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Interested committees:

Title: BS EN 63440 Ultrasonics - Measurement of biologically relevant temperature rise produced by medical ultrasonic equipment

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



87/827/CD

COMMITTEE DRAFT (CD)

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IEC TC 87 : ULTRASONICS

SECRETARIAT:

United Kingdom

SECRETARY:

Mr Petar Luzajic

OF INTEREST TO THE FOLLOWING COMMITTEES:

SC 62B, SC 62D

PROPOSED HORIZONTAL STANDARD:

☐

Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☐ SAFETY

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- any relevant patent rights of which they are aware and to provide supporting documentation,
- any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "in some countries" clauses. See AC/22/2007.

TITLE:

Ultrasonics - Measurement of temperature rise produced by medical ultrasonic equipment

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS – MEASUREMENT OF TEMPERATURE RISE PRODUCED
BY MEDICAL ULTRASONIC EQUIPMENT****FOREWORD**

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International Standard IEC 63440 has been prepared by subcommittee WG14: Determination of ultrasound exposure parameters, of IEC technical committee 87:Ultrasonics.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

Full information on the voting for the approval of this International Standard 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.

In this particular standard, the following print types are used:

- 140 - requirements, compliance with which can be tested, and definitions: in roman type
141 - notes, explanations, advice, introductions, general statements, exceptions, and references: in
142 smaller type
143 - test specifications: in italic type
144 - words in bold are defined terms in Clause 3

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

- 148 • reconfirmed,
149 • withdrawn,
150 • replaced by a revised edition, or
151 • amended.

152

153 The National Committees are requested to note that for this document the stability date
154 is 20XX.

155 THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED
156 AT THE PUBLICATION STAGE.

157

158

INTRODUCTION

159 This International Standard specifies the measurement methods, calculations, requirements
160 and guidelines for determining temperature rise from medical ultrasonic equipment. It describes
161 how temperature sensors and test objects can be used to determine ultrasonically-induced
162 temperature rise for each type of medical ultrasound equipment that can generate biologically-
163 relevant temperature rise within the human body.

164

ULTRASONICS – MEASUREMENT OF TEMPERATURE RISE PRODUCED BY MEDICAL ULTRASONIC EQUIPMENT

1 Scope

This International Standard is applicable to medical ultrasonic equipment capable of inducing a biologically-relevant temperature rise.

This Technical Standard establishes:

- the important characteristics, calculations and terminology for determining temperature rise for diagnostic, therapeutic and surgical ultrasound equipment
- requirements for temperature rise measurements for each type of medical ultrasound equipment;
- general test methods for in still air and using test objects to determine standardized temperature rises.
- validation procedures;

This Technical Standard does not address methods for simulation of temperature rise

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 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

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

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”

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

For the purposes of this document, the terms and definitions given in IEC 60601-2-5, IEC 60601-2-37 and IEC 60601-2-62 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**hot spot**

The position on the **applied part** of the **transducer assembly** where the spatial peak temperature is observed

3.2**invasive transducer assembly**

transducer which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

[SOURCE: from 60601-2-37 2015, definition 201.3.207]

3.3**thermal steady state**

condition where temperature does not change over time

Note: for the purposes of this standard we are approximating steady state when the rate of change of temperature is $\leq 0,12$ °C per minute for three consecutive minutes.

3.4**thermal offset**

ΔT_{offset}

equilibrium difference between a) the temperature of the test object-transducer interface when the TRANSDUCER ASSEMBLY is connected to the ULTRASONIC DIAGNOSTIC EQUIPMENT or other power supply and acoustically not transmitting and b) the test object ambient temperature at the same test object-transducer interface location when the TRANSDUCER ASSEMBLY was not present.

[SOURCE: IEC 60601-2-37 ed. 2]

3.5**treatment head**

assembly comprising an **ultrasonic transducer** and associated parts for local application of **ultrasound** to the **patient**.

Note 1 to entry: A **treatment head** is also referred to as an **applicator**

3.6**ultrasound**

acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 16 kHz)

[SOURCE: IEC 802-01-01, modified]

4 List of Symbols

ΔT_{offset} thermal offset

5 Measurement of patient contact surface temperature for Diagnostic Ultrasound**5.1 Thermal sensor requirements**

5.1.1 Thermal sensor types

The temperature of the applied part of the **transducer assembly** should be measured with an appropriate measurement device, such as **thermocouple** or **infrared camera**.

5.1.2 Spatial averaging and heat dissipation

The size of the temperature measurement area of the sensor should be such that any averaging effect is minimized. For an infrared measurement system, the focus size, the pixel size of the thermal image and the depth of field should be such that any averaging effect is minimized.

