SLOVENSKI STANDARD

SIST EN 61391-1:2008

01-februar-2008

Ultrazvok - Impulzno-odmevni skenerji - 1. del: Tehnike za kalibriranje prostorskih merilnih sistemov in meritve karakteristike funkcije razprġitve toļk sistema (IEC 61391-1:2006)

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

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)

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 (CEI 61391-1:2006)

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

ICS:

11.040.55

SIST EN 61391-1:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61391-1

October 2006

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)

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
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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)

This European Standard was approved by CENELEC on 2006-10-01. 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.

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

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

Ref. No. EN 61391-1:2006 E

Foreword

The text of document 87/336/FDIS, future edition 1 of IEC 61391-1, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61391-1 on 2006-10-01.

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)	2007-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2009-10-01

Terms in **bold** in the text are defined in Clause 3.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61391-1:2006 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 61828	NOTE Harmonized as EN 61828:2001 (not modified).
IEC 61157	NOTE Harmonized as EN 61157:1994 (not modified).

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 61102	1991	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	EN 61102	1993
IEC 61685	2001	Ultrasonics - Flow measurement systems - Flow test object	EN 61685	2001

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
61391-1

Première édition
First edition
2006-07

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

Ultrasonics – Pulse-echo scanners –

Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response

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International Electrotechnical Commission
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CODE PRIX
PRICE CODE X

Pour prix, voir catalogue en vigueur
For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PULSE-ECHO SCANNERS –

Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response

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 61391-1 has been prepared by IEC technical committee 87: Ultrasonics.

The text of this standard is based on the following documents:

FDIS	Report on voting
87/336/FDIS	87/343/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.

Terms in **bold** in the text are defined in clause 3.

This standard is intended to be published in two or more parts:

– Part 1 deals with techniques for calibrating spatial measurement systems and measurement of system point-spread function response;
– Part 2 will deal with measurement of system sensitivity, dynamic range, and low-contrast resolution.

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.

INTRODUCTION

An ultrasonic pulse-echo scanner produces images of tissue in an ultrasonic **scan plane** by sweeping a narrow pulsed beam of **ultrasound** through the section of interest and detecting the echoes generated at tissue boundaries. A variety of **ultrasonic transducer** types are employed to operate in a transmit/receive mode for the ultrasonic signals. Ultrasonic scanners are widely used in medical practice to produce images of many soft-tissue organs throughout the human body.

This standard describes test procedures that should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use the standard to prepare their specifications; the users should employ the standard to check specifications. The measurements can be carried out without interfering with the normal working conditions of the machine. Typical **test objects** are described in the annexes. The structures of the **test objects** have not been specified in detail, rather suitable types of overall and internal structures are described. The specific structure of a **test object** should be reported with the results obtained using it. Similar commercial versions of these **test objects** are available.

The performance parameters specified and the corresponding methods of measurement have been chosen to provide a basis for comparison with the manufacturer's specification and between similar types of apparatus of different makes, intended for the same kind of diagnostic application. The manufacturer's specification should allow comparison with the results obtained from the tests in this standard. Furthermore, it is intended that the sets of results and values obtained from the use of the recommended methods will provide useful criteria for predicting the performance of equipment in appropriate diagnostic applications. This standard concentrates on measurements of images by digital techniques. Methods suitable for inspection by eye are covered here as well. Discussion of other visual techniques can be found in IEC 61390 [1] [1].

Where a diagnostic system accommodates more than one option in respect of a particular system component, for example the **ultrasonic transducer**, it is intended that each option be regarded as a separate system. However, it is considered that the performance of a machine is adequately specified, if measurements are undertaken for the most significant combinations of machine control settings and accessories. Further evaluation of equipment is obviously possible but this should be considered as a special case rather than a routine requirement.

1) Figures in square brackets refer to the Bibliography.

ULTRASONICS – PULSE-ECHO SCANNERS –

Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response

1 Scope

This International Standard describes methods of calibrating the spatial measurement facilities and **point-spread function** of ultrasonic imaging equipment in the ultrasonic frequency range 0,5 MHz to 15 MHz. This standard is relevant for ultrasonic scanners based on the pulse-echo principle of the types listed below:

– mechanical sector scanners;

– electronic phased-array sector scanners;

– electronic linear-array scanners;

– electronic curved-array sector scanners;

– water-bath scanners based on any of the above four scanning mechanisms;

– 3D-volume reconstruction systems.

