IEC 62359

Edition 2.0 2017-09

INTERNATIONAL STANDARD

AMENDMENT 1

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

IEC 62359:2010-10/AMD1:2017-09(en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 17.140.50

ISBN 978-2-8322-4821-8

FOREWORD

This amendment has been prepared by IEC technical committee 87: Ultrasonics.

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

FDIS	Report on voting
87/661/FDIS	87/665/RVD

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

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 website 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- withdrawn,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 publication may be issued at a later date.

Introduction to Amendment

The second edition of IEC 62359 was published in 2010. Since then, IEC 60601-2-37:2007/AMD1:2015 has been published and calls for provision of **attenuated spatial peak temporal average intensity**, $I_{\mathrm{spta},\alpha}$, and **attenuated spatial peak pulse average intensity**, $I_{\mathrm{sppa},\alpha}$, at specific spatial maximum points in the ultrasonic field on the **beam axis**. No IEC standard describes the determination of these quantities at these specific positions. IEC 62359 for determining the thermal indices currently uses similar values at other positions, therefore, the determination of **attenuated spatial peak temporal average intensity**, $I_{\mathrm{spta},\alpha}$, and **attenuated spatial peak pulse average intensity**, $I_{\mathrm{sppa},\alpha}$, has been added as an annex in this amendment.

Additionally, references to newly published collateral standards have been updated.

2 Normative references

Replace the first reference by the following:

IEC 60601-2-37:2007, *Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*
IEC 60601-2-37:2007/AMD1:2015

Replace the second reference by the following:

IEC 61157:2007, *Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment*
IEC 61157:2007/AMD1:2013

*Replace, in the third reference, "*IEC 61161:2006" *by "*IEC 61161:2013".

Replace the fifth reference by the following:

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*
IEC 62127-1:2007/AMD1:2013

3 Terms and definitions

Replace the first existing paragraph by the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-2-37, IEC 62127-1, IEC 62127-2, IEC 62127-3, IEC 61157 and IEC 61161 apply. Several of these are repeated below for convenience and others are listed because they have been modified for application to this standard.

3.3
acoustic repetition period

Replace the existing definition by the following new definition:

time interval between corresponding points of consecutive cycles, pulses or scans, depending on the current operating mode

Add the following new NOTES 2 and 3:

NOTE 2 For continuous wave modes, the **acoustic repetition period** is the time interval between corresponding points of consecutive cycles

NOTE 3 For **combined operating modes** where transmit pulsing of the constituent modes may be interrupted, the ***arp*** determination should take into account non-pulsing time to calculate an average period.

Replace "NOTE 2" *by* NOTE 4".

3.4
acoustic working frequency

Replace, in the existing definition, the words "at the position corresponding to the **spatial-peak temporal-peak acoustic pressure**" *by* "on the **beam axis**, beyond the **break-point depth**, corresponding to **depth of maximum pulse-intensity integral** z_{pii}."

Replace, in existing NOTE 2, the words "at the position of maximum **pulse-pressure-squared integral**" *by* "at the **depth for peak pulse-intensity integral**".

3.7
attenuated peak-rarefactional acoustic pressure

Replace, in the existing definition, the words "at a specified distance from" *by* "on a plane perpendicular to the **beam axis** at a specified distance z from".

Replace, in the definition list after Equation (2), the words "z is the distance from the **external transducer aperture** to the point of interest" *by* "z is the distance from the **external transducer aperture** along the **beam axis** to the plane containing the point of interest".

3.8
attenuated pulse-intensity integral

Replace, in the definition, the words "at a specified distance from" *by* "on a plane perpendicular to the **beam axis** at a specified distance z from".

Replace, in the definition list after Equation (3), the words "z is the distance from the **external transducer aperture** to the point of interest" *by* "z is the distance from the **external transducer aperture** along the **beam axis** to the plane containing the point of interest".

Replace "NOTE" *by* "NOTE 1".

Add new NOTE 2:

NOTE 2 For measurement purposes of this standard, pii_α is equivalent to $1/(\rho c)$ times the **attenuated pulse-pressure-squared integral** at depth z, with ρc denoting the characteristic acoustic impedance of pure water.

