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Date: 30 October 2024

Origin: International

Latest date for receipt of comments: 18 December 2024

Project No. 2022/00994

Responsible committee: EPL/87 Ultrasonics

Interested committees:

Title: BS EN IEC 63440 Ultrasonics - Measurement of 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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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

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.	



87/883/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 63440 ED1

DATE OF CIRCULATION:

2024-10-25

CLOSING DATE FOR COMMENTS:

2025-01-17

SUPERSEDES DOCUMENTS:

87/847/CD, 87/882/CC

IEC TC 87 : ULTRASONICS

SECRETARIAT:

United Kingdom

SECRETARY:

Mr Petar Luzajic

OF INTEREST TO THE FOLLOWING COMMITTEES:

SC 62B, SC 62D

HORIZONTAL FUNCTION(S):

ASPECTS CONCERNED:

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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:

- requirements, compliance with which can be tested, and definitions: in roman type

- 179 - notes, explanations, advice, introductions, general statements, exceptions, and references: in
180 smaller type
- 181 - test specifications: in italic type
- 182 - words in bold are defined terms in Clause 3

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

- 186 • reconfirmed,
- 187 • withdrawn,
- 188 • replaced by a revised edition, or
- 189 • amended.

190

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

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

195

196

INTRODUCTION

197 This International Standard specifies the measurement methods, calculations, requirements
198 and guidelines for determining temperature rise from medical ultrasonic equipment. It describes
199 how temperature sensors and test objects can be used to determine ultrasonically-induced
200 temperature rise for each type of medical ultrasound equipment that can generate temperature
201 rise within the human body. This standard allows the determination and use of Extrapolated
202 Temperature or Temperature-Rise values, in-lieu of measuring to the standard 30
203 minutes. Extrapolation can begin once the temperature rise over a 3 minute period (see
204 definition 3.6) has reached thresholds shown in 5.1.8. Extrapolation is not allowed for closed
205 loop systems.

206

207

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 is meant to support the safety standards through providing the details of temperature measurements necessary to confirm with safety requirements therein and 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 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 to entry: Ambient temperature is expressed in degree Celsius (°C).

Note 2 to entry: During the measurement of the ambient temperature, the measuring instrument or **transducer assembly** should be shielded from draughts and radiant heating.

[Source: from IEC 845-27-110]

3.2

Closed-loop power adjustment

The ultrasound system, independent of the operator, automatically adjusts transmit-related parameters which affect acoustic or thermal output.

Note 1 to entry: Examples include ultrasound systems which monitor probe temperature and automatically increase or decrease Tx voltage or other Tx-related parameters to increase or decrease probe temperature.

Note 2 to entry: Section 5.xxx excludes the use of extrapolated temperature values for Closed Loop systems.

3.3

cooling period

the time period when the acoustic power is 'off' (i.e., non-energized transducer elements)

3.4

dT1_1minAvg

ΔT_{1Avg}

the absolute value of the average temperature rise or fall over a specified time of not less than 1 minute, where the time used for averaging shall be specified, calculated from at least 10 samples

3.5

dT3Xmin_avg

ΔT_{3Xmin_avg}

the absolute value of the average temperature rise or fall over a specified time of not less than 3 minutes, where the time, X, used for averaging shall be specified

3.6

Extrapolated_30minute_Temperature_or_ Extrapolated_30minute Temperature_Rise (consider removing Temperature rise and DT(30) LinExtrp(t))

DT(30)_LinExtrp(t), T30_LinExtrp(t)

TBD

Note 1 to entry: per section 5.1.8, extrapolation is allowed only for non-closed-loop systems.

3.7

hot spot

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

3.8

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

294 Note to entry: **Invasive transducer assemblies** include cavity transducers (transoesophageal echocardiography or
295 TEE, trans vaginal or TV, transrectal, or laparoscopy), catheter transducers (intracardiac cardiac
296 echocardiography or ICE, intravascular ultrasound or IVUS, or intravascular echocardiography), and intraoperative
297 transducers used in an invasive manner.

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

299 3.9

300 Linear least squares fit temperature rise

301 LLS4

302 temperature rise calculated over a specified time of not less than 4 minutes using a linear least
303 square fit

304 3.10

305 thermal steady state

306 condition where temperature does not change over time

307 Note 1 to entry: For the purposes of this standard **thermal steady state** is approximated by a temperature change
308 over a three minute period that is less than or equal to 1% of the following values: in still air, 27 C; in simulated use
309 with external transducers, 10 C; in simulated use with invasive transducers, 6 C. These values come from the IEC
310 60601-2-37 limits for air and for simulated use method B.

