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TECHNICAL SPECIFICATION

colour inside

Ultrasonics – Field characterization – Infrared imaging techniques for determining temperature elevation in tissue-mimicking material and at the radiation surface of a transducer in still air

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IEC TS 63070:2019-02(en)

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ULTRASONICS – FIELD CHARACTERIZATION – INFRARED IMAGING TECHNIQUES FOR DETERMINING TEMPERATURE ELEVATION IN TISSUE-MIMICKING MATERIAL AND AT THE RADIATION SURFACE OF A TRANSDUCER IN STILL AIR

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IEC TS 63070, which is a Technical Specification, has been prepared by IEC technical committee 87: Ultrasonics.

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The text of this Technical Specification is based on the following documents:

Draft TS	Report on voting
87/677/DTS	87/688A/RVDTS

Full information on the voting for the approval of this Technical Specification can be found in the report on voting indicated in the above table.

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INTRODUCTION

This Technical Specification describes primarily how to measure temperature elevation generated by an ultrasound transducer by using an infrared (IR) camera system aimed at insonified tissue-mimicking material located in still air.

Split TMM (tissue-mimicking material) is configured as a phantom to observe temperature elevation and distribution for assessing fields generated by diagnostic ultrasound equipment and by physiotherapy and high intensity therapeutic ultrasound (HITU) equipment.

Temperature measurement of the radiating surface of an ultrasound transducer under the still-air condition is also considered for the evaluation of extensive temperature distributions as required in IEC 60601-2-37:2007 and IEC 60601-2-37:2007/AMD1:2015.

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1 Scope

This document is applicable to ultrasonic equipment designed for the medical field of application. It covers both diagnostic and therapeutic (physiotherapy and HITU) equipment.

This document describes transducer evaluation by the infrared imaging technique using a split TMM-phantom for qualitative and quantitative estimation of temperature distributions in tissue-mimicking material, resulting from absorption of ultrasound and from heating of the transducer itself.

This document also describes a method to measure transducer-surface temperature, while the transducer is driven under the still-air condition.

NOTE 1 When the transducer is in contact with tissue-mimicking material, the heating of the transducer itself depends on the actual efficiency of the transducer, on the specific conditions for thermal transfer to or from the tissue-mimicking material, and on the transmitting/receiving electronic circuits, such as a switching circuit or pre-amplifier in some cases.

NOTE 2 The test objects specified in this document are for the measurement of temperature rise and not for the determination of thermal index, which is, by definition in IEC 62359:2010 and IEC 62359:2010/AMD1:2017, an algebraic combination of acoustical field quantities and therefore is not a physically measurable quantity.

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2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-2-5:2009, *Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment*

IEC 60601-2-37:2007, *Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*
IEC 60601-2-37:2007/AMD1:2015

IEC 60601-2-62:2013, *Medical electrical equipment – Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment*

IEC 61161:2013, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*
IEC 62127-1:2007/AMD1:2013

ISO 18434-1:2008, *Condition monitoring and diagnostics of machines – Thermography – Part 1: General procedures*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 62127-1:2007, IEC 62127-1:2007/AMD1:2013, IEC 61161:2013, IEC 60601-2-37:2007, IEC 60601-2-37:2007/AMD1:2015, IEC 60601-2-5:2009, IEC 60601-2-62:2013, ISO 18434-1:2008 and the following apply.

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- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
emissivity
ε
ratio of a target surface's radiance to that of a **black body** at the same temperature and over the same spectral interval

[SOURCE: ISO 18434-1:2008, 3.4]

3.2
black body
ideal perfect emitter and absorber of thermal radiation at all wavelengths

[SOURCE: ISO 18434-1:2008, 3.3]

4 Symbols and abbreviated terms

ε	**emissivity**
HITU	high intensity therapeutic ultrasound
IR	infrared
T	temperature
ΔT	temperature rise
TMM	tissue mimicking material

5 Methods of use

5.1 General

There are several methods to measure temperature rise using an infrared (IR) camera system. Two of them are further described in this document: the split TMM setup and the "still air" setup.

Each of these setups has its own procedures and requirements, see Clause 8.

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5.2 Consideration of perfusion

The utilized phantom does not have the functionality of perfusion as a human body. So perfusion should additionally be taken into account and referred to as necessary [1] [2] [3] [4] [5][1].

5.3 Effects of environment

Due to reflections of infrared radiation, the environment may affect the measurement of the temperature on a surface. The setup of the IR-camera, the general surroundings and the surroundings of the target should be such that environmental effects are negligible compared to the measured temperature rise of the target due to ultrasound.

A suitable procedure is described in A.3 b).

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6 IR-camera specifications

6.1 General

For these measurements the IR-camera should have the following specifications.

