IEC

IEC 62359

Edition 2.0 2010-10

INTERNATIONAL STANDARD

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Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

Ultrasons – Caractérisation du champ – Méthodes d'essai pour la détermination d'indices thermique et mécanique des champs d'ultrasons utilisés pour le diagnostic médical

IEC 62359:2010

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX XB

ICS 17.140.50

ISBN 978-2-88912-181-6

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ULTRASONICS – FIELD CHARACTERIZATION – TEST METHODS FOR THE DETERMINATION OF THERMAL AND MECHANICAL INDICES RELATED TO MEDICAL DIAGNOSTIC ULTRASONIC FIELDS

FOREWORD

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International standard IEC 62359 has been prepared by IEC technical committee 87: Ultrasonics.

This second edition cancels and replaces the first edition, published in 2005. It constitutes a technical revision.

Major changes with respect to the previous edition include the following:

- The methods of determination set out in the first edition of this standard were based on those contained in the American standard for Real–Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (ODS) and were intended to yield identical results. While this second edition also follows the ODS in principal and uses the same basic formulae and assumptions (see Annex A), it contains a few significant modifications which deviate from the ODS.

- One of the primary issues dealt with in preparing this second edition of IEC 62359 was "missing" *TI* equations. In Edition 1 there were not enough equations to make complete "at-surface" and "below-surface" summations for *TIS* and *TIB* in combined-operating modes. Thus major changes with respect to the previous edition are related to the introduction of new calculations of thermal indices to take into account both "at-surface" and "below-surface" thermal effects.

For the specific technical changes involved please see Annex E.

The text of this standard is based on the following documents:

FDIS	Report on voting
87/445/FDIS	87/453/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

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

This standard may be used to support the requirements of IEC 60601-2-37.

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

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

– notes, explanations, advice, introductions, general statements, exceptions, and references: in smaller type

– *test specifications: in italic type*

– words in **bold** are defined terms in Clause 3

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of March 2011 have been included in this copy.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

Medical diagnostic ultrasonic equipment is widely used in clinical practice for imaging and monitoring purposes. Equipment normally operates at frequencies in the low megahertz frequency range and comprises an ultrasonic transducer acoustically coupled to the patient and associated electronics. There is an extremely wide range of different types of systems in current clinical practice.

The ultrasound entering the patient interacts with the patient's tissue, and this interaction can be considered in terms of both thermal and non-thermal effects. The purpose of this International standard is to specify methods of determining thermal and non-thermal exposure indices that can be used to help in assessing the hazard caused by exposure to a particular ultrasonic field used for medical diagnosis or monitoring. It is recognised that these indices have limitations, and knowledge of the indices at the time of an examination is not sufficient in itself to make an informed clinical risk assessment. It is intended that these limitations will be addressed in future revisions of this standard and as scientific understanding increases. While such increases remain pending, several organizations have published **prudent-use statements.**

Under certain conditions specified in IEC 60601-2-37, these indices are displayed on medical ultrasonic equipment intended for these purposes.

ULTRASONICS – FIELD CHARACTERIZATION – TEST METHODS FOR THE DETERMINATION OF THERMAL AND MECHANICAL INDICES RELATED TO MEDICAL DIAGNOSTIC ULTRASONIC FIELDS

1 Scope

This International standard is applicable to medical diagnostic ultrasound fields.

This standard establishes

- parameters related to thermal and non-thermal exposure aspects of diagnostic ultrasonic fields;
- methods for the determination of an exposure parameter relating to temperature rise in theoretical tissue-equivalent models, resulting from absorption of ultrasound;
- methods for the determination of an exposure parameter appropriate to certain non-thermal effects.

NOTE 1 In Clause 3 of this standard, SI units are used (per ISO/IEC Directives, Part 2, ed. 5, Annex I b) in the Notes below definitions of certain parameters, such as beam areas and intensities, it may be convenient to use decimal multiples or submultiples in practice. Users must take care of decimal prefixes used in combination with the units when using and calculating numerical data. For example, beam area may be specified in cm^2 and intensities in W/cm^2 or mW/cm^2.

NOTE 2 Underlying calculations have been done from 0,25 MHz to 15 MHz for MI and 0,5 MHz to 15 MHz for *TI*.

NOTE 3 The thermal indices are steady state estimates based on the acoustic **output power** required to produce a 1°C temperature rise in tissue conforming to the "homogeneous tissue 0,3 $dBcm^{-1}MHz^{-1}$ attenuation model" [1] [1)] and may not be appropriate for radiation force imaging, or similar techniques that employ pulses or pulse bursts of sufficient duration to create a significant transient temperature rise. [2]

2 Normative references

The following referenced documents are indispensable for the application 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 61157:2007, *Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment*

IEC 61161:2006, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 61828:2001, *Ultrasonics – Focusing transducers – Definitions and measurement methods for the transmitted fields*

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

[1)] Figures in square brackets refer to Bibliography.

