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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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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.	



87/847/CD

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SECRETARIAT:

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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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TITLE:

Ultrasonics - Measurement of temperature rise produced by medical ultrasonic equipment

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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:

- 147 - requirements, compliance with which can be tested, and definitions: in roman type
148 - notes, explanations, advice, introductions, general statements, exceptions, and references: in
149 smaller type
150 - test specifications: in italic type
151 - words in bold are defined terms in Clause 3

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

- 155 • reconfirmed,
156 • withdrawn,
157 • replaced by a revised edition, or
158 • amended.

159

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

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

164

165

INTRODUCTION

166 This International Standard specifies the measurement methods, calculations, requirements
167 and guidelines for determining temperature rise from medical ultrasonic equipment. It describes
168 how temperature sensors and test objects can be used to determine ultrasonically-induced
169 temperature rise for each type of medical ultrasound equipment that can generate temperature
170 rise within the human body.

171

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 temperature rise.

This International 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 International 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**ambient temperature**

temperature of air or another medium in the vicinity of the device under test

Note 1: Ambient temperature is expressed in degree Celsius (°C)

Note 2: During the measurement of the ambient temperature, the measuring instrument or probe should be shielded from draughts and radiant heating.

[Source: from IEC 845-27-110]

3.2**dT1_1minAvg**

temperature rise over the last minute, averaged over the past minute with at least three samples

3.3**hot spot**

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

3.4**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.

Note: Invasive transducer assemblies include cavity transducers (Transesophageal Echocardiography or TEE, Trans Vaginal or TV, Transrectal, or Laparoscopy), catheter transducers (Intracardiac Cardiac Echocardiography or ICE, Intravascular Ultrasound or IVUS, or Intravascular Echocardiography), and Intraoperative transducers used in an invasive manner.

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

3.5**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.

3.6**thermal offset**

ΔT_{offset}

thermal steady state 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]

3.7**transducer assembly**

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

Note 1 to entry: A **transducer assembly** is also referred to as a **treatment head** or **applicator**

3.8**ultrasound**

acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 20 kHz)

[SOURCE: IEC 802-01-01]

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 a thermal 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.

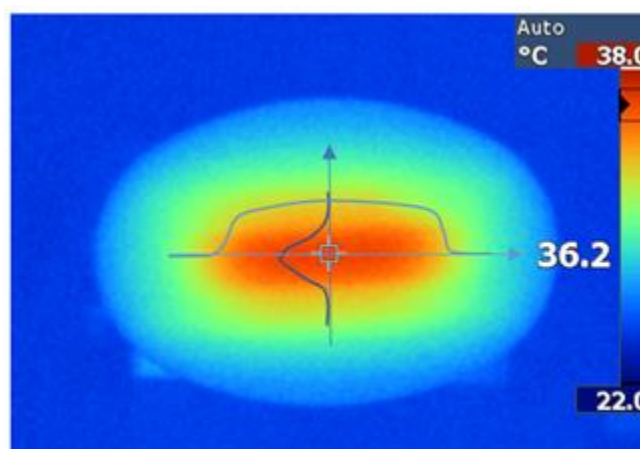


Figure 1 – hot spot location determination with infrared camera image

For a scanning pyrometer, the sensor size and spatial step size shall be sufficient to capture the hot spot while minimizing spatial averaging.

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

The wire diameter shall 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 shall be oriented such that the shortest distance is used to get off the **applied part** of the **transducer assembly** (mostly in elevation direction for diagnostic **ultrasound transducer assemblies**).

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.

The measurement sampling rate should be high enough, that short temperature peaks (e.g., in shear wave elastography mode) are recorded with sufficient temporal resolution.

The temperature resolution should be less than or equal to 0.1 deg C.

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 and for relative temperature measurements in case method b is used.

Note 5: Instructions and examples for measurement uncertainty calculation can be found in [1].

5.1.4 Positioning of thermal sensor

The thermal sensor shall be positioned at the **hot spot** of the **applied part** of the **transducer assembly**.

For **ultrasonic diagnostic equipment**, the **hot spot** location may change depending on the activated imaging mode. For example, some imaging devices may use a different transmit aperture position of the transducer array in 2D-mode and CW-mode, respectively. **Transducer assemblies** where matrix transducer arrays are used may show a **hot spot** which is not centered in elevation direction for a subset of transmit settings.