- The range of measurable temperature should cover 20 °C to 53 °C at minimum. In case the camera is to be used to measure the effect of HITU fields, the upper limit should be 70 °C or higher.
- The spatial resolution, which is the pixel size in an IR-image, should be equal to or less than 0,5 mm in lateral and vertical directions.
- The number of pixels of the thermal image should suffice for displaying the area required for observing the split TMM-phantom and the other setups that are used for tuning the focus, checking the scale and measuring the ambient temperature.
- The nominal temperature resolution should be less than 0,1 °C or 5 % of the temperature rise, whichever is larger. For example, it should be equal to or less than 0,25 °C when the measured temperature rise is 5 °C.
- PC-control may be useful for making the camera settings and for recording and analysing IR-images.

In general, thermal drift of the IR-camera, whether cooled or non-cooled, should be minimized and, when necessary, measured and corrected during analysis.

6.2 Test

Performance of a general functionality test is recommended for the IR-camera before beginning the measurement. A suitable test entails checking normal operation with no malfunction or alarms for temperature measurement after the warm-up time. Refer to the operations manual of the IR-camera for details.

6.3 Calibration

The IR-camera should have been calibrated within a year before use by a method traceable to a primary measurement standard. Calibration should also verify image uniformity and ambient temperature compensation in the specified temperature range. It is typically performed using a planar thermal-radiation source (a reference source) calibrated against a standard **black body**. This calibration may also be done using thin film thermocouples.

A suitable procedure is described in [6].

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1 Numbers in square brackets refer to the Bibliography.

7 Phantom specification and construction

7.1 Split TMM specifications

Measurement of the temperature inside a phantom is one goal for observations by the IR-camera. So one of the most important requirements of the phantom is its ability to be split into two pieces of TMM with flat (or slightly convex) cross-sectional surfaces that can be exposed to the IR-camera. TMM is vulnerable to dehydration and mechanical damage. A practical phantom may be kept in a rigid housing in order to avoid dehydration and malfunction caused by cracking the TMM during the operation of combination and separation during the measurement procedure. See Annex A.

The TMM should have acoustic and thermal properties that mimic the appropriate tissue of the human body. The **emissivity** of the split surface should be known. One of the applicable materials equivalent to soft tissue is specified in IEC 60601-2-37:2007 and IEC 60601-2-37:2007/AMD1:2015; its **emissivity** was determined in [7] to be 0,94 by comparison with **black body** tape.

Minimizing multiple reflections of ultrasound between the transducer and the bottom surface of the phantom should be taken into consideration. Lining material, which is used in other circumstances to absorb ultrasound propagating in a water tank and has a high attenuation property, may be appropriately placed at the bottom of the phantom to be effective for this purpose. Bone-mimicking material or sterilized bone fragments [8] [9] [10] should be used as necessary with soft-tissue mimicking material.

If high temperature rise is expected in the TMM, such as when heating with a HITU system, then the properties of the TMM should be known and stable, over the range of expected temperature rises during the measurement.

7.2 Periodic validation

Periodic validation should be performed from the viewpoint of both acoustic and thermal properties. The specified values of attenuation coefficient, thermal conductivity and heat capacity in IEC 60601-2-37:2007 and IEC 60601-2-37:2007/AMD1:2015 should be maintained within the specified tolerances. The period between validations should be one year.

The replacement with new split TMM phantom should be considered when the structural abnormality like cracks and/or the degradation like change of colour are found by visual inspection.

The properties of the selected tissue-mimicking phantom should be appropriate to the tissue being simulated and the purpose of the measurement.

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8 Measurement procedure

8.1 Split TMM setup

8.1.1 General

In an infrared measurement there are two phases: first, the ultrasound transducer coupled to the TMM (see recommendation in the last paragraph of 8.1.1) is driven and it generates an acoustic field in the TMM. Heat is generated inside the TMM. Secondly, after a given time of insonation, the configuration of the phantom is changed to allow the IR-camera to observe the two-dimensional temperature distribution over a cross-sectional plane that was inside the TMM during the first phase.

To enable IR-measurements inside the TMM, the TMM consists of two blocks, which make contact during the heating phase and which have to be quickly separated directly after switching off the electrical drive to the transducer, so that the temperature distribution over the separated surface can be measured by the IR-camera. To pull the blocks firmly together and subsequently to separate them quickly, a mechanism has to be built on which the blocks are stable, secure and movable. The IR-camera looks at the front surface (split surface) of the TMM after opening. The infrared picture has to be saved in a format (two-dimensional, colour-coded) that can be processed off-line to calculate, for example, the one-dimensional temperature profiles in lateral and axial directions.

The thermal cooling rate, in air on the exposed surface, after opening the TMM-blocks, has been measured to be about 0,3 °C/s in the first 20 s after switching off the ultrasound radiation. Corrections are to be made by extrapolation back to the moment of opening the split TMM-blocks and switching off the ultrasound (It is assumed that these occur at the same time.).

Care should be taken that the pressure to keep the two parts of TMM together is not changing the properties of the TMM. Appropriate pressure is required to realize the firm combination of TMM blocks while also avoiding destruction. Refer to A.3 c).

8.1.2 Emissivity

The appropriate **emissivity** value for the split TMM should be applied either at the time of measurement or during later analysis. See [7] for example.

