SLOVENSKI STANDARD
SIST EN 61391-1:2008/A1:2018

01-februar-2018

Ultrazvok - Impulzno-odmevni skenerji - 1. del: Tehnike za kalibriranje prostorskih merilnih sistemov in meritve karakteristike funkcije razpršitve točk - Dopolnilo A1 (IEC 61391-1:2006/A1:2017)

Ultrasonics - Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of point-spread function response (IEC 61391-1:2006/A1:2017)

Ultraschall - Impuls-Echo-Scanner - Teil 1: Verfahren für die Kalibrierung von räumlichen Messsystemen und Messung der Charakteristik der Punktverwaschungsfunktion des Systems (IEC 61391-1:2006/A1:2017)

Spécifications pour types particuliers de fils de bobinage - Partie 0-7: Exigences générales - Fil de section circulaire, isolé en continu, en cuivre émaillé, sans défaut électrique (IEC 61391-1:2006/A1:2017)

Ta slovenski standard je istoveten z: **EN 61391-1:2006/A1:2017**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 61391-1:2008/A1:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61391-1:2006/A1

December 2017

ICS 17.140.50

English Version

Ultrasonics - Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response (IEC 61391-1:2006/A1:2017)

Ultrasons - Scanners à impulsion et écho - Partie 1: Techniques pour l'étalonnage des systèmes de mesure spatiaux et des mesures de la réponse de la fonction de dispersion ponctuelle du système (IEC 61391-1:2006/A1:2017)

Ultraschall - Impuls-Echo-Scanner - Teil 1: Verfahren für die Kalibrierung von räumlichen Messsystemen und Messung der Charakteristik der Punktverwaschungsfunktion des Systems (IEC 61391-1:2006/A1:2017)

This amendment A1 modifies the European Standard EN 61391-1:2006; it was approved by CENELEC on 2017-08-14. 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.

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

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

European foreword

The text of document 87/650/FDIS, future IEC 61391-1:2006/A1, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61391-1:2006/A1:2017.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2018-06-01
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2020-12-01

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 61391-1:2006/A1:2017 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 61391-1:2006, the following notes have to be **added** for the standards indicated:

IEC 62563-1:2009	NOTE	Harmonized as EN 62563-1:2010 (not modified).
IEC 61391-2:2010	NOTE	Harmonized as EN 61391-2:2010 (not modified).

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 Where 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	Year	Title	EN/HD	Year
In Annex ZA of EN 61391-1:2006 replace IEC 61102:1991 by the following:				
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007
Add to Annex ZA of EN 61391-1:2006 the following new references:				
IEC 60050-801	1994	International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics	-	-
IEC 60050-802	2011	International Electrotechnical Vocabulary - Part 802: Ultrasonics	-	-

IEC 61391-1

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INTERNATIONAL STANDARD

colour inside

AMENDMENT 1

Ultrasonics – Pulse-echo scanners –
Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 17.140.50

ISBN 978-2-8322-4289-6

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
87/650/FDIS	87/653/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this 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.

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.

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2 Normative references

Replace:

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*

with:

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

Insert the following new normative references in proper numerical sequence:

IEC 60050-801:1994, *International Electrotechnical Vocabulary – Chapter 801: Acoustics and electroacoustics*

IEC 60050-802:2011, *International Electrotechnical Vocabulary – Part 802: Ultrasonics*

3 Terms and definitions

Replace the first two paragraphs with the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60050-801:1994, IEC 60050-802:2011, IEC 62127-1:2007 and the following apply. See also related International Standards, Technical Specifications and Technical Reports for definitions and explanations [1] [2] [3] [4] [34] [35] [36] [37] [38] [39].

3.25
point-spread function
PSF

Add the following new sentence at the end of the NOTE:

The problem is solved by PSF mapping – see Annex D.

Add the following new terms and definitions to Clause 3, starting with 3.45.

3.45
accuracy
closeness of agreement between a test result and the accepted reference value

[SOURCE: ISO 5725-1:1994, 3.6]

3.46
axial resolution in a PSF-map
twice the Half-Width-at-Half-Maximum (HWHM) of a function's trace created from a set of increasing **pixel** values, commencing near zero and terminating at the first maximum value (centre of the **PSF**) and representing the leading edge of the echo signal from a point reflector located on the main beam axis

Note 1 to entry: The **axial resolution in a PSF map** differs from the **axial resolution** specified by 3.5. It is used for the **PSF**-mapping only to simplify the data acquisition.

Note 2 to entry: A detailed explanation of the **axial resolution in the PSF-map** measuring method is in D.6.1.4.

Note 3 to entry: The axial resolution mainly depends on the ultrasound frequency used, not on sonograph construction.

Note 4 to entry: **Axial resolution in a PSF-map** is expressed in metres.

3.47
brightness
luminance as perceived by the human visual system

[SOURCE: IEC 62563-1:2009, 3.1.2]

3.48
contrast
C
ratio of the difference of the luminance of two image areas, $L_1 - L_2$, divided by the average of the two luminance values:

$$C = 2\,(L_1 - L_2)/(L_1 + L_2)$$

[SOURCE: IEC 62563-1:2009, 3.1.6]

3.49
dynamic imaging
real-time imaging
imaging with a frame rate that is high enough to observe moving structures in apparently continuous motion

3.50
elevational resolution in a PSF-map
difference of point-reflector displacements in passing through the scanning plane in an elevational direction, which result in decreases of MER of −6 dB compared to the MER-value in the beam centre

Note 1 to entry: The **elevational resolution in a PSF-map** differs from the **elevational resolution** specified by 3.12. It is used for the **PSF**-mapping only to simplify the data acquisition.