3.9
attenuated spatial-average temporal-average intensity

Replace, in the definition, the words "at a specified distance from" *by "*on a plane perpendicular to the **beam axis** at a specified distance z from".

Replace, in the definition list after Equation (4), the words "z is the distance from the **external transducer aperture** to the point of interest" *by* "z is the distance from the **external transducer aperture** along the **beam axis** to the plane containing the point of interest".

3.10
attenuated spatial-peak temporal-average intensity

Replace, in the definition, the words "at a specified distance from" *by* "on a plane perpendicular to the **beam axis** at a specified distance z from".

Replace, in the definition list after Equation (5), the words "z is the distance from the **external transducer aperture** to the point of interest" *by* "z is the distance from the **external transducer aperture** along the **beam axis** to the plane containing the point of interest".

3.11
attenuated temporal-average intensity

Replace, in the definition, the words "at a specified distance from" *by* "on a plane perpendicular to the **beam axis** at a specified distance z from".

Replace, in the definition list after Equation (6), the words "z is the distance from the **external transducer aperture** to the point of interest" *by* "z is the distance from the **external transducer aperture** along the **beam axis** to the plane containing the point of interest".

3.13
beam-axis

Replace the term "**beam-axis**" *by* "**beam axis**".

3.17
bone thermal index

Delete, in the definition, "or neonatal cephalic (through the fontanelle)".

3.19
break-point depth

Add, after the existing definition, *the words* "**acoustic working frequency** and intensity parameters (such as **attenuated spatial-peak temporal-average intensity**)"

Add, after "where D_{eq} is the **equivalent aperture diameter**" *the words* "for **non-scanning modes**".

Replace the existing NOTE 2 by the following new note:

NOTE 2 For **scanning modes,** use the **non-scanning mode** D_{eq} value calculation [Equation (8)]. Do this 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).

3.21
cranial-bone thermal index

Replace the existing definition by the following new definition:

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

3.22
default setting

Replace, in the definition, "**ultrasonic diagnostic equipment**" *by* "**medical diagnostic ultrasonic equipment**".

3.23
depth for mechanical index

Replace, in the definition, the words "to the plane of maximum **attenuated pulse-intensity integral** (pii_{α})" *by* "to the plane of maximum **attenuated pulse-pressure-squared-integral** ($ppsi_{\alpha}$)".

Add new NOTE 1:

NOTE 1 Because z_{MI} may occur closer to the transducer than the **break-point depth** z_{bp}, use of $ppsi_{\alpha}$ rather than pii_{α} is technically more appropriate. If $z_{ppsi,\alpha}$ is larger than z_{bp}, then $z_{ppsi,\alpha}$ and $z_{pii,\alpha}$ are equal.

Replace "NOTE" *by* "NOTE 2".

3.24
depth for peak pulse-intensity integral

Replace the existing term, definition and note by the following new term, definition and notes:

3.24
depth for maximum pulse intensity integral
depth z on the **beam axis** and beyond the **break-point depth** z_{bp} from the **external transducer aperture** to the plane of maximum **pulse-intensity integral** (pii) as approximated by the **pulse-pressure-squared integral** ($ppsi$)

NOTE 1 **Depth for maximum *pii*** is expressed in metres (m).

NOTE 2 **Depth for maximum *pii*** is termed "depth for peak pulse-intensity integral" in IEC 60601-2-37:2007/AMD1:2015.

NOTE 3 At this depth the **acoustic working frequency** is determined.

3.27
Discrete-perating mode

Replace the term "**Discrete-perating mode**" *by* "**discrete-operating mode**".

Replace, in the definition, "**ultrasonic diagnostic equipment**" *by* "**medical diagnostic ultrasonic equipment**".

3.28
equivalent aperture diameter

Replace the existing definition and equation by the following new definition and equation:

diameter of a circle the area A of which is the –12 dB **output beam area** A_{ob} for **non-scanning modes** and the –12 dB **scanned aperture area** A_{sa} for **scanning modes**, given by

$$D_{eq} = \sqrt{\frac{4}{\pi} A} \tag{8}$$

Replace the existing NOTE 1 by the following new note:

NOTE 1 Equation (8) is used in the calculation of the **cranial-bone thermal index**; for **non-scanning modes** with $A = A_{ob}$ and for **scanning modes** with $A = A_{sa}$.

