BEST PRACTICE GUIDE: USE OF THERMAL IMAGERS TO PERFORM TRACEABLE NON-CONTACT SCREENING OF HUMAN BODY TEMPERATURE

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BEST PRACTICE GUIDE

USE OF THERMAL IMAGERS TO PERFORM TRACEABLE NON-CONTACT SCREENING OF HUMAN BODY TEMPERATURE

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1. Scope

This document applies to thermal imagers that are used for the screening of human body temperature. Screening in this case means investigation of human body temperature based on objective measurement. Superficially for rapid measurements usually of a high number of people thermal imaging seems to be an optimal solution. However users shall take great care to develop a measurement protocol that does not jeopardize the reliability and accuracy of the measurement. For thermal imagers measuring human body temperature in the direct (unadjusted) mode with the emissivity set to that of the skin, the temperature range should be at least 30 °C to 40 °C. For thermal imagers measuring human body temperature in the indirect (adjusted) mode (that is, those determining core body temperature using an internal algorithm based on a measurement of skin temperature), the temperature range should cover at least 35 °C to 42 °C.

2. Objective

The objective of this document is to detail the good practice and provide operating procedures for the screening of human body temperature when using the thermal imagers mentioned in the scope, in order to detect, with the highest possible reliability, people with an elevated body temperature, which could imply the presence of an infectious disease, and so enhance the effectiveness of thermal imaging in limiting the infections spread.

3. Terms and definitions

Although in the metrology community the following terms and definitions are well known, there is great need for a common understanding in the public. Therefore, some of the most common terms and definitions, which are important for this document, are given here.

Measurement traceability

Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

Calibration

Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. Calibration should not be confused with adjustment nor with verification.

Adjustment (of a measuring system)

Set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured.

Verification

Provision of objective evidence that a given item fulfils specified requirements.

Accuracy

The accuracy[1] of a measurement (system) is closeness of the agreement between the result of a measured quantity value and the true value of a measured quantity.

Limits of error

The limits of error are the maximum overestimate and the maximum underestimate from the combination of the sampling and the non-sampling errors.

Measurement uncertainty

Measurement uncertainty is a non-negative parameter characterizing the statistical dispersion of the values being attributed to a measurand or measured quantity.

Measurement result

The measurement result is complete only if it is accompanied by a statement of the associated uncertainty. The result of a measurement after correction for recognized systematic effects is still only an estimate of the value of the measurand because of the uncertainty arising from random effects and from imperfect correction of the result for systematic effects.

Interlaboratory comparison (ILC)

Interlaboratory comparison (ILC) means organisation, implementation and evaluation of the results of measurement and testing of the same or similar test items/samples carried out by two or more than two laboratories in conformity with pre-determined conditions. Interlaboratory comparisons (ILCs) are organised either to check the ability of laboratories to deliver accurate testing results to their customers or to find out whether a certain analytical method performs well and is fit for its intended purposes.

Sensitivity

The sensitivity of a screening test is defined in variety of ways, typically such as sensitivity being the ability of a screening test to detect a true positive, being based on the true positive rate, reflecting a test's ability to correctly identify all people who have a condition, or, if 100%, identifying all people with a condition of interest by those people testing positive on the test.

Specificity

The specificity of a test is defined in a variety of ways, typically such as specificity being the ability of a screening test to detect a true negative, being based on the true negative rate, correctly identifying people who do not have a condition, or, if 100%, identifying all patients who do not have the condition of interest by those people testing negative on the test.

[1] Many manufacturers use the term accuracy in their specifications to describe 'limits of error'.

4. Protocol for screening of the human body temperature with a thermal imager

Thermal imagers as measuring instruments play an important role in many applications. In a growing number of applications, their role is to make quantitative temperature measurements. Included in such applications is human body temperature monitoring for pandemic management. To ensure that these measurements are performed correctly we should be able to determine the traceability of a measurement. Thus, we need to know the corrections of an instrument and their associated uncertainties for the whole measurement process. This should begin with a traceable calibration of a thermal imager in an accredited calibration laboratory.

Screening of human body temperature with a thermal imager is not an effective method to determine, if someone has COVID-19, but it could be used as a diagnostic tool for identifying people with an elevated body temperature, which is a possible sign of infection. An elevated temperature detected by a thermal imager should then be confirmed with a recognised calibrated clinical thermometer (ear, axilla, oral).

The accuracy of body temperature by thermal imaging systems depends on a very careful set-up, operation by a trained operator, and proper preparation of the person being measured. Therefore, simultaneous temperature screening of multiple people has very limited reliability and should not be used, in spite of its obvious advantages (multiple people being measured in real time).

The main disadvantages of thermal imaging for accurate human body measurement are:

- Unknown and non-standardized relation between the temperature of a measured area (forehead, eye canthus, etc.) and core body temperature. Once this difference is rigorously evaluated by traceable thermometry (it is the subject of research) it could be accounted for in the thermal imaging system or applied as a correction after measurement.
- Influence of environmental conditions, ideally the measurements should be performed in the below conditions:
    - A controlled environment (temperature 18 °C to 24 °C, relative humidity 10 % to 75 %, where there is no draft and no dust. Large deviations from required controlled ambient conditions may lead to increased uncertainty.
    - Avoid reflective backgrounds (metallic surfaces, glass, mirrors, etc.).
    - Avoid sources of radiant heat (direct or indirect sunlight, heating sources, incandescent, halogen and tungsten bulb lighting, etc.) in the vicinity (especially in the field of view but also in a fixed and short distance from the person being measured).
- Variations in the conditions of individuals:
    - Persons should wait in the measurement room at least 10 minutes for acclimatisation, or more (30 minutes), if they were previously engaged in physical activity, bathing, having sunbathed, or similar.
    - Remove face or forehead obstructions (mask, glasses, scarf, hat, hair on the facial area, cosmetics, etc.) – prior to the acclimatisation period
    - The person's face must be clean and dry (no sweat!).