8.1.3 Procedure

Annex A gives an example of IR-measurement procedures from setups to obtained results. The sequential steps in the procedure are as follows.

a) Initial temperature equilibrium of TMM: In order to obtain initial stability and uniformity of the temperature distribution on the cross-sectional surface, the wrapped TMM is kept for more than one hour on the laboratory table.

b) Focus adjustment of IR-camera: The focus adjustment of the IR-camera is performed according to manufacturer's recommendations for obtaining maximum temperature with the sharpest edge.

   The location and angle of TMM to the IR-camera should be adjusted and be recorded to minimize the reflection of unexpected IR-signals, which are mainly generated by the IR-camera itself.

c) Coupling of TMM: A set of two split TMM-blocks [(A) and (B)] is made by coupling their cross-sectional surfaces under water that is in thermal equilibrium with the ambient temperature. This process is for making tight acoustic and thermal coupling between a pair of TMM-blocks before the measurement.

d) Alignment of transducer: The alignment of the transducer is performed for coincidence between the scan plane of the transducer and the cross-sectional plane of the split TMM.

e) Shielding from stray IR-radiation and air currents: A cardboard box surrounding the phantom is closed.

f) Driving the transducer: The transducer is driven for a certain period, for example, three minutes. This drive period is an example for presenting the measurement procedure. The insonation time should be specified depending on the purpose of measurement.

g) Acquiring the infrared image: The infrared image is quickly acquired for the cross-sectional surface of the split TMM-block (B) just after the split TMM-block (A) is decoupled and removed. The correction of temperature by extrapolation backward to opening time should be considered when the cooling is not negligible between the times of opening the TMM-blocks and recording the IR-image.

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8.2 Still-air setup

8.2.1 General

To comply with IEC 60601-2-37:2007, IEC 60601-2-37:2007/AMD1:2015, IEC 60601-2-5:2009 and IEC 60601-2-62:2013, the measurement of the transducer surface temperature in still air is demanded. Such measurement can be performed using an IR-measurement system.

8.2.2 Emissivity

The appropriate **emissivity** value for the transducer radiating surface should be applied either at the time of measurement or during later analysis.

8.2.3 Procedure

Medical ultrasound committee in Japan Electronics and Information Technology Industries Association (JEITA) has published guidance in a technical report on the measurement procedure above [11] (in Japanese). It may be useful as a reference for making improvements on the measurement technique.

The sequence of the procedure is outlined in 1) to 9). Details from [11] are given in Annex B.

1) Warm up the infrared camera.
2) Perform black body calibration and outside temperature calibration.
3) Set the temperature detection mode in which the maximum temperature is tracked automatically.
4) Adjust the alignment of ultrasound transducer in the position for surface temperature measurement.
5) Set the **emissivity** correction approximately for the material of the surface of the ultrasound transducer.
6) Leave the measuring system untouched until the temperature of the ultrasound transducer surface becomes equal to the ambient temperature.
7) Measure the temperature of the ultrasound transducer surface.
8) Activate the ultrasound transducer and start measurement.
9) Calculate and obtain the temperature elevation.

Some guidance can also be found in the TNO report [12].

Environmental conditions should meet the requirement of IEC 60601-2-37:2007 and IEC 60601-2-37:2007/AMD1:2015.

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9 Uncertainty determination

Where it is necessary to determine the 95 %-confidence, overall uncertainty of the measurement or any parameter for the purposes of this document, customary uncertainty analysis and estimation methods should be used [13]. See Annex C for guidance.

Annex A
(informative)

Measurement example using a split TMM setup

A.1 General

Annex A gives an example of the procedures and measurements specified in 8.1. Background information related to this method is given in the literature [7] [12] [14] [15] [16] [17] [18] [19].

A.2 Measurement setups

The infrared image was obtained for the cross-sectional surface of a split TMM-phantom based on the concept of Figure A.1 and actual setups of Figure A.2.

The TMM was prepared according to the recipe of IEC 60601-2-37:2007 and IEC 60601-2-37:2007/AMD1:2015; it is an agar-based material. Glycerol and aluminium powder were also included in the TMM for mimicking thermal and acoustic characteristics of human tissue. The thermal and acoustic properties of the TMM are specified in IEC 60601-2-37:2007 and IEC 60601-2-37:2007/AMD1:2015 as follows:

- specific heat capacity: (3 500 ± 500) J kg^{-1} K^{-1};
- thermal conductivity: (0,5 ± 0,1) W m^{-1} K^{-1};
- attenuation at 5 MHz: (2,5 ± 1,0) dB cm^{-1}.

A pair of split TMM-blocks was prepared by cutting a piece of TMM into two pieces in order to achieve complete combination of cross-sectional surface during the period that the transducer was driven. The applied infrared **emissivity** of 0,94 was evaluated using **black body** tape on the surface of the TMM and it was close to that of water, which was the dominant ingredient in the TMM. No skin-mimicking layer was structured on the top surface of TMM, i.e. it was the same as the structure of a thermal test object (TTO).

