \end{aligned} \quad (3)$$

So, there are two conditions on  $\varepsilon_{\text{instr}}$  and  $T_{\text{amb}}$  that are required for  $T_{\text{meas}}$  to be equal to  $T$ : (either  $\varepsilon_{\text{instr}} = 1$  or  $T_{\text{amb}} = T_{\text{det}}$ ) and (either  $\varepsilon_{\text{instr}} = \varepsilon$  or  $T_{\text{amb}} = T$ ). Generally, both conditions won't hold, so there will be a difference between  $T_{\text{meas}}$  and  $T$ .

This difference will be treated as an uncertainty component. Here, it will be assumed that the thermometer has been allowed to equilibrate with the environment, so that  $T_{\text{det}} = T_{\text{amb}}$  (although it will be assumed that there is an uncertainty associated with the value of  $T_{\text{det}}$ ). Additionally, it should be assumed that the emissivity of the target (skin on the forehead) varies in a range [10, 11, 12] with a rectangular distribution.

The sensitivity coefficients  $\partial T_{\text{meas}} / \partial \varepsilon$  and  $\partial T_{\text{meas}} / \partial T_{\text{det}}$  are given by [24].

$$\frac{\partial T_{\text{meas}}}{\partial \varepsilon} = \frac{(AT_{\text{meas}} + B)^2 [S(T) - S(T_{\text{amb}})] [1 - \exp(-c_2 / (AT_{\text{meas}} + B))]}{\varepsilon_{\text{instr}} c_2 A S(T_{\text{meas}})} \quad (4)$$

and

$$\frac{\partial T_{\text{meas}}}{\partial T_{\text{det}}} = - \frac{(1 - \varepsilon_{\text{instr}})(AT_{\text{meas}} + B)^2 S(T_{\text{det}}) [1 - \exp(-c_2 / (AT_{\text{meas}} + B))]}{\varepsilon_{\text{instr}} (AT_{\text{det}} + B)^2 S(T_{\text{meas}}) [1 - \exp(-c_2 / (AT_{\text{det}} + B))]}, \quad (5)$$

where  $A$  and  $B$  are the wavelength and bandwidth coefficients of the Sakuma–Hattori equation,

$$S(T) = \frac{C}{\exp(c_2/(AT + B)) - 1}. \quad (6)$$

The combined standard uncertainty  $u(T_{\text{meas}})$ , is given by

$$u(T_{\text{meas}}) = \sqrt{\left(\frac{\partial T_{\text{meas}}}{\partial \varepsilon} u(\varepsilon)\right)^2 + \left(\frac{\partial T_{\text{meas}}}{\partial T_{\text{det}}} u(T_{\text{det}})\right)^2} \quad (7)$$

Note that there are also uncertainties due to uncertainties in the estimated values of  $A$  and  $B$ , but they are insignificant. Note also that because the correction  $T - T_{\text{meas}}$ , as calculated from equation (3), would not be applied during use, the total expanded uncertainty ( $k = 2$ ) is, in accordance with the GUM, given by

$$U(T_{\text{meas}}) = 2u(T_{\text{meas}}) + |T - T_{\text{meas}}|. \quad (8)$$

The expanded uncertainty given by equation (8) gives the uncertainty in the temperature of the skin at the time of measurement and does not consider the relationship between skin temperature and core body temperature.