IEC 62127-2:2007, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

IEC 62127-3:2007, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 62127-1:2007, IEC 62127-2:2007, IEC 62127-3:2007, IEC 61157:2007 and IEC 61161:2006 (several of which are repeated below for convenience) apply.

NOTE Units below definitions are given is SI units as per ISO/IEC Directives, Part 2, ed. 5, Annex I b). Users must be alert to possible need to convert units when using this standard in situations where data are received in units that are different from those used in the SI system.

3.1
acoustic attenuation coefficient
α
coefficient intended to account for ultrasonic attenuation of tissue between the **external transducer aperture** and a specified point

NOTE 1 A linear dependence on frequency is assumed.

NOTE 2 **Acoustic attenuation coefficient** is expressed in decibels per metre per hertz (dB m^{-1} Hz^{-1}).

3.2
acoustic absorption coefficient
μ_0
coefficient intended to account for ultrasonic absorption of tissue in the region of interest

NOTE 1 A linear dependence on frequency is assumed.

NOTE 2 **Acoustic absorption coefficient** is expressed in neper per metre per hertz (Np m^{-1} Hz^{-1}).

3.3
acoustic repetition period
arp
time interval between corresponding points of consecutive cycles for continuous wave systems

NOTE 1 The **acoustic repetition period** is equal to the **pulse repetition period** for non-automatic scanning systems and to the **scan repetition period** for automatic scanning systems.

NOTE 2 The **acoustic repetition period** is expressed in seconds (s).

[IEC 62127-1:2007, definition 3.2, modified]

3.4
acoustic working frequency
frequency of an acoustic signal based on the observation of the output of a **hydrophone** placed in an acoustic field at the position corresponding to the **spatial-peak temporal-peak acoustic pressure**

NOTE 1 The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Specific acoustic-working frequencies are defined in 3.4.1 and 3.4.2.

NOTE 2 For pulsed waveforms the **acoustic-working frequency** shall be measured at the position of maximum **pulse-pressure-squared integral**.

NOTE 3 **Acoustic frequency** is expressed in hertz (Hz).

[IEC 62127-1:2007, definition 3.3, modified]

3.4.1
zero-crossing acoustic-working frequency
f_{awf}
number of consecutive half-cycles (irrespective of polarity) divided by twice the time between the commencement of the first half-cycle and the end of the n-th half-cycle

NOTE 1 Any half-cycle in which the waveform shows evidence of phase change shall not be counted.

NOTE 2 The measurement should be performed at terminals in the receiver, that are as close as possible to the receiving transducer (hydrophone) and, in all cases, before rectification.

NOTE 3 This frequency is determined according to the procedure specified in IEC/TR 60854 [3].

NOTE 4 This frequency is intended for continuous-wave systems only.

3.4.2
arithmetic-mean acoustic-working frequency
f_{awf}
arithmetic mean of the most widely separated frequencies f_1 and f_2, within the range of three times f_1, at which the magnitude of the acoustic pressure spectrum is 3 dB below the peak magnitude

NOTE 1 This frequency is intended for pulse-wave systems only.

NOTE 2 It is assumed that $f_1 < f_2$.

NOTE 3 If f_2 is not found within the range < 3 f_1, f_2 is to be understood as the lowest frequency above this range at which the spectrum magnitude is -3 dB from the peak magnitude.

3.5
attenuated bounded-square output power
$P_{1\text{x}1,\alpha}(z)$
The maximum value of the **attenuated output power** passing through any one square centimeter of the plane perpendicular to the **beam axis** at depth z

NOTE 1 At z = 0 (the transducer surface) $P_{1\text{x}1,\alpha}(z)$ becomes the **bounded-square output power**, that is, at z = 0, $P_{1\text{x}1,\alpha} = P_{1\text{x}1}$.

NOTE 2 **Attenuated bounded-square output power** is expressed in watts (W).

3.6
attenuated output power
$P_\alpha(z)$
value of the acoustic **output power** after attenuation, at a specified distance from the **external transducer aperture**, and given by

$$P_\alpha(z) = P\,10^{(-\alpha z\, f_{\text{awf}}/10\,\text{dB})} \tag{1}$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** to the point of interest;

f_{awf} is the **acoustic working frequency**;

P is the **output power** measured in water.

NOTE 1 **Attenuated output power** is expressed in watts (W).

NOTE 2 In the case of stand-offs the P should represent the **output power** emanating from the stand-off.

