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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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CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope 7
2 Normative references 7
3 Terms and definitions 8
4 Symbols and abbreviated terms 8
5 Methods of use 8
5.1 General 8
5.2 Consideration of perfusion 9
5.3 Effects of environment 9
6 IR-camera specifications 9
6.1 General 9
6.2 Test 9
6.3 Calibration 9
7 Phantom specification and construction 10
7.1 Split TMM specifications 10
7.2 Periodic validation 10
8 Measurement procedure 10
8.1 Split TMM setup 10
8.1.1 General 10
8.1.2 Emissivity 11
8.1.3 Procedure 11
8.2 Still-air setup 12
8.2.1 General 12
8.2.2 Emissivity 12
8.2.3 Procedure 12
9 Uncertainty determination 12
Annex A (informative) Measurement example using a split TMM setup 13
A.1 General 13
A.2 Measurement setups 13
A.3 Procedures 16
A.4 Data analysis 17
A.5 Improved split TMM-phantom 18
Annex B (informative) Measurement procedure under the condition of still air 20
B.1 General 20
B.2 Measurement setups 20
B.3 Procedures 20
Annex C (informative) Guidance on uncertainty determination 23
Bibliography 25

Figure A.1 – Concept of measurement 14
Figure A.2 – Setups for thermal equilibrium and measurement 15
Figure A.3 – Analysis of thermal image 18
Figure A.4 – Improved split TMM phantom 19

Figure B.1 – Example of a measurement setup for the transducer surface-temperature test in still air using an infrared camera.....21
Figure B.2 – Flow chart of the transducer surface-temperature test in still air using an infrared camera 22

Table A.1 – Results of measurement 18

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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.

A bilingual version of this publication may be issued at a later date.

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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.

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*