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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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CONTENTS

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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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Technical Specifications are subject to review within three years of publication to decide whether they can be transformed into International Standards.

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

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.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

Terms in **bold** in the text are defined in Clause 3.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- transformed into an International Standard,
- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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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.

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

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.

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- 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.

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).

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.

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