The infrared camera was controlled by a PC. The original software acquired infrared images of 320 × 240 (pixels) through an IEEE 1394 connection.

The nominal temperature accuracy was ±2 °C or ±2 % of reading (whichever is larger). At the distance of 35 cm from the camera in the applied setup, the spatial resolution was approximately 0,5 mm and the area of the field of view was approximately (140 × 105) mm^2.

The cardboard box was applied for avoiding both the incidence of unexpected infrared radiation from the ambient and the drift of temperature due to air flow in the laboratory. The reflection of the infrared radiation that was generated by the camera itself and observed as temperatures of 40 °C to 50 °C was also carefully removed by setting the TMM at an angle to the normal direction to the camera.

The background reflection temperature of 21,5 °C was measured without TMM in the cardboard box and was set on the camera.

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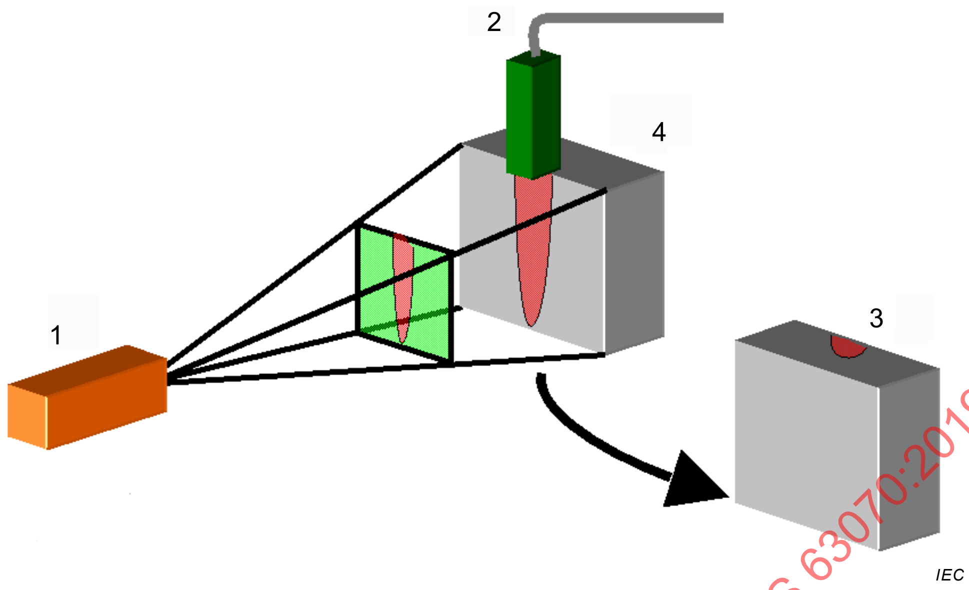

Key

1 infrared camera

2 transducer

3 split TMM (A)

4 split TMM (B)

Figure A.1 – Concept of measurement

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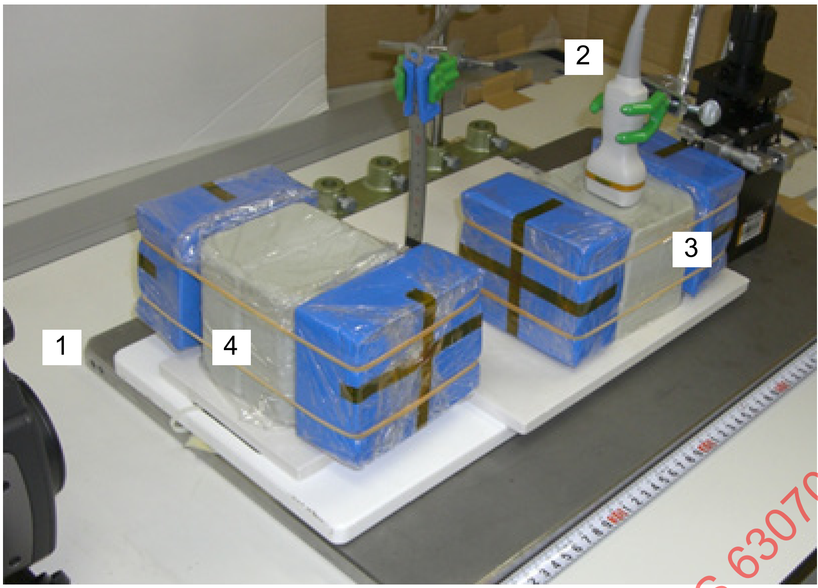

a) Setup of the equipment while achieving thermal equilibrium

b) A cardboard box used as a wind shield during actual measurement

Key

1 infrared camera

2 transducer

3 split TMM in measurement

4 split TMM as a spare

5 wind shield

Figure A.2 – Setups for thermal equilibrium and measurement

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A.3 Procedures

The setups shown in Figure A.2 were used with the following procedure to acquire the infrared image of the cross-sectional surface of the split TMM-(B).

a) Thermal equilibrium of TMM: A pair of TMM-blocks was wrapped in thin plastic film to avoid evaporation of water and was kept on the table for more than one hour to establish thermal equilibrium of the TMM, in order to obtain initial stability and uniformity of temperature distribution on the cross-sectional surface.

b) Focus adjustment of camera: The focus adjustment of the infrared camera was performed using two indices/criteria on the PC.

