# INTERNATIONAL STANDARD

# IEC 62359

First edition
2005-04

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



Reference number
IEC 62359:2005(E)

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE X

*For price, see current catalogue*

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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

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

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

| FDIS | Report on voting |
|---|---|
| 87/300/FDIS | 87/305/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.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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- withdrawn;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.

A bilingual version of this standard may be issued at a later date.

# 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: $\alpha$

Unit: decibels per centimetre per megahertz, dB $cm^{-1}$ $MHz^{-1}$

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

**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: $f_{\text{awf}}$

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

$\alpha$ is the **acoustic attenuation coefficient**;

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

$f_{\text{awf}}$ is the **acoustic working frequency**;

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

Symbol: $P_\alpha$

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

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

where

$\alpha$ is the **acoustic attenuation coefficient**;

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

$f_{\text{awf}}$ is the **acoustic working frequency**;

$p_\text{r}(z)$ is the **peak-rarefactional acoustic pressure** measured in water.

Symbol: $p_{\text{r},\alpha}$

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

$\alpha$ is the **acoustic attenuation coefficient**;

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

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

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

Symbol: $I_{pa,\alpha}$

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

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

where

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

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



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

where

$\alpha$ is the **acoustic attenuation coefficient**;

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

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

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

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

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

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

where

$\alpha$ is the **acoustic attenuation coefficient**;

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

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

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

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

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

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

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]