To perform reliable and accurate temperature measurements with a thermal imager, all of the following conditions must be met:

- the system must be set up in controlled environmental conditions (as described above), with the proper location and a suitable fixed distance (as short as possible depending on the optics of a thermal imaging camera);
- the system must be set up and turned on at least 30 minutes prior to measurements,
- the system must be operated according to the manufacturer's instructions and additional instructions related to the particular case, written by experts in thermal imaging;
- the operator of the system must be properly trained (e.g. at least read and consider this guideline carefully;

- the person being measured should be prepared properly (as described above) and looking straight to the thermal imaging camera.
- the image shall cover the whole face of the person being measured. If an external temperature reference source (ETRS) is used, the facial area is covered with a smaller part of the thermal image, which might lower the measurement accuracy.

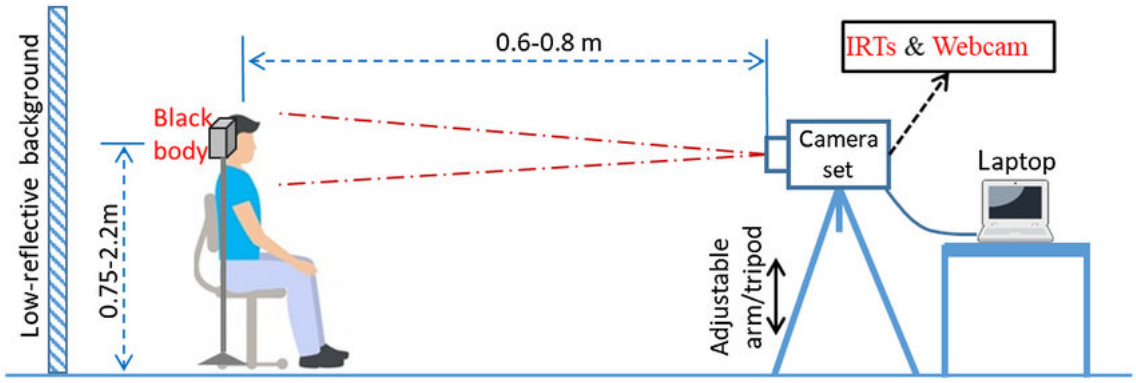


Figure 1. Example of the thermal imaging system setup (https://doi.org/10.1117/1.JBO.25.9.097002 Clinical Evaluation of Fever-Screening Thermography: Impact of Consensus Guidelines and Facial Measurement Location)

Figure 1 is given as an example only. Measuring distance depends on a thermal imaging system optics, blackbody could be ETRS, person could sit or stand, etc.

5. Detailed explanation of thermal imaging

5.1. Introduction

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

- Contact methods.
- Non-contact methods.

Contact methods are those in which the temperature sensor is in direct contact with an object. Such methods require some waiting time to obtain thermal equilibrium between the object and the thermometer, which depends on the time constant of the measuring instrument and the thermal properties of the object.

Non-contact methods are based on the fact that all bodies emit thermal radiation. Thermal radiation can be detected and measured by an appropriate sensor at a certain distance. In this case, there is no direct contact between the temperature sensor and the object whose temperature is being measured. However, non-contact temperature measurements are generally less accurate than contact ones because of the following effects, among others:

- The object's capacity to emit thermal radiation is limited; this is characterized by the term emissivity. In many cases, the emissivity of the object is not known within an acceptable degree of confidence.
- The nature of the environment through which the thermal radiation propagates from the object to the temperature sensor (environmental conditions).
- The presence of hot or cold objects in the vicinity of the object (potential sources of reflected radiation), especially when measuring highly reflective surfaces. Note however that human skin is not a highly reflective.
- The thermometer's ability to properly collect the emitted thermal radiation from the specified area on the object (optical characteristics of the lenses – field of view, size-of-source effect, transmittance, distance… – detector wavelength, alignment, etc.)
- And specifically for body temperature measurement there is a complex relationship between the measuring site and the reference site (i.e., the location on the patient to which the output temperature refers), which can be influenced by circadian rhythm, age, etc.

The patient's body temperature is an important vital sign for assessing overall health, typically in combination with blood pressure and heart rate. Determining whether a patient is afebrile, febrile, or hypothermic is the aim of a clinical temperature measuring device. In the case of measuring human body temperature, the purpose of a clinical thermometer is to evaluate the actual temperature of a reference body site and to determine how this is related to the core body temperature.

Core body temperature is generally considered to be the temperature of the blood in the heart and the brain [1]. However, core is more a concept than a practical body site. Pulmonary artery, distal esophagus, or urinary bladder are recognized as the temperature sites where we could obtain core body temperature, but insertion of an invasive catheter is required. Often this may not be justified outside of operating rooms or critical care units. Temperature measurements of the tympanic membrane are considered less invasive and, whenever possible, should be used for the purpose of determining core body temperature [2], [3], [4].

