

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

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National foreword

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**Ultrasonics –
Field characterization –
Test methods for the determination of thermal and mechanical indices
related to medical diagnostic ultrasonic fields
(IEC 62359:2005)**

Ultrasons –
Caractérisation du champ –
Essais pour la détermination des indices
d'échauffement et mécaniques
des champs d'ultrasons utilisés
pour le diagnostic médical
(CEI 62359:2005)

Ultraschall –
Charakterisierung von Feldern -
Prüfverfahren für die Ermittlung des
thermischen und des mechanischen
Indexes bezogen auf medizinisch-
diagnostische Ultraschallfelder
(IEC 62359:2005)

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Foreword

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Endorsement notice

The text of the International Standard IEC 62359:2005 was approved by CENELEC as a European Standard without any modification.

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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 which 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 a 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.

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 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 In this standard where multiples or submultiples of SI units are used this is clearly stated and the usage is self-consistent.

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 safety of ultrasonic medical diagnostic and monitoring equipment*

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*

IEC 61157:1992, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*

IEC 61161:1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz* ¹⁾
Amendment 1 (1998)

3 Terms and definitions

For the purposes of this International standard, the terms and definitions given in IEC 61102:1991, IEC 61157:1992 and IEC 61161:1998 (several of which are repeated below for convenience) and the following apply.

3.1

acoustic attenuation coefficient

coefficient intended to account for ultrasonic attenuation of tissue between the source and a specified point

Symbol: α

1) A consolidated edition (1.1) exists, including IEC 61161:1992 and its Amendment 1 (1998).

Unit: decibels per centimetre per megahertz, dB cm⁻¹ MHz⁻¹

3.2

acoustic working frequency

arithmetic mean of the most widely separated frequencies f_1 and f_2 at which the amplitude of the pressure spectrum of the acoustic signal is 3 dB lower than the peak amplitude

[3.4.2 of IEC 61102:1991, modified]

Symbol: f_{awf}

Unit: megahertz, MHz

3.3

attenuated output power

value of the acoustic **output power** after attenuation and at a specified distance from the transducer, and given by

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

where

α is the **acoustic attenuation coefficient**;

z is the distance from the source to the point of interest;

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

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

Symbol: P_{α}

Unit: milliwatts, mW

3.4

attenuated peak-rarefactional acoustic pressure

value of the **peak-rarefactional acoustic pressure** after attenuation and at a specified point, and given by

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

where

α is the **acoustic attenuation coefficient**;

z is the distance from the source to the point of interest;

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

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

Symbol: $p_{r,\alpha}$

Unit: megapascals, MPa

3.5

attenuated pulse-average intensity

value of the acoustic **pulse-average intensity** after attenuation and at a specified point, and given by

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

where

- α is the **acoustic attenuation coefficient**;
- z is the distance from the source to the point of interest;
- f_{awf} is the **acoustic working frequency**;
- $I_{\text{pa}}(z)$ is the **pulse-average intensity** measured in water.

Symbol: $I_{\text{pa},\alpha}$

Unit: watts per centimetre squared, W cm^{-2}

3.6

attenuated pulse-intensity integral

value of the **pulse-intensity integral** after attenuation and at a specified point, and given by

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

where

- α is the **acoustic attenuation coefficient**;
- z is the distance from the source to the point of interest;
- f_{awf} is the **acoustic working frequency**;
- I_{pi} is the **pulse-intensity integral** measured in water.

Symbol: $I_{\text{pi},\alpha}$

Unit: millijoules per centimetre squared, mJ cm^{-2}

3.7

attenuated spatial-peak temporal-average intensity

value of the **spatial-peak temporal-average intensity** after attenuation and at a specified distance z , and given by

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

where

- α is the **acoustic attenuation coefficient**;
- z is the distance from the source to the point of interest;
- f_{awf} is the **acoustic working frequency**;
- $I_{\text{zpta},\alpha}(z)$ is the **spatial-peak temporal-average intensity**, at a specified distance z measured in water.