   One criterion was visual measurement of the sharpness of a line on a metal scale located close to the TMM; the metal scale made a reflected image of infrared radiation generated from the camera itself. The other criterion was maximization of the temperature of the reflected image of the metal scale. In addition, the image of the metal scale was used to determine the scale value (mm/pixel).

   Undesired infrared radiation that is generated in the surrounding environment or at a detector device inside the IR-camera should not be included in the thermal image. To remove such undesired infrared radiation in the thermal image, during preparation of setups and after the adjustment of the focal condition of the IR-camera, adjust the angular position of the split TMM block relative to the IR-camera on the table, while observing a live thermal image. Make a position mark on the table when the angular position is suitable, so that it can be used repeatedly to set the split TMM block to obtain the appropriate thermal image in the actual measurement.

c) Coupling of TMM: After the thin film was removed, a pair of split TMM-blocks was formed by coupling their cross-sectional surfaces under water that was in thermal equilibrium with the ambient temperature. The pair of blocks was fixed together on the table by specified rubber bands with a compressive force of approximately $2,2 \times 10^3$ N m^{-2}. For applying pressure on the combined TMM blocks, an additional block that has a flat surface on the contact side should be put in the back side of each TMM block. The rubber band is set over each stacked structure comprising one additional block, the combined TMM blocks and another additional block. See Figure A.2 a) where the additional blocks are coloured blue. In this case extruded polystyrene was used as the additional blocks which were covered with adhesive tape (coloured blue) to prevent small pieces from being generated at the surface.

d) Alignment of transducer: Alignment of the transducer was performed to achieve coincidence between the scan plane of the transducer and the cross-sectional plane of the split TMM-blocks. The acoustic output was set so low that temperature rise was negligible. The echo of a metal wire that was located at the lowest edge of the cross section was observed as an indicator of co-planarity. Except for an acoustic window for the transducer, the TMM was wrapped by thin plastic film again to avoid evaporation of water during the period when the transducer was driven.

e) Shielding the camera and phantom: A cardboard box surrounding the setup was closed to shield the camera and phantom from stray IR-radiation and air currents, respectively.

f) Driving the transducer: The transducer was driven for three minutes in the cardboard box. The insonation time of three minutes was applied in the above case. It should be considered from the viewpoint of the measurement objective to achieve an informative image.

g) Acquiring an infrared image: The thin film and transducer were removed. The infrared image was quickly acquired for the cross-sectional surface of the split TMM-block (B) just after the split TMM-block (A) was decoupled and removed. Except for the infrared camera, the setup was still covered by the cardboard box during the acquisition.

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A.4 Data analysis

In this case the measurement depth of 5 mm was intentionally specified for evaluating a maximum temperature in the infrared image.

NOTE 1 This measurement was originally performed to compare the temperature rise between a split TMM and a TTO (Thermal Test Object) phantom, which was manufactured by NPL and referenced in IEC TS 62306:2006 [7]. Since a single thermocouple was embedded at 5 mm depth in the TMM of the TTO phantom, the same depth of 5 mm was specified on the infrared image as well.

The temperature rise is defined in Formula (A.1) for the split TMM-block (B).

$$\Delta T_{\mathrm{TMM\_5}}(t_3) = T_{\mathrm{TMM\_5}}(t_3) - T_{\mathrm{TMM\_ref}}(t_3) \tag{A.1}$$

where

$\Delta T_{\mathrm{TMM\_5}}(t_3)$ is temperature rise at t = 3 min and at the depth of 5 mm;

$T_{\mathrm{TMM\_5}}(t_3)$ is maximum temperature at t = 3 min and at the depth of 5 mm;

$T_{\mathrm{TMM\_ref}}(t_3)$ is reference temperature.

Both $\Delta T_{\mathrm{TMM\_5}}(t_3)$ and $\Delta T_{\mathrm{TMM\_ref}}(t_3)$ were determined in the same infrared image.

It was easy to find the maximum temperature because its position at 5 mm depth in the infrared image was determined by the software and indicated by the intersection of the green dotted lines (see NOTE 2). On the other hand, determination of the reference temperature should be carefully considered. In this measurement the calculation of average temperature in a rectangular area was performed for obtaining the reference temperature. The chosen area was a portion of the infrared image at base temperature as indicated by the long black arrow in Figure A.3 (see NOTE 3).

NOTE 2 The typical position of maximum temperature was obtained at the surface, which was slightly dented after the transducer was removed.

NOTE 3 The reference temperature was determined as an average temperature of the rectangular area specified by the diagonal positions (108, 32) and (188, 122) in Figure A.3.

A maximum temperature rise of 2,2 °C was obtained for data sample no. 3 as shown in Figure A.3. The results of measurements repeated four times are shown in Table A.1. The average and standard deviation of $\Delta T_{\mathrm{TMM\_5}}(t_3)$ were 2,2 °C and 0,3 °C, respectively.