311 3.11

312 thermal offset

313 ΔT_{offset}

314 difference between a) the temperature of the APPLIED PART of the TRANSDUCER ASSEMBLY
315 at steady state in the measurement setting before transmitting begins and b) the steady state
316 temperature at the same location in the measurement setting when the TRANSDUCER
317 ASSEMBLY was not present

318 Note 1 to entry: The value of the thermal offset can be positive, negative or zero.

319 Note 2 to entry: The thermal offset is defined at the thermal steady state condition.

320 [SOURCE: IEC 60601-2-37 ed. 3]

321 3.12

322 transducer assembly

323 those parts of medical diagnostic ultrasonic equipment comprising the ultrasonic transducer
324 and/or ultrasonic transducer element group, together with any integral components, such as an
325 acoustic lens or integral stand-off

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

327 Note 2 to entry: The **transducer assembly** is usually separable from the **ultrasound instrument control**.

328

329 3.13

330 ultrasound

331 acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about
332 20 kHz)

333 [SOURCE: IEC 802-01-01]

334 3.14 ultrasound instrument console

335 electronic unit to which the **transducer assembly** is attached

336

337 4 List of Symbols

338 ΔT_{1Avg}

339

340 ΔT_{3Xmin_avg}

DT(30)_LinExtrp(t), T(30)_LinExtrp(t)

LLS4

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 a thermocouple or an 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 images and the depth of field should be such that any averaging effect is minimized.

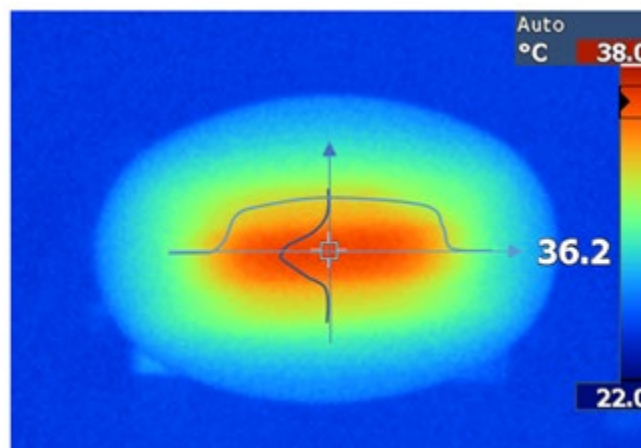


Figure 1 – hot spot location determination with infrared camera image

When using a scanning pyrometer, ensure that the sensor size and spatial step size are sufficient to capture the **hot spot** and reduce spatial averaging.

The impact of heat dissipation can be reduced by using thin wires which are thermally isolated behind the thermocouple junction.

The wire diameter shall be less than 0,25 mm in case of round wires and the cross-section area should be less than 0,05 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**).

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.

5.1.3 Measurement accuracy and measurement uncertainties

According to IEC 60601-2-37, the measurement uncertainties shall be determined and recorded according to the principles established in [1]. These uncertainties shall be recorded in the test report. For additional details see Annex B.

The temperature resolution should be less than or equal to 0,1°C.

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.

Note 1 to entry: Thermocouples can be more accurate if the thermocouple offset and slope correction are performed for each individual thermocouple.

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

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

Note 4: Instructions and examples for measurement uncertainty calculation can be found in [1].

5.1.4 Positioning of thermal sensor (infrared camera, thermocouple, thermistor, or pyrometer)

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

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. When using matrix transducer arrays for **transducer assemblies**, a subset of transmit settings may produce a **hot spot** that is not centered in the elevation direction.

