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**Ultrazvok - Karakterizacija polj - Preskusne metode za ugotavljanje termičnih in mehanskih znakov glede medicinskih diagnostičnih ultrazvočnih polj - Dopolnilo A1**

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

Ultraschall - Charakterisierung von Feldern - Prüfverfahren für die Ermittlung des thermischen und des mechanischen Indexes bezogen auf medizinische Ultraschalldiagnostikfelder  
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Ultrasons □ Caractérisation du champ □ Méthodes d'essai pour la détermination d'indices thermique et mécanique des champs d'ultrasons utilisés pour le diagnostic médical

**Ta slovenski standard je istoveten z: EN 62359:2011/A1:2018**

**ICS:**

11.040.55      Diagnostična oprema      Diagnostic equipment

**SIST EN 62359:2011/A1:2018**      en

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EUROPEAN STANDARD

**EN 62359:2011/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2018

ICS 17.140.50

English Version

Ultrasonics - Field characterization - Test methods for the  
determination of thermal and mechanical indices related to  
medical diagnostic ultrasonic fields  
(IEC 62359:2010/A1:2017)

Ultrasons - Caractérisation du champ - Méthodes d'essai  
pour la détermination d'indices thermique et mécanique des  
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Ultraschall - Charakterisierung von Feldern - Prüfverfahren  
für die Ermittlung des thermischen und des mechanischen  
Indexes bezogen auf medizinische  
Ultraschalldiagnostikfelder  
(IEC 62359:2010/A1:2017)

This amendment A1 modifies the European Standard EN 62359:2011; it was approved by CENELEC on 2017-11-03. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN 62359:2011/A1:2018 (E)

## European foreword

The text of document 87/661/FDIS, future edition 1 of IEC 62359:2010/A1:2017, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 62359:2011/A1:2018.

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2018-08-03
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2020-11-03

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

## Endorsement notice

The text of the International Standard IEC 62359:2010/A1:2017 was approved by CENELEC as a European Standard without any modification.

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Replace the Annex ZA by the following:

**Annex ZA**  
(normative)  
**Normative references to international publications**  
**with their corresponding European publications**

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.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cenelec.eu](http://www.cenelec.eu).

Publication	Year	Title	EN/HD	Year
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	EN 60601-2-37	2008
-	-		+ A11	2011
+ A1	2015		+ A1	2015
IEC 61157	2007	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment	EN 61157	2007
+ A1	2013		+ A1	2013
IEC 61161	2013	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	2013
IEC 61828	2001	Ultrasonics - Focusing transducers - Definitions and measurement methods for the transmitted fields	EN 61828	2001
IEC 62127-1	2007	Ultrasonics - Hydrophones -- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007
+ A1	2013		+ A1	2013
IEC 62127-2	2007	Ultrasonics - Hydrophones -- Part 2: Calibration for ultrasonic fields up to 40 MHz	EN 62127-2	2007
IEC 62127-3	2007	Ultrasonics - Hydrophones -- Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz	EN 62127-3	2007

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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**

[SIST EN 62359:2011/A1:2018](https://standards.iteh.ai/catalog/standards/sist/31efecff-be8a-4e49-9904-d29abf5792fc/sist-en-62359-2011-a1-2018)

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INTERNATIONAL  
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ICS 17.140.50

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**Warning! Make sure that you obtained this publication from an authorized distributor.**

## 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.

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

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## 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**,  $I_{\text{spta},\alpha}$ , and **attenuated spatial peak pulse average intensity**,  $I_{\text{sppa},\alpha}$ , 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**,  $I_{\text{spta},\alpha}$ , and **attenuated spatial peak pulse average intensity**,  $I_{\text{sppa},\alpha}$ , 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

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Replace the first existing paragraph by the following new paragraph:

SIST EN 62359:2011/A1:2018

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,  $p_{i_a}$  is equivalent to  $1/(\rho c)$  times the **attenuated pulse-pressure-squared integral** at depth  $z$ , with  $\rho c$  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  $p_{ii}$ ,  $MI$ , and  $f_{awt}$  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** ( $p_{ii\alpha}$ )" 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  $p_{ii\alpha}$  is technically more appropriate. If  $z_{ppsi,\alpha}$  is larger than  $z_{bp}$ , then  $z_{ppsi,\alpha}$  and  $z_{p_{ii,\alpha}}$  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** ( $p_{ii}$ ) as approximated by the **pulse-pressure-squared integral** ( $ppsi$ )

NOTE 1 **Depth for maximum  $p_{ii}$**  is expressed in metres (m).

NOTE 2 **Depth for maximum  $p_{ii}$**  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

$$D_{eq} = \sqrt{\frac{4}{\pi} A} \quad (8)$$

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:

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

Replace "NOTE 2" by "NOTE 3". [SIST EN 62359:2011/A1:2018](https://standards.iteh.ai/catalog/standards/sist/31efecff-be8a-4e49-9904-d29abf5792fc/sist-en-62359-2011-a1-2018)  
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### 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