Measurement sites that could also be used to infer core body temperature are:

- Oral, rectal, or axillary sites, which are traditionally measured by contact thermometers. However, these sites are chosen more for convenience rather than for being reliable representations of core body temperature.
- The ear canal and tympanic membrane combination is suitable for routine non-contact measurement of human body temperature. The auditory canal is nearly an ideal blackbody cavity for infrared body temperature measurement. Anatomically, the auditory canal is a slightly curved tube about 2.5-3 cm long in an adult. The canal is well insulated from the exterior and is near the major brain arteries. It ends with the tympanic membrane, only about 3 cm from the hypothalamus, which is the body thermal regulation centre and shares the same blood supply. The deep ear canal temperature-tympanic membrane combination, as measured by an infrared (IR) ear thermometer, is relatively close to the hypothalamus temperature. IR ear thermometers have proven to be accurate under controlled conditions and their traceability can be assured and verified [5], [6].
- The IR radiation emitted by skin can be used to determine the surface temperature of a human body. However, surface body temperature greatly depends on both the skin blood perfusion and the environmental conditions and, therefore, except under carefully controlled conditions, skin temperature cannot be independently and accurately correlated with core body temperature.

There are different temperatures for each reference body site, according to the balance between heat production, heat transfer, and heat losses. Laboratory verification of a clinical temperature measuring device alone is not sufficient because the adjustment algorithm for obtaining the indicated temperature includes the characteristics of the patient and the environment. Therefore, the accuracy of a clinical thermometer must be verified in two steps [7]:

- By comparing its indicated temperature in the direct[2] mode with that of a reference thermometer that has a specified uncertainty for measuring the true temperature at the reference site. For a clinical contact thermometer in equilibrium, clinical accuracy can be sufficiently determined under laboratory conditions that create an equilibrium state between the two thermometers (calibration).
- By using statistical methods that compare the indicated temperature in the indirect[3] mode with that of a reference clinical thermometer that has a specified clinical accuracy to represent a reference body site temperature. For a clinical thermometer operating in the indirect (adjusted) mode the laboratory accuracy is verified in the direct mode and the clinical accuracy is validated in the indirect (adjusted) mode with a sufficiently large group of human subjects. This procedure is performed by the manufacturer.

A clinical thermometer should state the reference body site whose temperature is intended to be measured. If a clinical thermometer measures more than one reference body site, they shall be clearly displayed; for instance: mode C, adjusted to core; mode O, adjusted to oral; mode E, adjusted to ear canal; etc. A clinical thermometer in the indirect (adjusted) mode displays temperature which is calculated by the internal mathematical algorithm based on statistical correlation from the value of the direct temperature measurement on a measurement site to the value of a selected reference core or non-core body site.

[2] Also called calibration, test, or unadjusted mode.
[3] Also called adjusted mode.

6. Principle of temperature measurement with non-contact thermometers and thermal imagers

Forehead or skin infrared thermometers and thermal imagers are optoelectronic instruments that are capable of non-contact measurement of the infrared radiation emitted from the surface of a human body (skin) and transformation of that measurement into a radiance temperature. They have some advantages compared to contact thermometers:

- Shorter response time (one second compared to 10 seconds or even minutes).
- Non-contact measurement (keeping a certain distance between the instrument and the subject being measured).

Technically, the skin temperature measurement is similar to that of the ear canal [8], but with two significant differences. The first difference is that the skin emissivity may vary from site to site in the range from 0.94 to 0.999 [9], [10][4], whereas the ear canal has an effective emissivity close to 1.

The second difference is the field of view (see section 6), which in many forehead thermometers and thermal imagers can be quite large, whereas the field of view of an ear thermometer is restricted to the tympanic membrane, or deep ear canal/tympanic membrane combination. This may require performing measurements over relatively short and preferably fixed distances with proper focus. To prevent spurious readings, the design of a thermal imager should ensure that infrared radiation is collected from a limited and well specified area of the skin surface, avoiding any stray thermal radiation from neighbouring tissues (e.g., hair) and objects having different surface temperatures and emissivity (see Figure 2).

Figure 2. The field of view of a thermal imager must contain the object being measured in proper focus. The image on the left shows proper focus, while the image on the right shows an out of focus image.

6.1. Thermal imager specifics

The detector of a thermal imager is a so-called focal plane array (FPA), which is a matrix of small detectors, each forming one pixel of a thermal image consisting of a large number of pixels in the horizontal and the vertical directions. The detector of a thermal imager can be either cooled or uncooled. Although uncooled detectors offer significant advantages in terms of cost, lifetime, size, weight and power, cooled sensors offer significantly enhanced sensitivity, and in many cases also increased range and better resolution, because of the lower electronic noise during operation [11].

[4] As 0.999 is typically the emissivity of a high quality blackbody the authors of this guide believe that the realistic value of skin emissivity to be considerably less than this. Metrologically based evaluations of skin emissivity are urgently required.

Thermal imagers that are developed specially for temperature screening may have an external temperature reference source (ETRS), which is a radiation source of known temperature in the form of a greybody or blackbody and could act as a temperature reference. The ETRS is placed in the field of view together with a human face, possibly in the same focal plane. The ETRS provides a stable source of radiation to compensate for detector drift.

