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Ultraljud – Fältkaraktärisering – Provning för bestämning av termiska och mekaniska index i diagnostiska ultraljudsfält

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

Som svensk standard gäller europastandarden EN 62359:2011. Den svenska standarden innehåller den officiella engelska språkversionen av EN 62359:2011.

Nationellt förord

Europastandarden EN 62359:2011

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 62359, Second edition, 2010 - Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields**

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Tidigare fastställd svensk standard SS-EN 62359, utgåva 1, 2008, gäller ej fr o m 2014-02-01.

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SEK Svensk Elstandard

Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard.se

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

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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

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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 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 $\text{dBcm}^{-1}\text{MHz}^{-1}$ 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*