STN

Ultrazvuk Charakterizovanie polí Skúšobné metódy na určenie tepelných a mechanických indexov ultrazvukových polí používaných v lekárskej diagnostike Zmena A1

STN EN 62359/A1

34 0874

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/18

STN EN 62359 z júla 2011 sa bez tejto zmeny A1 môže používať do 3.11.2020.

Obsahuje: EN 62359:2011/A1:2018, IEC 62359:2010/AMD1:2017

STN EN 62359/A1: 2018

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM EN 62359:2011/A1

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 champs d'ultrasons utilisés pour le diagnostic médical (IEC 62359:2010/A1:2017) 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.

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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

STN EN 62359/A1: 2018

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- latest date by which the national standards conflicting with this document have to be withdrawn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

EN 62359:2011/A1:2018 (E)

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.

Publication IEC 60601-2-37	<u>Year</u> 2007	Title Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	<u>EN/HD</u> EN 60601-2-37	<u>Year</u> 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 z	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 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





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IEC 62359

Edition 2.0 2017-09

INTERNATIONAL STANDARD

AMENDMENT 1

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 17.140.50 ISBN 978-2-8322-4821-8

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IEC 62359:2010/AMD1:2017 © IEC 2017

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, $I_{\rm spta,\alpha}$, and attenuated spatial peak pulse average intensity, $I_{\rm sppa,\alpha}$, 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, $I_{\rm spta,\alpha}$, and attenuated spatial peak pulse average intensity, $I_{\rm sppa,\alpha}$, has been added as an annex in this amendment.

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

IEC 62359:2010/AMD1:2017 © IEC 2017 – 3 –

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

koniec náhľadu – text ďalej pokračuje v platenej verzii STN