Thermal imagers have a direct threshold temperature setting either with a pre-set value or a value that is set manually. The threshold temperature represents the value above which a person is potentially febrile.

Temperature screening could be performed in two different ways, depending on the number of measured individuals:

- Mass screening of a controlled flow of people (not recommended in general; therefore, this should be avoided, if possible).
- Screening of an individual person at the fixed distance and in a stationary position (preferable solution).

Three standards concerning thermal imagers for temperature screening have been developed recently: IEC 80601-2-59: 2017 Medical electrical equipment – Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening [12]; ISO/TR 13154: 2017 Medical electrical equipment – Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph [13]; SS 582:Part 1:2020 Specification for thermal imagers for human temperature screening – requirements and test methods [14], and SS 582:Part 2:2020 Specification for thermal imagers for human temperature screening – Implementation guidelines [15].

The standards IEC 80601-2-59 and SS 582:2020 for the purpose of temperature screening require the thermal imager to have at least 320 × 240 pixels, of which at least 240 × 180 pixels shall cover the region of interest (ROI), which is the complete face in the measurement of human body temperature.

7. Operating instructions

The operating instructions should contain information about the general and specific use of the equipment. The most important specifications for thermal imagers are:

- Measurement range.
- Spectral response.
- Environmental conditions (temperature, relative humidity).
- Laboratory accuracy.
- Thermal image uniformity.
- Minimum resolvable temperature difference.
- Clinical accuracy (if it is determined).
- Information on whether the thermal imager measures in direct (unadjusted) mode or in indirect (adjusted) mode, with clear indication and explanation of adjusted modes. General-purpose thermal imagers do not display the temperature of a reference body site; therefore, appropriate adjustment for the temperature limit at the measurement site should be determined in the measurement protocol.
- Distance to the object. The thermal imager should be placed at the correct distance from the skin (typically as close as possible to the minimum focus distance). The manufacturer should indicate the distance range in the specifications.
- Time necessary to warm up after switching on the thermal imager.
- Response time.
- Drift between self-corrections (if the thermal imager performs self-corrections).

  - Use of an external temperature reference source (ETRS). Self-corrections may not be sufficient to compensate for drift, so the use of the ETRS may provide a way to correct temperature measurement results during measurements. The reference temperature results should be traceable through contact or non-contact thermometry, and ETRS emissivity should be accounted for as an uncertainty, if using contact thermometry for purposes of traceability.
- Batteries and/or power supply information.
- Condition of the object being measured (the skin should be clean; there should be no sweat, face creams, makeup, or other barrier).
- Other relevant information (maintenance, calibration, etc.).

The use of a thermal imager alone to detect people with an elevated body temperature compatible, for example, with the symptoms of an infection, or for a similar purpose in any other health emergency (like a pandemic), is not recommended because of the high uncertainty in determining temperature, as it is shown in section 8. If a thermal imager identifies a possible febrile individual, then that measurement should be confirmed with a calibrated clinical thermometer, as recommended in the standard [15].

8. Influence quantities and accuracy

The accuracy of thermal imagers depends on several influence quantities, which limit the capacity to determine (core) body temperature. Part of the accuracy is related to the target and its condition, part to the conditions along the transmission path between the target and the thermal imager, and part to the accuracy of the thermal imager itself.

8.1. Capacity to determine (core) body temperature

Skin temperature greatly depends on both the skin blood perfusion and the environmental conditions. It is very important to realise that the temperature of freely radiating skin in an uncontrolled environment cannot be reliably correlated with core body temperature. Given that caveat to be effective, thermal imagers for screening of body temperature must be used in a stable indoor environment (temperature 18 °C to 24 °C, relative humidity 10 %rh to 75 %rh, free from drafts or direct airflow, minimized or prevented direct or indirect exposure to: sunlight, lighting, sources of heat, etc.). **In addition, the person being measured should have been allowed to acclimatise for at least 10 minutes to the environmental conditions after coming indoors from outside where it could have been hot, cold, wet, etc.**

In [16], after collecting and studying different publications, it was concluded that clinical studies do not support the use of forehead thermometers for determination of fever, not even in a clinical setting, because their performance was generally outside the clinically acceptable limits. The same applies also for thermal imagers, but in special cases where screening is necessary as an additional safety measure, it can still be better, if thermal imagers are used properly (e.g. according to the instruction given in this protocol).

More studies need to be performed for clinical validation of non-contact temperature measuring devices (forehead thermometers, thermal imagers) to determine if there is a reliable correlation (and under what conditions) between possible measurement sites (forehead, eye canthus, neck, wrist …) and reference body sites, as well as to verify the level of accuracy and measurement uncertainty in all these cases. If a thermal imager is used for fever screening only, sensitivity and specificity are more important. The example of clinical evaluation of fever-screening thermography is presented in [17].