Symbol: $I_{\text{zpta},\alpha}(z)$

Unit: milliwatts per centimetre squared, mW cm^{-2}

3.8

attenuated temporal-average intensity

value of the **temporal-average intensity** after attenuation and at a specified point, and given by

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

where

- α is the **acoustic attenuation coefficient**;

z is the distance from the source to the point of interest;
 f_{awf} is the **acoustic working frequency**;
 $I_{\text{ta}}(z)$ is the **temporal-average intensity** measured in water.

Symbol: $I_{\text{ta},\alpha}(z)$

Unit: milliwatts per centimetre squared, mW cm⁻²

3.9

beam area

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

[3.6 of IEC 61102:1991, modified]

NOTE For measurement purposes the **pulse intensity integral** can be taken as being proportional to the **pulse pressure-squared integral**

3.10

beam alignment axis

straight line joining the points of maximum **pulse intensity integral** measured at several different distances in the far field. For the purposes of alignment, this line may be projected to the face of the **ultrasonic transducer**

[3.5 of IEC 61102:1991, modified]

3.11

bone thermal index

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

Symbol: *TIB*

Unit: None

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

3.12

bounded output power

output power emitted in **scanning mode** from a region of the active area of the transducer whose width in the scan plane is limited to 1 cm

Symbol: P_1

Unit: milliwatts, mW

3.13

break-point depth

value equal to 1,5 times the **equivalent aperture diameter**, and given by

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

where

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

Symbol: z_{bp}

Unit: centimetres, cm

3.14

combined-operating mode

mode of operation of an **equipment** which combines more than one **discrete-operating mode**

[3.6 of IEC 61157:1992, modified]

3.15

cranial-bone thermal index

thermal index for applications, such as paediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body

Symbol: *TIC*

Unit: None

NOTE See 5.4.3 and 5.5.3 for methods of determining the **cranial bone thermal index**.

3.16

default setting

specific state of control, the **ultrasonic diagnostic equipment** will enter upon power-up, new **patient** select or change from non-foetal to foetal applications

3.17

depth for bone thermal index

distance from the plane where the **–12 dB output beam dimensions** are determined along the **beam alignment axis** to the plane where the product of **attenuated output power** and **attenuated pulse-intensity integral** is maximum

Symbol: z_b

Unit: centimetres, cm

3.18

depth for soft-tissue thermal index

distance from the plane where the **–12 dB output beam dimensions** are determined along the **beam alignment axis** to the plane at which the lower value of the **attenuated output power** and the product of the **attenuated spatial-peak temporal-average intensity** and 1 cm^2 is maximized over the distance range equal to, or more than, 1,5 times the **equivalent aperture diameter**

Symbol: z_s

Unit: centimetres, cm

NOTE In this standard, the restricted definition of **spatial-peak temporal-average intensity** from 3.49 of IEC 61102:1991 relating to a specified plane is used where **spatial-peak temporal-average intensity** is replaced by **attenuated spatial-peak temporal-average intensity**.

3.19

discrete-operating mode

mode of operation of **ultrasonic diagnostic equipment** in which the purpose of the excitation of the **ultrasonic transducer** or **ultrasonic transducer** element group is to utilize only one diagnostic methodology

[3.7 of IEC 61157:1992]

3.20**equivalent aperture diameter**

diameter of a circle whose area is the **–12 dB output beam area** and given by

$$D_{\text{eq}} \equiv \sqrt{\frac{4}{\pi} A_{\text{aprt}}}$$

where A_{aprt} is the **–12 dB output beam area**.

Symbol: D_{eq}

Unit: centimetres, cm

NOTE This formula gives the diameter of a circle whose area is the **–12 dB output beam area**. It is used in the calculation of the **cranial-bone thermal index** and the **soft tissue thermal index**.

3.21**equivalent beam area**

value of the area of the acoustic beam at the distance z in terms of power and intensity, and given by

$$A_{\text{eq}}(z) \equiv \frac{P_{\alpha}(z)}{I_{\text{zpta},\alpha}(z)} = \frac{P}{I_{\text{zpta}}(z)}$$

where

$P_{\alpha}(z)$ is the **attenuated output power**, at the distance z ;

$I_{\text{zpta},\alpha}(z)$ is the **attenuated spatial-peak temporal-average intensity**, at the distance z ;

P is the **output power**;

$I_{\text{zpta}}(z)$ is the **spatial-peak temporal-average intensity**, at the distance z ; and

z is the distance from the source to the specified point.

