SLOVENSKI STANDARD
SIST EN 62359:2011

01-april-2011

Nadomešča:
SIST EN 62359:2007

Ultrazvok - Karakterizacija polj - Preskusne metode za ugotavljanje termičnih in mehanskih znakov glede medicinskih diagnostičnih ultrazvočnih polj (IEC 62359:2010)

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

Ultraschall - Charakterisierung von Feldern - Prüfverfahren für die Ermittlung des thermischen und des mechanischen Indexes bezogen auf medizinische Ultraschalldiagnostikfelder (IEC 62359:2010)

Ultrasons - Caractérisation du champ - Méthodes d'essai pour la détermination d'indices thermique et mécanique des champs d'ultrasons utilisés pour le diagnostic médical (CEI 62359:2010)

Ta slovenski standard je istoveten z: **EN 62359:2011**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 62359:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62359

February 2011

ICS 17.140.50

Supersedes EN 62359:2005

English version

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

Ultrasons – Caractérisation du champ –
Méthodes d'essai pour la détermination d'indices thermique et mécanique des champs d'ultrasons utilisés pour le diagnostic médical
(CEI 62359:2010)

Ultraschall -
Charakterisierung von Feldern -
Prüfverfahren für die Ermittlung des thermischen und des mechanischen Indexes bezogen auf medizinische Ultraschalldiagnostikfelder
(IEC 62359:2010)

This European Standard was approved by CENELEC on 2011-02-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 Central Secretariat or to any CENELEC member.

This European Standard 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 62359:2011 E

Foreword

The text of document 87/445/FDIS, future edition 2 of IEC 62359, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62359 on 2011-02-01.

This European Standard supersedes EN 62359:2005.

Major changes with respect to EN 62359:2005 include the following:

– The methods of determination set out in EN 62359:2005 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 EN 62359:2010 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 EN 62359:2010 was “missing” *TI* equations. In EN 62359:2005 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 EN 62359:2005 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.

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

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2011-11-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2014-02-01

Annex ZA has been added by CENELEC.

Endorsement notice

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

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 61689 NOTE Harmonized as EN 61689.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

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

Publication	Year	Title	EN/HD	Year
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	EN 60601-2-37	-
IEC 61157	2007	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment	EN 61157	2007
IEC 61161	2006	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	2007
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
IEC 62127-2	2007	Ultrasonics - Hydrophones - Part 2: Calibration of hydrophones to be used in 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

IEC 62359

Edition 2.0 2010-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX XB

ICS 17.140.50

ISBN 978-2-88912-181-6

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of requirements for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

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 neper per metre per hertz (Np m^{-1} Hz^{-1}).

3.2
acoustic absorption coefficient
μ_a
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 decibels per metre per hertz (dB 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 $f_1 < f_2$.

3.5
attenuated bounded-square output power
$P_{1\mathrm{x}1,\alpha}(z)$
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) $P_{1\mathrm{x}1,\alpha}(z)$ becomes the **bounded-square output power**, that is, at z = 0, $P_{1\mathrm{x}1,\alpha} = P_{1\mathrm{x}1}$.

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

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

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