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INTERNATIONAL STANDARD



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

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CONTENTS

FOI	REWORD	.4
INT	RODUCTION	.6
1	Scope	.7
2	Normative references	.7
3	Terms and definitions	.7
4	Symbols	15
5	General conditions	16
6	Techniques for calibrating 2D-measurement systems	17
	6.1 Test methods	17
	6.2 Instruments	17
	6.3 Test settings	18
	6.4 Test parameters	
7	Methods for calibrating 3D-measurement systems	
	7.1 General	
	7.2 Types of 3D-reconstruction methods	
	7.3 Test parameters associated with reconstruction problems	
8	7.4 Test methods for measurement of 3D-reconstruction accuracy Measurement of point-spread and line-spread functions (high-contrast spot size)	
0	8.1 General	
	8.2 Test methods	
	8.3 Instruments Document. Preview.	28 28
	8.4 Test settings	29
	8.5 Test parameters	
Anr	nex A (normative) Test objects – Calibration of 2D-spatial measurement systems	36
	nex B (normative) Test objects – Measurement and calibration of 3D-image on the second s	
Anr	nex C (normative) Test objects – Measurement of point-spread function response	43
Anr	nex D (informative) Quality parameters derived by PSF-mapping analysis	48
Bib	liography	64
Fig	ure A.1 – Concentric circular arrays of nylon filaments	37
Fig	ure A.2 – Regular 2D-array of nylon filaments	38
Fig	ure B.1 – Tissue mimicking ovoid target phantom	40
Fig	ure B.2 – Composite of two cross-sectional views of test object shown in Figure B.1	40
-	ure B.3 – Projection view from top of test object shown in Figure B.1	
-	ure B.4 – Projection view from end window of test object shown in Figure B.1	
-	ure C.1 – Filament test object for measuring the LSF	
-	ure C.2 – Axial resolution test object	
-	ure C.3 – Movable single filament in water	
-	ure C.5 – Slice thickness measurement and calculation	
	ure D.1 – Principal schematic of the PSF-analyser function	
Fig	ure D.2 – Principle of elimination of internal multi-reflections in the spherical target ng filtration in time domain	

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Figure D.4 – The derivation of FWHM-value from the lateral-amplitude profile of PSF received-echo signal ($a_{r,max}(x_i,z_k) = 221$) with reflector positioned on axis of the ultrasound beam in point (x_i,z_k) of the measuring grid	57
Figure D.5 – The FWHM-derivation from the elevational (transversal) profile of MER in one point of the measuring grid	58
Figure D.6 – The derivation of the reflected-signal axial-profile from the ROI	59
Figure D.7 – The enumeration of the $W_{H,HM}$ parameter from the axial-profile line: $a_{r,max}(x,z) = 243$	59
Figure D.8 – The distribution of FWHM over a scan area of width 20 mm to depth 80 mm, made with a monofocal scan using a linear 5 MHz transducer	60
Figure D.9 – The distribution of FWHM over a scan area of width 20 mm to depth 80 mm, made with the same system as for Figure D.7 but using three focal points (F1, F2 and F3) for the scan	60
Figure D.10 – Plot of the distribution of MER-intensity over the scanning area 30 mm wide and 40 mm deep	61
Figure D.3 – A pixel maximum level and PSF-trace estimation in ROI stored digital data	56
Figure D.11 – The elevational profile recorded from $a_{r,max}(x_i,y,z_k)$ values for a spherical target passing perpendicularly to the scanning plane in one point (x_i,z_k) of the	
measuring grid	62
Table 1 – Expected values for the two ellipsoidal objects in Figure B.3	27
Table 2 – Suggested table of reported values	27

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IEC 61391-1:2006

- 4 -

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PULSE-ECHO SCANNERS –

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

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IEC 61391-1 edition 1.1 contains the first edition (2006-07) [documents 87/336/FDIS and 87/343/ RVD] and its amendment 1 (2017-07) [documents 87/650/FDIS and 87/653/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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

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 the base publication and its amendment will remain unchanged until the stability 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

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- withdrawn,
- replaced by a revised edition, or
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INTRODUCTION

- 6 -

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 objects** 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 s://standards.iteh.ai)

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.

C 61391-1:2006

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

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

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

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

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

3 Terms and definitions

For the purposes of this document, the <u>following</u> 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]. <u>[1-5]</u>

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

- 8 -

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

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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 targets 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] [IEC 60854: definition 3.14] and ards/iec/2bb4f020-0145-4ffc-8892-42fc1225a313/iec-61391-1-2006

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

3.26

scan line

one of the component lines which form a **B-mode** image on an ultrasound monitor. Each line is the envelope-detected **A-scan** line in which the echo amplitudes are converted to brightness values

3.27

scan plane

a plane containing the ultrasonic scan lines

[IEC 61102: definition 3.38, modified]