8.2. Accuracy of a thermal imager

Besides the standards [12], [13], [14], and [15], the guidelines VDI/VDE 5585 Part 1, Technical temperature measurement – Temperature measurement with thermographic cameras – 5585 Metrological characterization [18] and VDI/VDE 5585 Part 2, Technical temperature measurement – Temperature measurement with thermographic cameras [19] describe the metrological characteristics of a thermal imager and methods to evaluate these characteristics. The most important metrological characteristics that affect the accuracy of a thermal imager are:

- **Region of interest (ROI)**: usually the measured object cannot cover the entire field of view of a thermal imager. Therefore, a region of interest (ROI) must be defined within the image that is used to determine the temperature of the measured object. The ROI must always be smaller than the object being measured (also consider the size-of-source effect).
- **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. The emissivity of skin can be considered to be between 0.94 and 0.999, so the thermal imager must be adjusted for this emissivity. In general, we consider the emissivity of skin as 0.98±0.01.
- **Repeatability**: the standard deviation of measurements repeated over a very short time (several minutes) using the same device by the same operator when measuring a constant-radiance source.
- **Temperature of the environment**: an uncertainty arises if this parameter is set to a different value to the actual environmental temperature (or effective environmental temperature, if the environment is non-uniform). This uncertainty also depends on the emissivity setting.
- **Relative humidity of the environment**: an uncertainty arises if this parameter is set to a different value to the actual environmental relative humidity.
- **Measuring distance**: the measuring distance should be within a specified range, depending on the field of view of the thermal imager and the minimum focus distance.
- **Spectral range**: parameter which gives the lower and upper limits of the wavelength range over which the thermal imager detects radiation.
- **Warm-up time**: time needed after switching on the thermal imager to operate according to the given specifications.
- **Response time**: sensors do not change output state immediately when the input changes. The output changes to the new state over a period of time, called the response time, which is defined as the time required for a sensor output to change from its previous state to a final settled value within its tolerance limit.
- **Long-term stability**: reproducibility of the measurements repeated over a long time (months, years) when measuring a constant-radiance source. Long-term instability causes a slow variation of the output, also called a **drift**, and a periodic calibration is required to maintain the accuracy of the thermal imager[5]. The manufacturer should give information about the calibration period[6].
- **Short-term stability**: reproducibility of the measurements repeated over a short time (several hours or days) when measuring a constant-radiance source.

[5] It should be noted that this calibration should be done with the thermal imager indicating, where available, in the direct mode.

[6] 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 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”.

- **Stability of ETRS (if used):** the temperature stability of the ETRS influences the stability of reading of a thermal imager. It is important that the same level of stability is achieved during the entire period of measurement.
- **Inhomogeneity equivalent temperature difference (IETD):** indicates the smallest resolvable temperature difference, and corresponds to the noise that is distributed throughout the thermal image of a surface having uniform temperature.
- **Noise equivalent temperature difference (NETD)**: indicates the contribution to the uncertainty of measurement that is caused by high-frequency temporal instrument noise. It is the change in equivalent blackbody temperature that corresponds to a change in radiance that will produce a signal-to-noise ratio of 1 in an infrared imaging device. It is determined by a manufacturer and given in the specifications. Typical value at 30 °C is 20 mK to 100 mK.
- **Minimum detectable temperature difference (MDTD)**: indicates the smallest temperature difference that the thermal imager can consistently detect within the workable target area.
- **Field of view (target area, measurement field**): the field of view (FOV) of a thermal imager is defined by the horizontal angle, θ_H, and the vertical angle, θ_V, of its optics (Figure 5). The FOV consists of a number of IFOVs (the same as the number of detector pixels, defined in the Annex). The corresponding area of the FOV depends on the distance of the target from the thermal imager.
- **Non-uniformity (NU):** indicates the deviation between the displayed temperature values of individual detector elements (pixels) in an image when the detector is exposed to a source with homogeneous radiance, while neglecting the time-dependent intrinsic noise of the instrument. Causes of NU are the inhomogeneity of the detector responsivity across the detector area and the optical properties of the lens. Manufacturers try to compensate for the NU by means of signal processing software during the initial adjustment of the camera (NUC – non-uniformity correction). However, as perfectly homogeneous, large-area temperature radiation sources are typically not available, the initial NUC process is not perfect. Therefore, the residual error is expressed as the non-uniformity.
- **Size-of-source effect (SSE):** at a certain distance, a radiation thermometer or a thermal imaging camera has a given nominal field of view, which is defined by the optics. Theoretically, we could perform a measurement correctly and obtain an accurate result if the nominal field of view (sometimes marked as a circle in a viewfinder of a radiation thermometer) is completely filled by the source (dashed square in the Figure 3(a)). In practice, this is not always possible, either due to misalignment (Figure 3(b)) or due to limitations in the optics of instrument, which result in too large a field of view of a given source (Figure 3(c)). But even if the nominal field of view is completely filled by the target, some radiation from within the nominal field of view is lost and some radiation from outside is detected. This phenomenon is known as the size-of-source effect (SSE). Usually, it is expressed as a percentage of the signal coming from within the nominal field of view (100 % means no SSE). The result is a different measured temperature as the size of a stable-temperature source is changed [20]. The SSE is a consequence of radiation scattering on dust particles or other dirt on the lens, reflections at and between lens surfaces, diffraction, and aberrations in the optical system of the radiation thermometer or thermal imager [21].

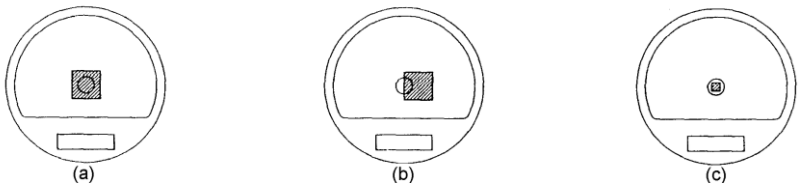


Figure 3. Presentation of (a) correct, (b) incorrect and (c) impossible measurement as viewed through the viewfinder of a radiation thermometer with marked nominal field of view.