3.7
attenuated peak-rarefactional acoustic pressure
$p_{\text{r},\alpha}(z)$
value of the **peak-rarefactional acoustic pressure** after attenuation, at a specified distance from the **external transducer aperture**, and given by

$$p_{r,\alpha}(z) = p_r(z) 10^{(-\alpha z f_{awf}/20 dB)} \quad (2)$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** to the point of interest;

f_{awf} is the **acoustic working frequency**;

$p_r(z)$ is the **peak-rarefactional acoustic pressure** measured in water.

NOTE Attenuated peak-rarefactional acoustic pressure is expressed in pascals (Pa).

3.8
attenuated pulse-intensity integral
pii$_{\alpha}$ **(z)**
value of the **pulse-intensity integral** after attenuation, at a specified distance from the **external transducer aperture**, and given by

$$pii_{\alpha}(z) = pii\,10^{(-\alpha z f_{awf}/10 dB)} \quad (3)$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** to the point of interest;

f_{awf} is the **acoustic working frequency**;

pii is the **pulse-intensity integral** measured in water.

NOTE **Attenuated pulse-intensity integral** is expressed in joules per metre squared, (J m^{-2}).

3.9
attenuated spatial-average temporal-average intensity
$I_{sata,\alpha}(z)$
value of the **spatial-average temporal-average intensity** after attenuation, at a specified distance from the **external transducer aperture**, and given by

$$I_{sata,\alpha}(z) = I_{sata}\,10^{(-\alpha z f_{awf}/10 dB)} \quad (4)$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** to the point of interest;

f_{awf} is the **acoustic working frequency**;

I_{sata} is the **spatial-average temporal-average intensity**, at a specified distance z measured in water.

NOTE **Attenuated spatial-average temporal-average intensity** is expressed in watts per metre squared, (W m^{-2}).

3.10
attenuated spatial-peak temporal-average intensity
$I_{spta,\alpha}(z)$
value of the **spatial-peak temporal-average intensity** after attenuation, at a specified distance from the **external transducer aperture**, and given by

$$I_{spta,\alpha}(z) = I_{spta}\,10^{(-\alpha z f_{awf}/10 dB)} \quad (5)$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** to the point of interest;

f_{awf} is the **acoustic working frequency**;

I_{spta} is the **spatial-peak temporal-average intensity**, at a specified distance z measured in water.

NOTE **Attenuated spatial-peak temporal-average intensity** is expressed in watts per metre squared, (W m^{-2}).

3.11
attenuated temporal-average intensity

$I_{ta,\alpha}(z)$

value of the **temporal-average intensity** after attenuation, at a specified distance from the **external transducer aperture**, and given by

$$I_{ta,\alpha}(z) = I_{ta}(z)10^{(-\alpha z f_{awf}/10\text{dB})} \tag{6}$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** to the point of interest;

f_{awf} is the **acoustic working frequency**;

$I_{ta}(z)$ is the **temporal-average intensity** measured in water.

NOTE **Attenuated temporal-average intensity** is expressed in watts per metre squared, (W m^{-2}).

3.12
beam area

$A_b(z)$

area in a specified plane perpendicular to the **beam axis** consisting of all points at which the **pulse-pressure-squared integral** is greater than a specified fraction of the maximum value of the **pulse-pressure-squared integral** in that plane

NOTE 1 If the position of the plane is not specified, it is the plane passing through the point corresponding to the **spatial-peak temporal-peak acoustic pressure** in the whole acoustic field.

NOTE 2 In a number of cases, the term **pulse-pressure-squared integral** is replaced everywhere in the above definition by any linearly related quantity, e.g.:

a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689 [4];

b) in cases where signal synchronisation with the scanframe is not available, the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity.**

NOTE 3 Some specified levels are 0,25 and 0,01 for the -6 dB and -20 dB beam areas, respectively.

NOTE 4 Beam area is expressed in metres squared (m^2).

[IEC 62127-1:2007, definition 3.7, modified]

3.13
beam-axis

straight line that passes through the beam centrepoints of two planes perpendicular to the line which connects the point of maximal pulse-pressure-squared integral with the centre of the external transducer aperture

NOTE 1 See Figure 1.

NOTE 2 The location of the first plane is the location of the plane containing the maximum **pulse-pressure-squared integral** or, alternatively, is one containing a single main lobe which is in the focal Fraunhofer zone. The location of the second plane is as far as is practicable from the first plane and parallel to the first with the same two orthogonal scan lines (*x* and *y* axes) used for the first plane.