NOTE 4 The higher temperature regions at the top and left side of the image may be due to the reflection of infra-red radiation that was generated by the heated detector in the camera. The stays with glossy surfaces were reflective. The surrounding region, which displayed a higher temperature, may make easier the identification of the TMM contour, as observed in Figure A.3.

NOTE 5 The red cross and yellow cross show the maximum temperature and the minimum temperature in the thermal image, respectively, in Figure A.3. They were accidentally in the background and at the outside of the TMM-block in this case. They are not considered in the infrared measurement.

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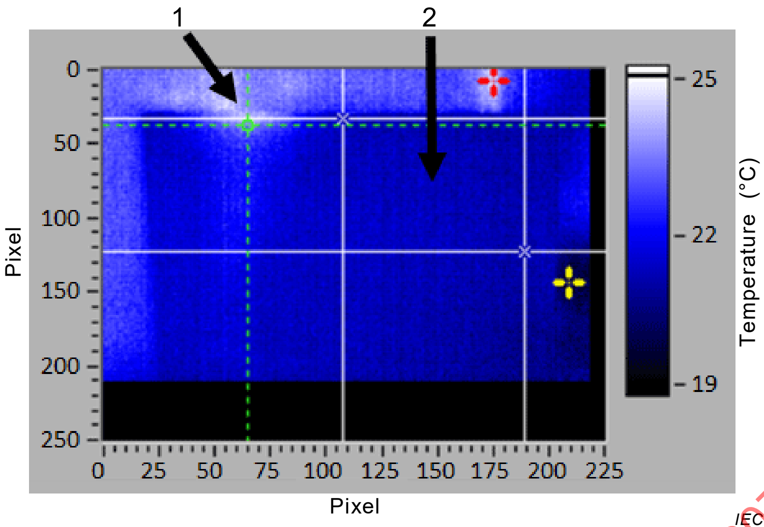

Key

1 green cross point as $T_{\mathrm{TMM\_5}}(t_3)$ = 23,4 °C

2 blue solid rectangular area for $T_{\mathrm{TMM\_ref}}(t_3)$ = 21,2 °C

Figure A.3 – Analysis of thermal image

Table A.1 – Results of measurement

Values in °C

Sample number	$\Delta T_{\mathrm{TMM\_5}}(t_3)$	$T_{\mathrm{TMM\_5}}(t_3)$	$T_{\mathrm{TMM\_ref}}(t_3)$
1	1,9	23,7	21,8
2	2,5	23,8	21,3
3	2,2	23,4	21,2
4	2,3	23,4	21,1

A.5 Improved split TMM-phantom

A split TMM-phantom [19] is shown with the following improvements in Figure A.4.

It has a plastic housing, except for an acoustic window, for both easy handling and keeping the properties stable. A hinge is useful for both combination and separation of the TMM-blocks.

The slightly convex shape of the cross-sectional surfaces makes tight combination of the TMM-blocks possible with a snap fastener.

A metal wire embedded at the bottom of the housing generates a reference echo in the B-mode image during the adjustment of alignment between the transducer and the TMM. It is useful to identify the position of a cross-sectional line at the bottom of the TMM.

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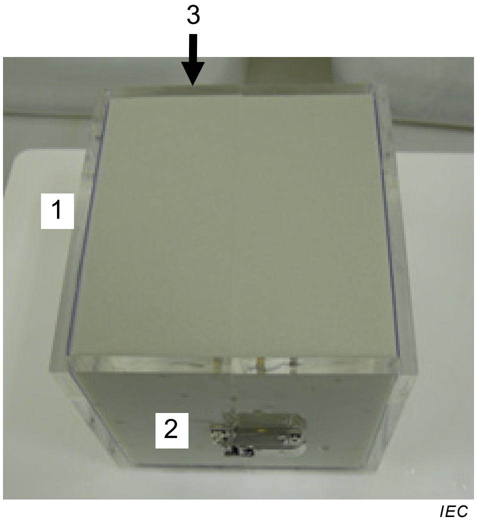
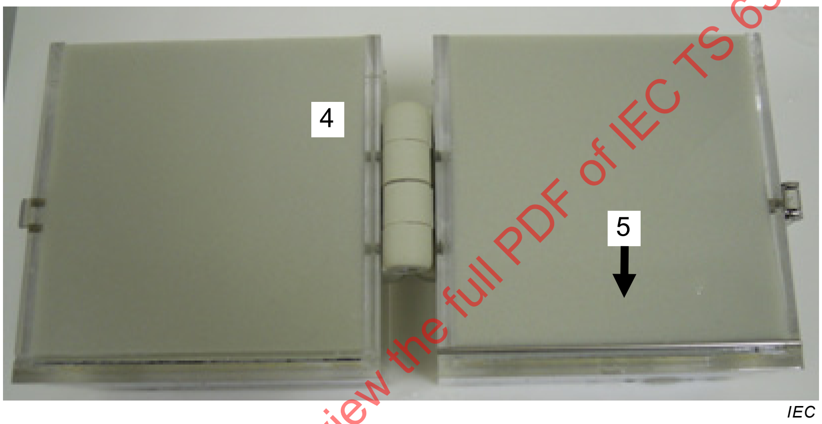
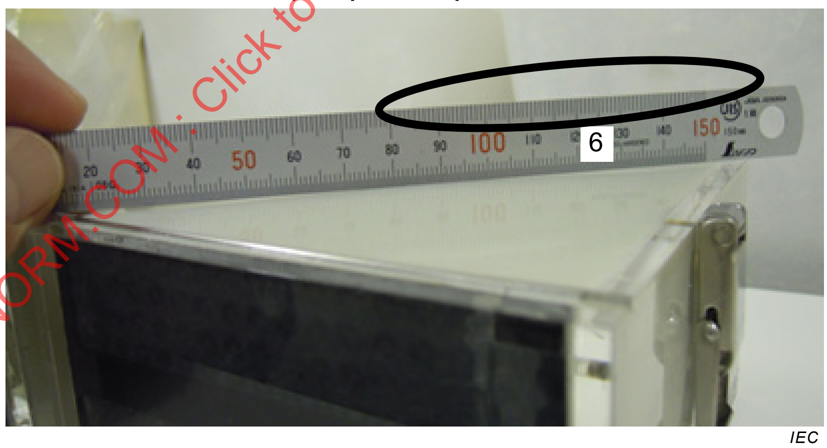