The above-mentioned parameters should be determined by the manufacturer or the calibration laboratory to assign an accuracy to the thermal imager, which should be traceable to the ITS-90 temperature scale in accordance with the requirements of the standard ISO/IEC 17025. Traceability of temperature to ITS-90 is usually provided by ISO/IEC 17025 accredited temperature calibration laboratories.

In addition to calibration in a laboratory as described above, to meet the accuracy requirements for body screening, a clinical validation is needed. A clinical accuracy test is intended for evaluation of the accuracy of built-in body site offsets and performance of the thermal imager in assessing the core body temperature of actual subjects. **For thermal imagers details of the clinical validation are not yet given in any standard.**

8.3. Measurement uncertainties in the calibration and use of thermal imagers

Measurement uncertainties are associated with both the thermal imager itself and the measurement method, which is also influenced by environmental conditions.

The following measurement uncertainties are related to the thermal imager:

- **Repeatability of the thermal imager:** uncertainty determined during calibration, calculated as the standard deviation of several measurements at one calibration point or from a curve fit through several calibration points. It includes the stability of a blackbody and ETRS.
- **Uncertainty of reading:** this uncertainty is directly related to the resolution of the thermal imager (usually only the largest of this component or the above component is included in the uncertainty budget).
- **Size-of-source effect (SSE):** the measured temperature of a target with constant radiance varies according to the target's size. This is caused by scattering and diffraction within the optical system of the measuring instrument. Additionally, an extreme SSE can result if the field of view of the device is greater than the target, so that it is not completely filled by the target. Due to this, thermal imagers should be used as close as possible to the skin surface to achieve a minimum field of view from which a measurement is taken, and they should also be calibrated in this manner.
- **Distance effect:** this is related to the SSE, because increasing the measurement distance increases the field of view of the thermometer relative to a fixed-diameter target (and also slightly diminishes the signal due to the atmospheric absorption). Consequently, as the distance to the target is increased, the temperature reading deviates from the true target temperature.
- **Drift between self-corrections** (if applicable): the drift between self-corrections in thermal imagers should be as small as possible (less than 0.3 °C) and the duration of the self-correction process should be as short as possible (less than 1 second). Self-correction may be performed automatically (preferred setting) or manually.
- **Non-uniformity:** as perfectly homogeneous, large area temperature radiation sources are typically not available [22], the initial NUC process is not perfect. Therefore, the residual error is expressed as the non-uniformity. To evaluate the non-uniformity of a thermal imager during calibration with a small-aperture blackbody, individual parts of the detector need to be evaluated separately [23]. Non-uniformity also includes the effects of NETD, MDTD and IETD.
- **Stability of external temperature reference source** (if applicable): if a thermal imager has an external temperature source (ETRS), its stability is extremely important because it influences directly the reading of the thermal imager. However, the repeatability of a thermal imager includes the stability of ETRS.

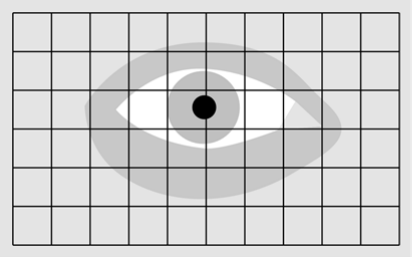
The following measurement uncertainties are related to the measurement method and environmental conditions in calibration or practical use:

Calibration system:

- **Blackbody:** uncertainty due to temperature and uniformity of a blackbody, determined by evaluation by an accredited laboratory or given in a manufacturer's specification (rarely extensive evaluation is performed and not for each device). Based on the standard 80601-2-59, the maximum expanded uncertainty of the blackbody source should be ≤0.2 °C while the combined stability and drift should be ≤0.05 °C. If ETRS is used its maximum expanded uncertainty should be ≤0.3 °C while the combined stability and drift should be ≤0.1 °C.
- **Emissivity of the blackbody:** the radiance temperature of a blackbody is less than its true temperature when ambient temperature is lower than the blackbody temperature, as a consequence of the blackbody emissivity being somewhat less than 1. The uncertainty in the radiance temperature depends on the uncertainty in the true temperature, the uncertainty in the thermal imager's spectral responsivity, and the uncertainty in the blackbody emissivity. For a well designed blackbody cavity the emissivity is generally in excess of 0.999 and this parameter makes a minimal contribution to the uncertainty.
- **Reference thermometer:** the uncertainty of the reference thermometer used to assign the temperature to the blackbody (resistance thermometer, thermocouple, radiation thermometer), obtained from its calibration certificate.
- **Auxiliary equipment:** (if applicable) the uncertainty of a measuring device (resistance bridge or nanovolt-meter) for a reference thermometer obtained from its calibration certificate.