Add new NOTE 2:

NOTE 2 Equation (8) with $A = A_{ob}$ is also used in calculating the **break-point depth**.

Replace "NOTE 2" *by* "NOTE 3".

3.33
medical diagnostic ultrasonic equipment

Replace "NOTE" *by* "NOTE 1".

Add new NOTE 2:

NOTE 2 IEC 60601-2-37:2007 uses the term "ultrasonic diagnostic equipment" instead of **medical diagnostic ultrasonic equipment**.

3.34
non-scanning mode

Replace, in the definition, the words "**ultrasonic diagnostic equipment**" *by* "**medical diagnostic ultrasonic equipment**".

3.37
output power

Replace, in the source, "IEC 61161:2006" *by* "IEC 61161:2013".

3.40
prudent-use statements

Replace the existing definition *by the following new definition:*

affirmations of the principle that only necessary clinical information should be acquired and that high exposure levels and long exposure times should be avoided

3.44
pulse repetition period

Add new NOTE 1:

NOTE 1 In general, for **non-scanning modes** the **pulse repetition period** needs to be adjusted to represent a ‘per-second’ average taking into account interruptions-in, or non-constant, pulsing; e.g. such as may occur in **combined operating modes**.

Replace "NOTE" *by* "NOTE 2".

3.49
scanning mode
Replace, in the definition, the words "an **ultrasonic diagnostic equipment**" *by* "a **medical diagnostic ultrasonic equipment**".

3.54
spatial-peak temporal-average intensity

Replace the existing NOTE 1 by the following new note:

NOTE 1 For systems in **combined-operating modes,** the averaging time period needs to be sufficient to include periods in which scanning or pulsing is interrupted.

3.56
thermal index

Replace, in the definition, the two occurrences of the words " **attenuated acoustic power"** *by* **"attenuated output power"**

Add the following new definitions:

3.61
instantaneous acoustic pressure
***p*(*t*)**
pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field

NOTE **Instantaneous acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.33, modified – The reference to IEV 801-01-19 has been removed in the definition]

3.62
attenuated instantaneous acoustic pressure
$\boldsymbol{p_\alpha(z,t)}$
value of the **instantaneous acoustic pressure** at time t after attenuation on a plane perpendicular to the **beam axis** at a specified distance z from the source, and given by

$$p_\alpha(z,t) = p(z,t)10^{(-\alpha z f_{\text{awf}}/20\ \text{dB})} \tag{26}$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the source to the point (plane) of interest;

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

$p(z,t)$ is the **instantaneous acoustic pressure**

NOTE **Attenuated instantaneous acoustic pressure** is expressed in pascals (Pa).

3.63
attenuated pulse-pressure-squared integral
***ppsi*$_\alpha$(*z*)**
time integral of the square of the **attenuated instantaneous acoustic pressure**, integrated over the acoustic pulse waveform, on a plane perpendicular to the **beam axis** at a specified distance z in an acoustic field

$$ppsi_\alpha(z) = \int p_\alpha{}^2(z,t)dt = \int \left[p(z,t)10^{(-\alpha z f_{\text{awf}}/20\text{ dB})}\right]^2 dt = ppsi(z)\times 10^{(-\alpha z f_{\text{awf}}/10\text{ dB})} \quad (27)$$

where

$p(z,t)$ is the **instantaneous acoustic pressure** at depth z.

α is the **acoustic attenuation coefficient**;

z is the distance from the source to the point (plane) of interest;

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

$ppsi$ is the **pulse-pressure-squared integral**

NOTE 1 **Attenuated pulse-pressure-squared integral** is expressed in pascal squared seconds (Pa^2s).

NOTE 2 See definition 3.43 for the non-attenuated version; with the addition here of the perpendicular plane at depth z.