Note 2 to entry: Detailed explanation of the method is in D.6.1.3.

Note 3 to entry: **Elevational resolution in a PSF-map** is expressed in metres.

3.51
overall gain
G_o
basic level of gain that is uniform for the whole scan area but modified by **TGC** relative to the depth of the scan

3.52
profile line
set of **pixel** values ordered along an abscissa according to the sequence during their acquisition

3.53
lateral resolution in a PSF-map
Full-Width at Half-Maximum (FWHM) of the **PSF**, measured in a lateral direction

Note 1 to entry: The **lateral resolution in a PSF-map** differs from the **lateral resolution** specified by 3.17. It is used for the **PSF**-mapping only to simplify the data acquisition.

Note 2 to entry: Detailed explanation of the method is in D.6.1.2.

Note 3 to entry: **Lateral resolution in a PSF-map** is expressed in metres.

3.54
measuring grid
matrix of points specified by Cartesian coordinates x_i and z_j defined in a plane parallel to the scanning plane

Note 1 to entry: Each point determines the position (x_i, z_j) in which individual measurement of **PSF** is performed.

Note 2 to entry: The step Δx is defined as an increment $x_{i+1} - x_i$ in the lateral direction. The step Δz is defined as an increment $z_{j+1} - z_j$ in the axial direction.

3.55
performance evaluation
tests performed to assess specific absolute performance of the object tested

Note 1 to entry: Typical times for ultrasound-system **performance evaluation** are at pre-purchase evaluation, new- and repaired-system acceptance testing, at time of performance difficulties, and at end-of-useful-life evaluations.

[SOURCE: IEC TS 62736:2016, 3.5]

3.56
precision
closeness of agreement between independent test results obtained under stipulated conditions

[SOURCE: ISO 5725-1:1994, 3.12]

3.57
scanning window
area on the surface of the **test tank** dedicated for transducer application to obtain a suitable sonogram of the target

Note 1 to entry: It is important that the **scanning window** be covered by flexible foil made of material with similar acoustic properties to the working liquid to avoid ultrasound field reflections and absorption.

Note 2 to entry: The foil flexibility should assure proper acoustical contact of any type of curved transducer.

Note 3 to entry: It is important that the foil covering the scanning-window be tough enough to prevent its damage during coupling the measured transducer to the **scanning window**, to prevent resultant leakage of working liquid from the measuring tank.

Note 4 to entry: The **scanning window** has the identical function as the **test object scanning surface** in the case of tissue-mimicking test objects (see 3.34).

3.58
side-lobe signal
echo signal generated by ultrasound signal transmitted/received in a direction different from the central axis of the transducer

3.59
test tank
tank designed to be suitable for providing specified kind of tests, which is filled with a **working liquid** and equipped with **scanning window**(s)

Replace the title of Clause 4 with the following new title:

4 Symbols and abbreviated terms

Add the following symbols and abbreviated terms to Clause 4:

D	diameter of the reflector sphere
$A_{\mathrm{r,max}}$	greatest $a_{\mathrm{r,max}}$ evaluated for whole measured volume
$a_{\mathrm{r,max}}$	MER **pixel** value evaluated from ROI
$a_{\mathrm{r,max}}(x,y,z)$	MER **pixel** value evaluated from ROI scanned for reflector in position (x,y,z)
C	**contrast**
G_{o}	**overall gain**
$I(x,y,z)$	ROI specified in a digital picture of scan stored with reflector in position (x,y,z)
M	number of quantization levels defined by $M = 2^m$ where m is number of **pixel** bits
p_x	**pixel** size in lateral (azimuthal) direction
p_z	**pixel** size in axial direction
$R_{\mathrm{A,PSF}}$	**axial resolution in a PSF-map**
$R_{\mathrm{E,PSF}}$	**elevational resolution in a PSF-map**
$R_{\mathrm{L,PSF}}$	**lateral resolution in a PSF-map**
$W_{\mathrm{F,HM}}$	value of FWHM (full width at half of maximum)

$W_{H,HM}$	value of HWHM (half width at half of maximum)
$W_{F,HM,n}$	normalized $W_{F,HM}$ according to Formula (D.3) in D.6.1.2
$W_{H,HM,n}$	normalized $W_{H,HM}$ according to Formula (D.3) in D.6.1.2
λ	ultrasound wavelength in the working liquid, calculated from the nominal frequency of the transducer used
ATGC	**automatic time-gain compensation**
FWHM	full width at half of maximum
HFHM	half width at half of maximum
LUT	look-up table
MER	maximum echo received
PSF	**point-spread function**
RF	radio frequency
ROI	region of interest
TGC	**time-gain compensation**
US	ultrasound

6.1 Test methods

Replace:

c) a tank containing degassed **working liquid**.

with:

c) a tank equipped with target holder to position the target at accurately specified positions and containing degassed **working liquid**.

Replace:

The specifications of these devices are given in the annexes.

with:

The specifications of these devices are given in Annexes A, B, C and D.

8.2 Test methods

Replace:

b) a tank containing degassed liquid;

with:

b) a tank containing degassed liquid and, optionally, movable targets as described in Clause C.4 and D.5.4.2;

8.4.1 General

Add, at the end of 8.4.1, the following new sentence:

“A setting should be specified by a test instruction for each test, if it differs from the general recommendations. See D.5.2.”