a) **Combined split TMM**



b) **Separated split TMM**



c) **Shape of cross-sectional surface**

Key

1 acrylic case housing

2 snap fastener

3 separation position of combined split TMM

4 hinge

5 metal wire

6 slightly convex surface of separated TMM

Figure A.4 – Improved split TMM phantom

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Annex B
(informative)

Measurement procedure under the condition of still air

B.1 General

Annex B gives an example of the measurement under the condition of still air, specified in this document. Background information related to this method is given in the literature [11] (in Japanese).

B.2 Measurement setups

Figure B.1 shows the setup of this measurement.

The transducer is set at one side of the wind shield; it is positioned on the axis of the IR-camera located at the opposite side of the box. The camera is controlled by a PC and the thermal image is acquired.

B.3 Procedures

The measurement procedure using an IR-camera is as given in 1) to 9).

Figure B.2 also shows this procedure as a flow chart.

1) Warm up the IR-camera for 30 min or for the period specified by the manufacturer.
2) Perform **black body** calibration and outside temperature calibration:

   The calibration of the IR-camera is usually performed using the **black body** cavity equipment. The surface temperature of the cavity is controlled as a reference temperature. The temperature of the cavity is measured by the IR-camera and the difference of the temperature between measured and reference is considered as a correction value as a result of calibration.
3) Set the temperature detection mode in which the maximum temperature is tracked automatically.
4) Adjust the alignment of the ultrasound transducer in the position for surface temperature measurement, so that the ultrasound-emitting surface of the ultrasound transducer is perpendicular to the optical axis of the infrared camera and then adjust the focus of the IR-camera.
5) Set the **emissivity** correction appropriately for the material of the surface of the ultrasound transducer. If the **emissivity** of the material is not known, the **emissivity** of the surface of the ultrasound transducer should be determined by comparative calibration using **black body** tape or another material with known **emissivity** before starting the measurement as follows.

   The black body sheet whose **emissivity** value is known is put on the surface material of the measured object, whose **emissivity** value is unknown. The temperature of the **black body** sheet gives a reference temperature. Next the temperature of the surface material is measured with tuning the **emissivity** value to obtain the same temperature as that of the **black body** sheet. The obtained **emissivity** value is considered as that of the surface material.
6) Leave the measuring system untouched until the temperature of the ultrasound transducer surface becomes equal to the ambient temperature.

   For example, the tolerance for the temperature difference between ambient and transducer surface is ±1 °C, which may be similar to the measurement uncertainty.

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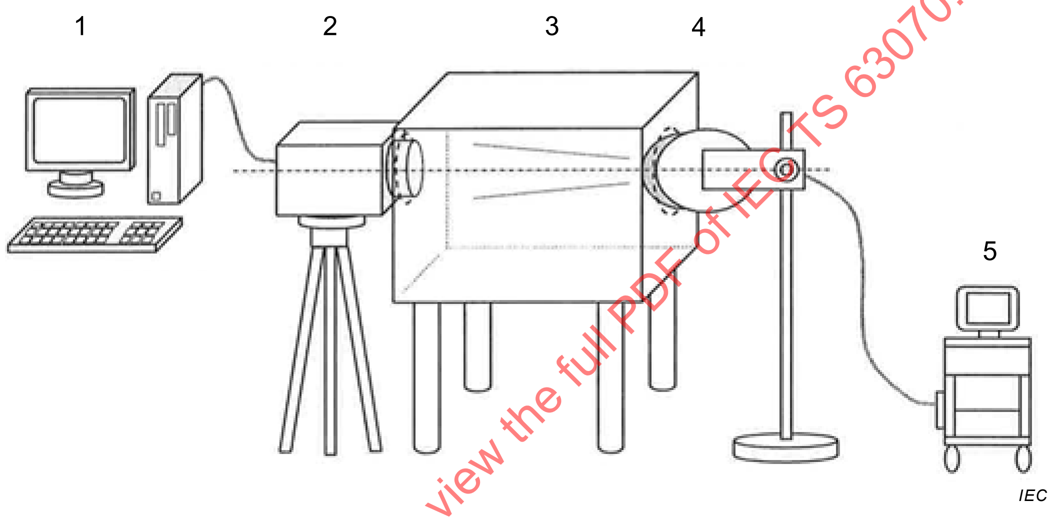
7) When the environmental condition becomes stable as described in 6), start to measure the temperature before driving the transducer.