3.64
attenuated scan intensity integral
***sii*$_\alpha$(*z*)**
sum of the **attenuated pulse intensity integrals** in one scan (one frame of **ultrasonic scan lines**) at depth z

NOTE 1 **Attenuated scan intensity integral** is expressed in joules per square metre (Jm^{-2}).

NOTE 2 For measurement purposes of this standard, $sii_\alpha(z)$ is equivalent to $1/(\rho c)$ times the **sum of attenuated pulse-pressure-squared integrals** at depth z, for $z \geq z_{\text{bp}}$, with ρc denoting the characteristic acoustic impedance of pure water.

NOTE 3 See definition 3.79 for the non-attenuated version.

3.65
attenuated spatial-peak pulse-average intensity
***I*$_{\text{sppa},\alpha}$(*z*)**
maximum value of the **spatial-peak pulse-average intensity** after attenuation, on a plane perpendicular to the **beam axis** at a specified distance z from the source, and given by

$$I_{\text{sppa},\alpha}(z) = \frac{1}{t_{\text{d}}(z)}\, pii_\alpha(z) \quad (28)$$

where

$t_{\text{d}}(z)$ is the **pulse duration** at the same depth z;

$pii_\alpha(z)$ is the **attenuated pulse-intensity integral** at depth z

NOTE 1 **Attenuated spatial-peak pulse-average intensity** is expressed in watts per square metre (Wm^{-2}).

NOTE 2 For measurement purposes of this standard, $pii_\alpha(z)$ is equivalent to $1/(\rho c)$ times the **attenuated pulse-pressure-squared integrals** at depth z, $ppsi_\alpha(z)$, for $z \geq z_{\text{bp}}$, with ρc denoting the characteristic acoustic impedance of pure water.

NOTE 3 See definition 3.81 for the non-attenuated version.

3.66
attenuated sum of pulse-pressure-squared integrals
$s_{\alpha}ppsi\ (z)$
attenuated value of the sum of **pulse-pressure-squared integrals** in one scan (one frame of **ultrasonic scan lines)** at depth z

NOTE 1 **Attenuated sum of pulse-pressure-squared integrals** is expressed in pascal squared seconds (Pa^2s).

NOTE 2 The **attenuated sum of pulse-pressure-squared integrals** at depth z will be equal to the **sum of attenuated pulse-pressure-squared integrals** if each **ultrasonic scan line** in the frame which is included in the sum has the same **acoustic working frequency**.

NOTE 3 See F.3.1.4.2 for additional explanation.

NOTE 4 See definition 3.83 for the non-attenuated version.

3.67
depth for maximum I_{sppa}
$z_{sppa,max}$
depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of maximum **spatial-peak pulse-average intensity**

NOTE 1 **Depth for maximum I_{sppa}** is expressed in metres (m).

NOTE 2 This depth is equivalent to the **depth for maximum *pii***.

3.68
depth for maximum $I_{sppa,\alpha}$
$z_{sppa,\alpha,max}$
depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of maximum **attenuated spatial-peak pulse-average intensity**

NOTE 1 **Depth for maximum $I_{sppa,\alpha}$** is expressed in metres (m).

NOTE 2 This depth is equivalent to the **depth for maximum pii_{α}**.

3.69
depth for maximum I_{spta}
$z_{spta,max}$
depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of maximum **spatial-peak temporal-average intensity**

NOTE 1 **Depth for maximum I_{spta}** is expressed in metres (m).

NOTE 2 For **non-scanning modes**, this depth is equivalent to the **depth for maximum *pii***. For **scanning modes**, it is equivalent to the **depth for maximum *sii***.

3.70
depth for maximum $I_{spta,\alpha}$
$z_{spta,\alpha,max}$
depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of maximum **attenuated spatial-peak temporal-average intensity**

NOTE 1 **Depth for maximum $I_{spta,\alpha}$** is expressed in metres (m).

NOTE 2 For **non-scanning modes**, this depth is equivalent to the **depth for maximum pii_{α}**. For **scanning modes**, it is equivalent to the **depth for maximum sii_{α}**.

3.71
depth for maximum pii_{α}
$z_{pii,\alpha}$
depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of maximum **attenuated pulse-intensity integral**