NOTE 3 In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.:

a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689,

b) in cases where signal synchronisation with the scan frame is not available the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

[IEC 62127-1:2007, definition 3.8]

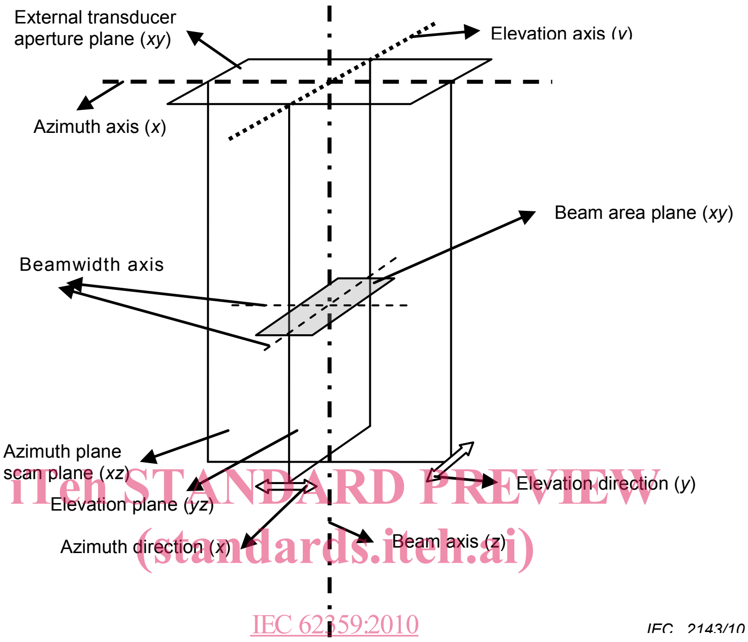

Figure 1 – Schematic diagram of the different planes and lines in an ultrasonic field
(modified from IEC 61828 and IEC 62127-1)

3.14
beam centrepoint

position determined by the 2D centroid of a set of **pulse-pressure-squared integrals** measured over the -6dB beam-area in a specified plane

NOTE Methods for determining 2D centroids are described in Annex B and C of IEC 61828.

3.15
beamwidth midpoint

linear average of the coordinates of the locations midway between each pair of points determining a **beamwidth** in a specified plane

NOTE The average is taken over as many **beamwidth** levels given in B.2 of IEC 61828 as signal level permits.

[IEC 62127-1:2007, definition 3.10, modified]

3.16
beamwidth

w_6, w_{12}, w_{20}

greatest distance between two points on a specified axis perpendicular to the **beam axis** where the **pulse-pressure-squared integral** falls below its maximum on the specified axis by a specified amount

NOTE 1 In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.:

a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689 [4],

b) in cases where signal synchronisation with the scan frame is not available the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

NOTE 2 Commonly used **beamwidth**s are specified at –6 dB, –12 dB and –20 dB levels below the maximum. The decibel calculation implies taking 10 times the logarithm to the base of 10 of the ratios of the integrals.

NOTE 3 **Beamwidth** is expressed in metres (m).

[IEC 62127-1:2007, definition 3.11]

3.17
bone thermal index
TIB
thermal index for applications, such as foetal (second and third trimester) or neonatal cephalic (through the fontanelle), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone

NOTE 1 See 5.4.2 and 5.5.2 for methods of determining the bone thermal index.

NOTE 2 See Annex A for rationale and derivation notes.

3.18
bounded-square output power
P_{1x1}
maximum value of the time average **acoustic output power** emitted from any one-centimetre square region of the active area of the transducer, the one-centimetre square region having 1 cm dimensions in the x- and y-directions

NOTE 1 The side of the 1 cm × 1 cm square should be aligned with the azimuth axis in accordance with Figure 1. See A.4.1.4 and Annex B for more detail.

NOTE 2 **Bounded-square output power** is expressed in watts (W).

3.19
break-point depth
z_{bp}
closest distance, to the solid surface of the transducer or the enclosure of any stand-off path, used during a search to determine below-surface *TIS* and *TIB*

$$z_{bp} = 1{,}5 \text{ x } D_{eq} \tag{7}$$

where D_{eq} is the **equivalent aperture diameter**.

NOTE 1 Specifically, for the **mechanical index**: the search should continue till the depth z_{MI}. Reasonable care should be taken not to go so close to the transducer face as to risk the integrity of the hydrophone or the validity of the measurement.

NOTE 2 For **scanning modes,** D_{eq} is calculated using the **output beam area** of one **ultrasonic scan line**; the central scan line, corresponding to the beam axis (i.e. the line where *pii*, *MI, and* f_{awf} are measured).

NOTE 3 See Annex A for rationale and derivation notes.

NOTE 4 **Breakpoint depth** is expressed in metres (m).

3.20
combined-operating mode
mode of operation of an **equipment** that combines more than one **discrete-operating mode**

[IEC 61157:2007, definition 3.17.1]

3.21
cranial-bone thermal index
TIC