8) Drive the ultrasound transducer during the specified period.

9) Calculate the difference between the maximum value of the temperature of the ultrasound transducer surface obtained during the test period and the temperature of the ultrasound transducer surface that was measured in 7) before driving the transducer. Add the nominal reference temperature, 23 °C, to the obtained difference, and use the resulting value for assessing the conformance to the requirement of IEC 60601-2-37:2007 and IEC 60601-2-37:2007/AMD1:2015, i.e. whether it is more than 50 °C or not.

Outside temperature calibration should be repeated periodically during the test period.

NOTE Basically, plastic like an acrylic plate has low transparency in the infrared rays. A plastic plate with a certain thickness, for example 1 cm, may be one of the candidates for a convenient material of the box for shielding from both infrared radiation and air flow.



Key

1 PC

2 infrared camera

3 wind shield

4 transducer

5 ultrasound system

Figure B.1 – Example of a measurement setup for the transducer surface-temperature test in still air using an infrared camera

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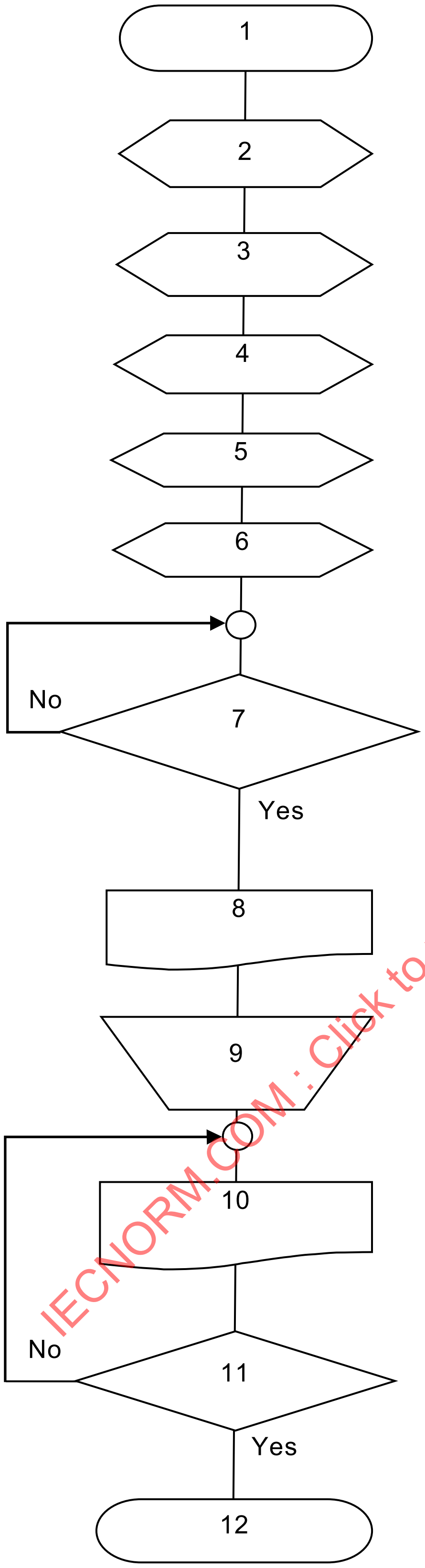
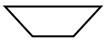


Key


Operation at the infrared camera


Operation at the ultrasound transducer or diagnostic ultrasound system

1 Transducer surface-temperature test in still air.

2 Warm up the infrared camera.

3 **Black body** calibration.

Outside temperature calibration.

4 Setting of automatic maximum temperature tracking.

5 Adjustment of focal length.

6 Setting of **emissivity** correction.

7 Is the initial temperature equal to the ambient temperature?

8 Measurement of the temperature of the ultrasound transducer surface immediately before the test is started.

9 Activation of the ultrasound transducer.

10 Measurement of the maximum temperature of the ultrasound transducer surface during the test period.

11 Has the test period ended?

12 Assess conformance to the requirement, whether it is more than 50 °C or not.

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Figure B.2 – Flow chart of the transducer surface-temperature test in still air using an infrared camera

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