

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

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 62359:2005 sisaldab Euroopa standardi EN 62359:2005 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 28.10.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 62359:2005 consists of the English text of the European standard EN 62359:2005.</p> <p>This document is endorsed on 28.10.2005 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>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.</p>	<p>Scope:</p> <p>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.</p>
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Võtmesõnad:

English version

**Ultrasonics –
Field characterization –
Test methods for the determination of thermal and mechanical indices
related to medical diagnostic ultrasonic fields
(IEC 62359:2005)**

Ultrasons –
Caractérisation du champ –
Essais pour la détermination des indices
d'échauffement et mécaniques
des champs d'ultrasons utilisés
pour le diagnostic médical
(CEI 62359:2005)

Ultraschall –
Charakterisierung von Feldern -
Prüfverfahren für die Ermittlung des
thermischen und des mechanischen
Indexes bezogen auf medizinisch-
diagnostische Ultraschallfelder
(IEC 62359:2005)

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 87/300/FDIS, future edition 1 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 2005-09-13.

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) | 2006-07-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2008-10-01 |

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62359:2005 was approved by CENELEC as a European Standard without any modification.

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 Where 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	- 1)	Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment	EN 60601-2-37	2001 2)
IEC 61102	1991	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	EN 61102	1993
IEC 61157	1992	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment	EN 61157	1994
IEC 61161	1992	Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz	EN 61161	1994
A1	1998		A1	1998

1) Undated reference.

2) Valid edition at date of issue.

INTERNATIONAL STANDARD

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First edition
2005-04

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



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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.
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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: α

Unit: decibels per centimetre per megahertz, dB cm⁻¹ MHz⁻¹

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