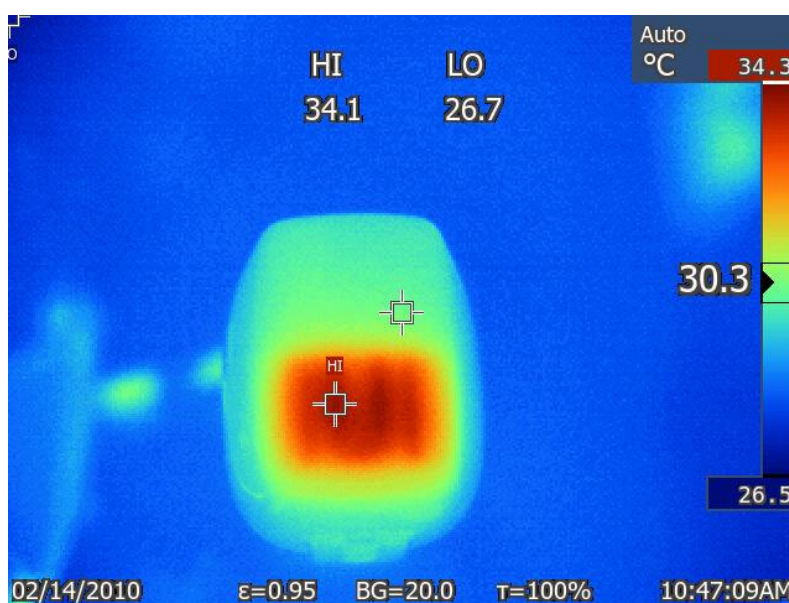


Figure 2 – off-centered hot spot location

308 If transducer assemblies have different hot spots in different imaging modes, each mode must
309 be measured using its hot spot.

310 Note 1: For mechanically-rocked probes, the hot spot in 3D/4D mode may not be the same as in 2D mode.

311 Note 2: The temperature measurement results might be impacted by a voltage drop, if uninsulated thermocouples
312 are used in electroconductive liquids. The impact on temperature results should be evaluated if uninsulated
313 thermocouples are used in electroconductive liquids.

314 5.2 Measurements in Still air

315 The **transducer assembly** shall be either suspended and held the in still air or placed in a
316 stationary position in an environmental chamber with minimal airflow across the **applied part**
317 of the **transducer assembly**. The applied part of the **transducer assembly** shall be clean with
318 no coupling gel applied. “In still air” means an environment without forced air movement (flow)
319 and an air temperature of $23\text{ °C} \pm 3\text{ °C}$ stable within $0,5\text{ °C}$ during one measurement.

320 5.2.1 Measurement setup description

321 5.2.1.1 Environmental chamber

322 If an environmental chamber, for example a cardboard or acrylic box, is used to reduce air flow,
323 the chamber (e.g. a cardboard or acrylic box) may be placed around the **transducer assembly**.

324 The size of the chamber shall be large enough to avoid a temperature increase of the
325 environmental air due to heat generated from the **transducer assembly**.

326 The environment temperature shall be measured during the still air measurement close to the
327 **transducer assembly**, but with enough distance to avoid a direct impact on temperature
328 measurement from heat generated by the **transducer assembly**.

329 Note 1: If other parts of the probe (e.g., probe cable) have an impact on the applied part temperature of the
330 **transducer assembly** (e.g., because of active cooling devices or heat exchangers), they should be in same still-air
331 conditions.

332 5.2.1.2 Positioning of infrared camera, thermocouple, thermistor, or pyrometer

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

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

340 Note 1: The infrared emissivity of the **applied part** of the **transducer assembly** may change as a function of the
341 viewing angle to the **applied part** surface, with maximum emissivity at normal viewing angles to the emitting surface.

342 Note2: A pyrometer can be used to determine the **hot spot** location, if scanning over the surface of the **applied part**
343 of the **transducer assembly** is performed.

344 The thermocouple junction, thermistor or pyrometer measurement point shall be positioned in
345 the centre of the **hot spot**.

346 If a thermocouple or thermistor is used for still-air measurement, the thermocouple or thermistor
347 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 3: A silicon-based conductivity paste should be used carefully, because this could lead to colour change or damage of the probe surface.

Note 4: The impact on spatial averaging should be considered, if a conductivity paste is used. A small diameter spot of paste, approximately the sensor diameter, and a thin layer, should be used - just enough to wet the junction between the probe and the sensor.

Note 5: The impact of conductivity paste on measurement results should be evaluated. Some conductivity pastes are electroconductive, which can impact measurement results if the thermocouple junction or thermocouple wires are not isolated.

Note 6: [Measurement procedure of the transducer surface temperature in still air using an infrared camera](#) is described in Annex D as informative.



Figure 3 – still-air measurement setup example

Alternatively, a thin narrow adhesive tape may be used to position the sensor at the **hot spot** location. An air gap between the tape and sensor should be avoided.

5.2.1.3 Initial steady-state condition

At the beginning of the test, the **transducer assembly** shall be in an thermal steadystate condition where the **applied part** of the **transducer assembly** shall be equal to the ambient air temperature.

The temperature of the **applied part** of the **transducer assembly** can be considered as equivalent with the ambient air temperature if they agree within 0.5°C.

For the purposes of this test, initial thermal steady state condition may be considered reached when **dT1_1minAvg** of the **applied part** is $\leq 0,12$ °C per minute for three consecutive minutes.

Note: For some **transducer assemblies** such as mechanically rocked 3D probes, or solid-state probes with integrated multiplexing electronics, the temperature of the **applied part** (surface temperatures) may not stabilize at an initial steady-state temperature equal to the air-ambient temperature when the acoustic power is 'off' (i.e.: non-energized transducer elements). Rather, a fixed thermal offset may exist.