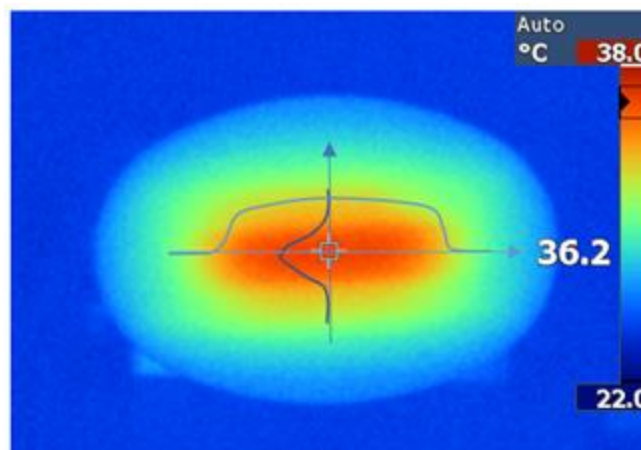


Figure 1 – hot spot location determination with infrared camera image

The heat dissipation over thermocouple metal wires should be minimized. Thin wires, which are thermally isolated behind the thermocouple junction reduce the impact of heat dissipation.

The wire diameter should be less than 0,4 mm in case of round wires and the cross-section area should be less than 0,1 mm² for non-circular wires (e.g. most thin film thermocouples).

The sensor wires should be oriented such that the shortest distance is used to get off the applied part of the transducer area (mostly in elevation direction for diagnostic ultrasound transducers).

5.1.3 Measurement accuracy and measurement uncertainties

According to IEC 60601-2-37, the measurement uncertainties shall be determined and recorded in the test report. For additional details see Annex B.

Note 1: **Thermocouples** can have higher accuracy if **thermocouple** offset and slope correction for each individual thermocouple is performed.

Note 2: A reference temperature chamber or an isothermal cold-junction block may be used to improve measurement accuracy. See Annex A- Reference temperature chamber

Note 3: **Infrared camera** measurements require a correction of the material specific infrared emission spectrum for accurate measurements.

Note 4: The measurement uncertainty shall be evaluated for absolute temperature measurements in case measurements are performed according to method a of IEC 60601-2-37 and for relative temperature measurements in case method b of IEC 60601-2-37 is used.

Note 5: Instructions and examples for measurement uncertainty calculation can be found in ISO/IEC Guide 98-3:2008, Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)".

5.2 Still air

Suspend and hold the **transducer assembly** in still air or place it in a stationary position in an environmental chamber, for example a cardboard or acrylic box, with minimal airflow across the **applied part** of the **transducer assembly**. Maintain a clean surface with no coupling gel applied. "In still air" means an environment without forced air movement (flow) and an air temperature of $23\text{ °C} \pm 3\text{ °C}$ stable within $0,5\text{ °C}$ during one measurement. The size of the environmental chamber should be large enough to avoid significant heating of the environment air.

5.2.1 Measurement setup description

5.2.1.1 Positioning of infrared camera, thermocouple, thermistor, or pyrometer

All **hot spots** of the **applied part** of the **transducer assembly** shall be located using an infrared camera, thermocouple, thermistor or pyrometer.

The **infrared camera** shall be positioned orthogonal to the **applied part** surface of the **transducer assembly**. In case of curved probes or probes with more complex surface shapes where an orthogonal positioning to the whole **applied part** of the **transducer** is not possible, the **infrared camera** shall be positioned approximately orthogonal to the **applied part**

Note 1: A pyrometer can be used to determine the **hot spot** location, if scanning over the surface of the **applied part** of the **transducer assembly** is performed.

The **thermocouple** junction, thermistor or pyrometer measurement point shall be positioned in the centre of the **hot spot** which leads to maximum temperature.

If a **thermocouple** or thermistor is used for still-air measurement, the **thermocouple** or thermistor shall be positioned with minimum impact on measurement result.

A thin thermally isolating stick, where the sensor is positioned on top may be used to press the sensor to the **applied part** of the **transducer assembly** (see Figure 2). A small amount of conductivity paste may be used to improve thermal contact.

Note 2: A silicon-based conductivity paste should be used carefully, because this could lead to colour change or damage of the probe surface.

Note 3: The impact on spatial averaging shall be considered, if a conductivity paste is used.

Note 4: The impact of conductivity paste on measurement results shall be evaluated. Some conductivity pastes are electroconductive, which can impact measurement results if the **thermocouple** junction or **thermocouple** wires are not isolated.

Note 5: The temperature measurement results might be impacted by a voltage drop, if uninsulated **thermocouples** are used in electroconductive liquids. The impact on temperature results should be evaluated if uninsulated **thermocouples** are used in electroconductive liquids.