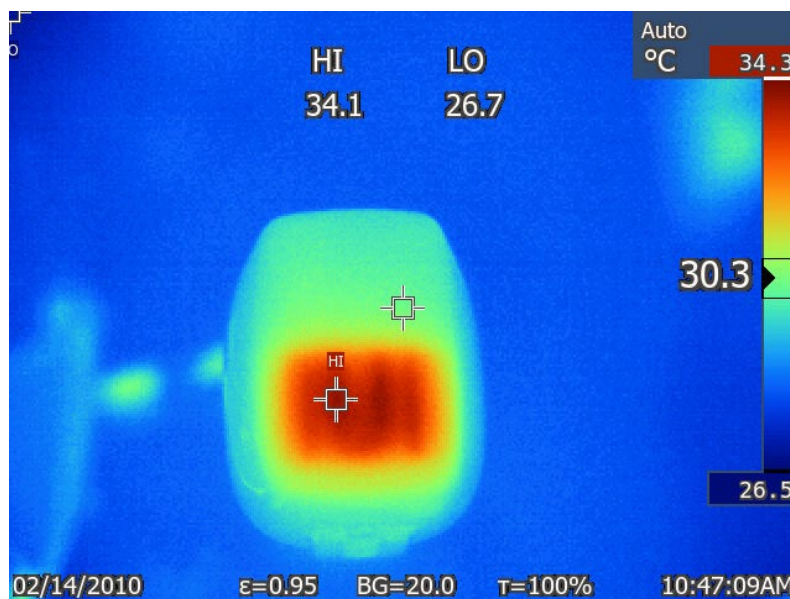


Figure 2 – off-centered hot spot location

If **transducer assemblies** have different **hot spots** in different imaging modes, each mode must be measured using its **hot spot**. For combined modes, the overall hot spot shall be measured.

Note to entry: For mechanically rocked **transducer assemblies**, the **hot spot** in 3D/4D mode is not always the same as in 2D mode.

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

Note 2 to entry: The infrared emissivity of the **applied part** of the **transducer assembly** may change as a function of the viewing angle to the **applied part** surface, with maximum emissivity at normal viewing angles to the emitting surface.

Note 3 to entry: 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**.

If a thermocouple or thermistor is used for ambient temperature 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 3). A small amount of conductivity paste may be used to improve thermal contact.

A silicon-based conductivity paste should be used carefully because this could lead to colour change or damage of the transducer surface.

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 **transducer assembly** and the sensor.

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 4 to entry: 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

434

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

437

438 5.1.5 Environmental chamber and ambient temperature monitoring

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

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

443 The **ambient temperature** shall be measured during the still air measurement close to the
444 **transducer assembly**, but with enough distance to avoid a direct impact on temperature
445 measurement from heat generated by the **transducer assembly**.

446 If other parts of the **transducer assembly** (e.g., cable) have an impact on the **applied part**
447 temperature of the **transducer assembly** (e.g., because of active cooling devices or heat
448 exchangers), they should be in same still-air conditions.

449 An additional temperature sensor for measurement of **ambient temperature** may be positioned
450 close to the **transducer assembly**, but with enough margin to avoid an impact from heat
451 generated by the **transducer assembly**.

452 The **ambient temperature** shall be $23^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

453 A direct airflow (e.g., from air conditions) may impact the measurement results and should be
454 avoided. The impact of airflow on measurement results may increase if an active cooling system
455 for the **transducer assembly** is used.

456 Some ultrasound consoles use fan systems for cooling. If the console is located close to the
457 measurement setup, the emitted warm air could impact the measurement result. The fan
458 systems of the console should be positioned with enough margin for the measurement setup.

459 Note 1 to entry: Additional heat capacity may be added to the thermocouple junction, if a thermocouple with small
460 size and low heat capacity is used for **ambient temperature** measurements (e.g., adding a drop of thermal
461 conductivity paste on the thermocouple junction). This reduces the variation of **ambient temperature** measurement
462 results if the temperature changes for a short time (e.g., opening a door for some seconds or a person walking near
463 the measurement setup). This is only relevant in measurement setups where no environmental chamber is used.
464 Such short variations of **ambient temperatures** do not have an impact on the **hot spot** measurement result.

465 Note 2 to entry: The impact of **ambient temperature** changes on the **transducer assembly** temperature might be
466 higher for **transducer assembly** with active cooling systems, where the cooling system is intended to reduce
467 temperature of the **transducer assembly**.

468 5.1.6 Sampling Rate

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

471 If linear extrapolation or a closed loop power system is used, then a minimum sampling rate of 10
472 samples/minute is required.

473 If linear extrapolation is not used and if not a closed loop power system, then a maximum sampling
474 rate of 3 samples/minute is acceptable.

475 5.1.7 Temperature Rise with One-Sensor or Two-Sensor Methods

476 Some temperature measurements involve measuring temperature rise, while others use
477 absolute temperature. Measurements in still air use temperature rise, and measurements in