Sources of uncertainty in practical use:

- **Emissivity of the target object:** a variation in the skin emissivity of 0.94 to 0.999 implies a certain variation in measured temperature for a fixed value of the instrumental emissivity, which can be treated as an uncertainty. Depending on the temperature of the detector, ambient temperature, wavelength range of the thermal imager, instrumental emissivity setting and actual emissivity of the skin, we can calculate a possible worst case: skin emissivity 0.999, instrumental emissivity set to 0.94, wavelength range 8–14 μm, ambient and detector temperature 23.0 °C, results in a temperature difference of 0.80 °C for a skin temperature of 37 °C.
- **Ambient conditions:** related to the distance effect due to atmospheric transmission. At short distances (a few meters) in a controlled environment we could consider them as negligible.
- **Measurement time:** time necessary to perform a measurement with the thermal imager (acclimatization time of a person being measured and speed of the person that moves in front of the thermal screening location).
- **Reflected radiation:** this is a portion of radiation from the hotter or colder objects in vicinity, which might influence the radiation of a measured surface on its way to the detector. Precautions must be taken to avoid the reflected radiation from such objects (e.g., by blocking with barriers).
- **Background radiation:** (related to the previous bullet point) this is the thermal radiation present in the environment at a particular location (not including the extraneous radiation sources in the previous bullet point). In thermal imagers this is compensated for by entering the value of environmental temperature into the thermal imager software.
- **Minimum target size**: In the case of a thermal imager, it is also important that enough pixels are covering the region of interest (Figure 4). The image on the left shows not enough pixels to measure the canthus, while the image on the right shows a more acceptable measurement.



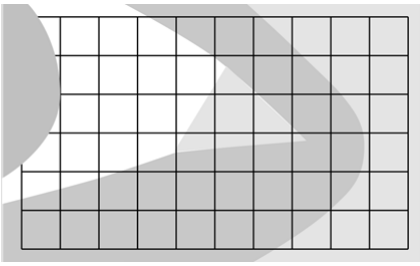


Figure 4. An example of a measurement of the canthus to estimate human body temperature. Each square represents a detector pixel which is presented on the display.

In Table 1 the best uncertainty budget is given when all the precautions listed in section 7 have been taken. The list does not include the uncertainty in the ability of the thermal imager to measure core body temperature, *which could well be significant* as there are currently no traceable studies published on the evaluation of core body temperature from forehead/skin temperature.

Table 1. Uncertainty budget for a thermal imager in calibration and use (the best case available at this time[7]). The expanded uncertainty is rounded to the typical resolution of a thermal imager (0.1 °C) and is achievable only if a thermal imager is calibrated and the calibration correction is applied.

Uncertainty component	Calibration / °C	In use / °C
Repeatability	0.1 (*)	0.2 (*)
Reading (resolution)	0.1/√12 (*)	0.1 /√12 (*)
Size-of-Source Effect (SSE)	0.1/√12	0.3/√12
Distance effect (included to SSE		
Drift (in the order of resolution)		0.1/√12 (**)
Non-uniformity	0.1/√12	0.1/√12
Blackbody (homogeneity)	(***)	
Emissivity of a blackbody (±0.005)	0.06	
Reference thermometer	0.01	
Auxiliary equipment	0.01	
Emissivity of a measured object (±0.01)[8]	/	0.14/√12 (****)
Ambient conditions	/	0.1/√12 (****)
Reflected radiation	/	0.2/√12 (****)
Background radiation	/	0.1/√12 (****)
Homogeneity of the measured area	/	0.2/√12 (****)
Combined standard uncertainty	**0.13**	**0.26**
Expanded uncertainty	**0.26**	**0.52**
Rounded uncertainty [~95 % confidence level]	**± 0.3 °C**	**± 0.6 °C**

(*) 10 measurements performed, the largest of both contributions is considered only
(**) A drift equal to the resolution has been considered
(***) included in non-uniformity
(****) best estimates in use

Detailed information on how to approach the evaluation of measurement data and assessment of the measurement uncertainty is described in the document Evaluation of measurement data — Guide to the expression of uncertainty in measurement [24].

9. Test methods/calibration of thermal imagers

The following test methods/calibration shall be performed according to the requirements of the relevant standards [12], [13], [14], [15], [18] and [19]:

- Drift between self-corrections

[7] The lowest uncertainty of measurement that could be achieved during calibration and use.
[8] Based on the results of CCT Supplementary Comparison between some NMIs [25] the achievable uncertainty of emissivity measurements is around 1 %.

- Minimum detectable temperature difference
- Uniformity of the detector (as presented on the display)
- SSE and distance effect

Best practice for standardized performance testing of thermal imagers intended for fever screening are described in the reviews [26] and [27].

10. Procedure of temperature screening

Most of the thermal imagers used are not of sufficient quality to be able to perform the process of reliable and accurate measurement of human body temperature, especially when we infer this temperature based on measuring the temperature of the forehead or anywhere on the face. Therefore, the method used is better described as a screening test, which in critical cases (around threshold values) must be confirmed with another calibrated clinical thermometer. Above all, the screening test enables fast and non-contact measurement of the temperature of a large number of people, sometimes several people at the same time; however, for the most reliable screening this approach is not recommended. Such measurements must be carefully planned to achieve maximum effectiveness in given conditions. Therefore, proper planning and consideration of the following elements are required:

- selection of a thermal imager and its calibration/evaluation prior to use;
- appropriate setup of a thermal imager in the room where the temperature measurement is being performed (controlled environment, no draft, no direct sunlight);
- setting of measurement parameters in the thermal imager (emissivity of the measured object, limit temperature, distance, focus, average ambient temperature (walls, ceiling and floor) due to background radiation, relative humidity) is necessary to obtain accurate temperature measurements;
- preparation of appropriate instructions for measurements and safety procedures related to the outcome of measurements;
- training of measurement performers (regular and periodic) to operate, set up and maintain the measurement system, and especially to correctly interpret the screening results;
- preparation of persons being measured.