Symbol: $A_{\text{eq}}(z)$

Unit: centimetres squared, cm²

3.22**equivalent beam diameter**

value of the diameter of the acoustic beam at the distance z in terms of the **equivalent beam area**, and given by

$$d_{\text{eq}}(z) = \sqrt{\frac{4}{\pi} A_{\text{eq}}(z)}$$

where

$A_{\text{eq}}(z)$ is the **equivalent beam area**;

z is the distance from the source to the specified point.

Symbol: $d_{\text{eq}}(z)$

Unit: centimetres, cm

3.23

mechanical index

mechanical index is given by

$$MI = \frac{p_{r,\alpha} f_{awf}^{-1/2}}{C_{MI}}$$

where

$C_{MI} = 1 \text{ MPa MHz}^{-1/2}$;

$p_{r,\alpha}$ is the **attenuated peak-rarefactional acoustic pressure**;

f_{awf} is the **acoustic-working frequency**.

Symbol: MI

Unit: None

3.24

non-scanning mode

mode of operation of **ultrasonic diagnostic equipment** that involves a sequence of ultrasonic pulses which give rise to ultrasonic scan lines that follow the same acoustic path

[3.12 of IEC 61157:1992, modified]

3.25

–12 dB output beam area

area of the ultrasonic beam derived from the **–12 dB output beam dimensions**

[3.13 of IEC 61157:1992, modified]

Symbol: A_{aprt}

Unit: centimetre squared, cm^2

3.26

–12 dB output beam dimensions

dimensions of the ultrasonic beam (**–12 dB pulse beam width**) in specified directions normal to the **beam alignment axis** and at the transducer output face

[3.14 of IEC 61157:1992, modified]

NOTE 1 For reasons of measurement accuracy, the **–12 dB output beam dimensions** can be derived from measurements at a distance chosen to be as close as possible to the face of the transducer, and if possible no more than 1 mm from the face.

NOTE 2 For contact transducers, these dimensions can be taken as the dimensions of the radiating element.

Symbol: X, Y

Unit: centimetres, cm

3.27

output power

time-average ultrasonic power radiated by an **ultrasonic transducer** into an approximately free field under specified conditions in a specified medium, preferably water

[3.5 of IEC 61161:1998]

Symbol: P

Unit: milliwatts, mW

3.28**peak-rarefactional acoustic pressure**

maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field during an acoustic repetition period

[3.34 of IEC 61157:1992, modified]

Symbol: p_r

Unit: megapascals, MPa

3.29**prudent-use statement**

affirmation of the principle advising avoidance of primarily high exposure levels and secondarily long exposure times while acquiring necessary clinical information

NOTE See Bibliography [1, 2, 3, 4, 5]²⁾

3.30**pulse beam-width**

distance between two points, on a specified surface in a specified direction passing through the point of maximum **pulse-pressure-squared integral** (p_i) in that surface, at which the **pulse-pressure-squared integral** is a specified fraction of the maximum value in that surface

[3.18 of IEC 61157:1992, modified]

Symbol: d_{-6} (for **pulse beam-width** defined at –6dB)

Unit: centimetres, cm

3.31**pulse duration**

1,25 times the interval between the time when the time integral of intensity in an acoustic pulse at a point reaches 10 % and when it reaches 90 % of the **pulse intensity integral**

[3.30 of IEC 61102:1991, modified]

Symbol: t_d

Unit: seconds, s

3.32**pulse-intensity integral**

time integral of the instantaneous intensity at a particular point in an acoustic field integrated over the acoustic pulse waveform

[3.31 of IEC 61102:1991]

Symbol: I_{pi}

Unit: millijoules per centimetre squared, mJ cm⁻²

3.33**pulse-pressure-squared integral**

time integral of the square of the instantaneous acoustic pressure at a particular point in an acoustic field integrated over the acoustic pulse waveform

[3.33 of IEC 61102:1991]

²⁾ Figures in square brackets refer to the Bibliography.