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

IEC 61685:2001, *Ultrasonics – Flow measurement systems – Flow test object*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

See also related standards and technical reports for definitions and explanations. [1-5]

3.1
A-scan
class of data acquisition geometry in one dimension, in which echo strength information is acquired from points lying along a single **beam axis** and displayed as amplitude versus time of flight or distance

3.2
acoustic coupling agent (also, coupling agent)
a material, usually a gel or other fluid, that is used to ensure acoustic contact between the transducer and the patient's skin, or between the transducer and the surface of a sealed test object

3.3
acoustic working frequency
arithmetic mean of the frequencies f_1 and f_2 at which the amplitude of the acoustic pressure spectrum is 3 dB below the peak amplitude

(See 3.4.2 of IEC 61102)

3.4
automatic time-gain compensation
ATGC
automatic working time gain control based on the observed decrease in echo amplitudes due to the attenuation in ultrasonic pulse amplitude with depth

3.5
axial resolution
minimum separation along the beam axis of two equally scattering volumes or **targets** at a specified depth for which two distinct echo signals can be displayed

3.6
backscatter coefficient
mean acoustic power scattered in the 180° direction by a specified object with respect to the direction of the incident beam, per unit solid angle per unit volume, divided by the incident beam intensity. For a volume filled with many scatterers, the scatterers are considered to be randomly distributed. The mean power is obtained from different spatial realisations of the scattering volume

NOTE **Backscatter coefficient** is commonly referred to as the differential scattering cross-section per unit volume in the 180° direction

3.7
backscatter contrast (normalized)
difference between the **backscatter coefficients** from two defined regions divided by the square root of the product of the two **backscatter coefficients**

3.8
beam axis
the longitudinal axis of the pulse-echo response pattern of a given **B-mode scan line**, a pulse-echo equivalent to the transmitted beam axis of IEC 61828 [2]

3.9
B-scan
class of data acquisition geometry in which echo information is acquired from points lying in an ultrasonic **scan plane** containing interrogating ultrasonic beams. See **B-mode** below.

NOTE B-scan is a colloquial term for **B-mode** scan or image. (See 3.10)

3.10
Brightness-modulated display
B-mode
method of presentation of **B-scan** information in which a particular section through an imaged object is represented in a conformal way by the scan plane of the display and echo amplitude is represented by local brightness or optical density of the display

[IEC 60854: definition 3.18, modified]

3.11
displayed dynamic range
ratio, expressed in decibels, of the amplitude of the maximum echo that does not saturate the display to the minimum echo that can be distinguished in the display under the scanner test settings

3.12
elevational resolution
minimum separation perpendicular to the ultrasonic **scan plane** of two equally scattering **target**s at a specified depth for which two distinct echo signals can be displayed. Often used here informally for slice thickness for purposes of 3D-scanning

3.13
field-of-view
area in the ultrasonic **scan plane** which is insonated by the **ultrasound beam** during the acquisition of echo data to produce one image frame

3.14
frame rate
number of sweeps comprising the full-frame refresh rate that the ultrasonic beam makes per second through the **field-of-view**

3.15
gain
ratio of the output to the input of a system, generally an amplifying system, usually expressed in decibels

3.16
grey scale
range of values of image brightness, being either continuous between two extreme values or, if discontinuous, including at least three discrete values

[IEC 60854: definition 3.14]

3.17
lateral resolution
minimum separation of two **line targets** at a specified depth in a **test object** made of **tissue-mimicking material** for which two distinct echo signals can be displayed. The **line targets** should be perpendicular to the scanned plane; the separation between the **target**s should be perpendicular to the beam-alignment axis

3.18
line-spread function
LSF
characteristic response in three dimensions of an imaging system to a high-contrast **line target**

3.19
line target
cylindrical reflector whose diameter is so small that the reflector cannot be distinguished by the imaging system from a cylindrical reflector with diameter an order of magnitude smaller, except by signal amplitude. The backscatter from a standard **line target** should be a simple function of frequency over the range of frequencies studied

3.20
M-mode
time-motion mode
method of presentation of **M-scan** information in which the motion of structures along a fixed **beam axis** is depicted by presenting their positions on a line which moves across a display to show the variation with time of the echo

3.21
M-scan
time-motion scan
class of acquisition geometry in which echo information from moving structures is acquired from points lying along a single beam axis. The echo strength information is presented using an **M-mode** display

3.22
nominal frequency (of a transducer)
intended **acoustic working frequency** of a transducer as quoted by the designer or manufacturer

[adapted from definition 3.7 of IEC 60854]

3.23
pixel
picture element
smallest spatial unit or cell size of a digitized 2-dimensional array representation of an image. Each **pixel** has an address (x-and y-coordinates corresponding to its position in the array) and a specific brightness level

NOTE **Pixel** is a contraction of 'picture element'.

3.24
point target
reflector whose scattering surface dimensions are so small that it cannot be distinguished (except by signal amplitude) by the imaging system from a similar **target** whose scattering surface is an order of magnitude smaller. The backscatter cross section of a standard point **target** should be a simple function of frequency over the range of frequencies studied.

3.25
point-spread function
PSF
characteristic response in three dimensions of an imaging system to a high-contrast **point target**.

NOTE For most ultrasound systems, an individual ultrasound **PSF** cannot be used as the overall system impulse response, due to changes in the **PSF** with depth, with other positions in the region of use and with system focal and frequency settings.