Further details are available in the standard ISO/TR 13154: 2017 Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph [13], in the guideline SS 582:Part 2:2020 Specification for thermal imagers for human temperature screening – Implementation guidelines [15] and in the book The thermal human body: a practical guide to thermal imaging [28], which presents a thorough overview of thermal imaging for medical purposes.

11. Annex A: Thermal imager field of view (FOV) and size-of-source effect (SSE)

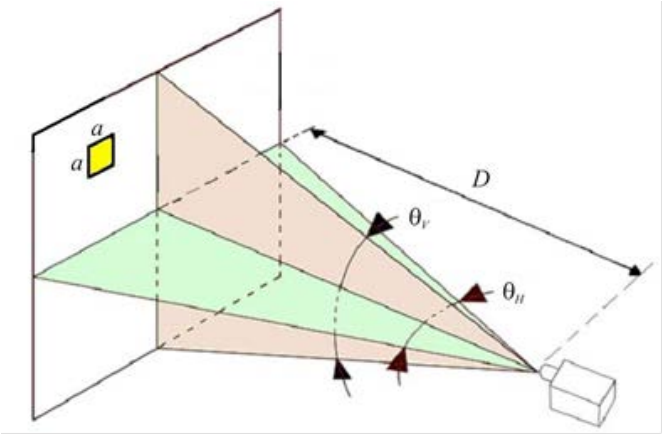


Figure 5. Field of view (FOV) and instantaneous field of view (IFOV) of a thermal imager

A very important factor to consider is the spot size – that is, the area (*a* by *a*) covered by each detector element (pixel) on the measured object (see Figure 5), defined as the spatial resolution or instantaneous field of view (IFOV). The complete field of view (FOV) of a thermal imager is defined by the horizontal angle, Θ_H, and the vertical angle, Θ_V, subtended by the full target. IEC 80601-2-59 specifies that the face should fill at least 240 × 180 pixels and that the IFOV should not be larger than 1 mm × 1 mm on the face.

A thermal imager with a higher resolution is typically more accurate at a given distance than a thermal imager with the same FOV and lower resolution due to a better optic system. If we want the highest temperature accuracy, we must ensure that the smallest object or region of interest (ROI) is fully subtended by at least 10 × 10 pixels [29]. Although manufacturers of thermal imagers recommend that the measured ROI should be covered with an array of at least 3 × 3 pixels, the study [30] showed that for the specified accuracy, the measured area, providing it has a homogeneous temperature, should be covered by at least 10 × 10 pixels, of which we should take into account only the central 3 × 3 pixels for the final result of measured temperature (Figure 6). This means that at least seven pixels from the border of the central ROI (3 × 3 pixels), which covers the area with homogeneous temperature, should be excluded from the calculation of the temperature. That is valid for high-resolution and high-quality thermal imagers. Thermal imagers with low-resolution typically exhibit worse SSE due to a worse optic system (cheaper thermal imaging systems). For such thermal imagers it is preferable that the ROI of at least 17 × 17 pixels covers the area with homogeneous temperature, of which we should take into account only the central 3 × 3 pixels for the final result of measured temperature, as shown in Figure 6.

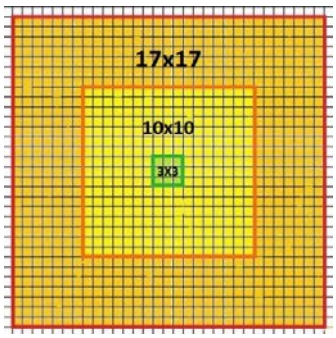


Figure 6. Number of pixels in the thermal imager detector to be exposed to a stable and uniform heat flux to obtain an accurate temperature measurement.

The instantaneous field of view (IFOV) is important for determining how large an area a single pixel on the detector can see in terms of the field of view (FOV). It can be calculated using the following equation:

$$\text{IFOV/mrad} = \text{FOV} / (\text{number of pixels}) \cdot (3.14/180) \cdot 1000, \quad (1)$$

where FOV is the camera's field of view in degrees (horizontal or vertical), number of pixels refers to the number of pixels across the entire horizontal or vertical direction, and the rest of the equation is the conversion factor (17.44) to mrad. To calculate the IFOV in millimetres, we must multiply the IFOV in mrad by the distance, *d*, in metres:

$$\text{IFOV/mm} = \text{IFOV/mrad} \cdot d/\text{m}. \quad (2)$$

For example, if the horizontal FOV is 45° and the number of pixels in the horizontal direction is 640, then the IFOV is 1.23 mrad. Almost the same number is calculated for a vertical FOV of 34° and 480 pixels. That means that one pixel at a distance of 1 m corresponds to an area of 1.23 mm × 1.23 mm = 1.51 mm^2 on the target. Theoretically, at this distance, we need a target with dimensions of 3.69 mm × 3.69 mm = 13.62 mm^2 at least to cover 3 by 3 pixels, or 151 mm^2 to cover 10 by 10 pixels.

Another very important factor is correct focusing (sharp image). Poor focusing could largely diminish the accuracy. It is important to understand that the digital zoom does not improve the accuracy of measurement.

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