IEC 61391-1

Edition 1.0 2017-07

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

IEC 61391-1:2006-07/AMD1:2017-07(en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing 20 000 terms and definitions in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
65 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

IEC 61391-1

Edition 1.0 2017-07

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

Warning! Make sure that you obtained this publication from an authorized distributor.

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.

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_0
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."

8.5.1 General

Add, to the end of the fifth paragraph starting "To overcome this limitation …", the following new text:

"The complications generated by interference and multiple reflections inside the spherical target may be solved by time-domain analysis of the received echo when a larger and/or highly reflective sphere is used. See D.5.4.2."

8.5.4 Scan slice thickness (elevational PSF and LSF) or elevational resolution

Add, at the end of 8.5.4, the following new text:

"The most accurate and flexible method to derive the complex set of parameters based on the PSF mapping analysis is described in Annex D."

C.4 Movable single filament or wire in water (Figures C.3, C.4)

Add, at the end of Clause C.4, the following new single-sentence paragraph:

"The use of a movable spherical target for assessing quality parameters derived by **PSF**-mapping analysis is described in Annex D. "

Insert after Annex C the following new Annex D

Annex D
(informative)

Quality parameters derived by PSF-mapping analysis

D.1 General

A quality assessment system is vitally needed to provide an accurate and well-defined set of production-quality parameters for new or refurbished scanners or transducers in acceptance tests before their introduction to medical practice. It is important that products delivered by third-party sales groups, system-refurbishers and/or transducer manufacturers be carefully tested to be able to declare technical parameters of their products to be comparable to those of the new, originally manufactured systems. The methods used for quality assessment in medical applications are not certain and accurate enough to be used for such kinds of technical **performance evaluation**. **PSF**-mapping analysis gives reliable parameters suitable for this kind of tests. These parameters do not directly indicate the effectivity of a clinical diagnostic process, even though a close correlation between the assessed technical quality and success in the diagnostic process may be expected [40].

The ultrasound scanner used as a diagnostic system is composed of the system-control/user-interface unit and the ultrasonic-transducer assembly. Either unit can contain the transmitter- and the receiver- electronic systems and some of the beam-former electronics. The **ultrasonic transducer** converts electrical signals to ultrasound field and vice versa. Electrical and acoustic parameters of the transducer determine quality of the scanning **ultrasound beam**. The electronic system controls the transmitted and received ultrasound signal, conversion from mechanical to electrical signals, and the signal processing and conversion to video-signal inputted to the imaging unit. The imaging unit transfers the information to the human preceptors. The **PSF**-distribution analysis evaluates qualitative parameters of the whole ultrasound-scanner system, excluding the display unit. The analysed signal is affected by the quality of the whole imaging cycle, and the transmitting and receiving parts of the scanner. The analysed system function is affected by a complex set of control functions. Therefore, it is important that the combination of the control settings of the scanner be exactly specified and recorded as a part of the measurement.

D.2 Method

Annex D describes a method for precise and reliable measurement of several qualitative parameters of whole ultrasound scanning systems including both the transmitting and receiving parts of the systems, excluding the parameters of scanner display. The method is based on **PSF**-distribution analysis over a scanning area. In the case of **PSF**-mapping, the measured parameters are derived by analysis of sonograms generated by scanning a spherical target moving over a defined scanning volume on a specified trajectory.

The **PSF**-mapping system evaluates a set of parameters acquired over a user-defined area in one scanning plane of a B-mode grey-scale sonogram, scanned in a tank filled by degassed working liquid and using one measuring procedure. The whole target sonogram is not evaluated in the **PSF**-mapping analysis. The test signal is obtained by reflection of a transmitted ultrasound wave from a point-reflector surface and working-liquid boundary only. The point reflector used is a highly reflective sphere of diameter D [41].

The method is suitable for all kinds of echo(reflections)-evaluating sonographs using different types of beam-forming and plane-wave compounding of ultrasound signal in the frequency range 0,5 MHz to 50 MHz. The upper frequency limit is determined by a ball target of minimum diameter available to assure reflection effectivity and fulfil the condition $\lambda \leq D \leq 4\lambda$, where λ is the ultrasound wavelength in the working liquid [42]. Further limiting factors are a minimum size of step and precise mechanical construction of the positioning system to assure measurement reliability and adequate scan size.

The method is relevant for all the types of transducers used with these scanners, including

- mechanical probes including annular arrays,
- electronic phased arrays,
- linear arrays,
- curved arrays,
- two-dimensional arrays, and
- 3D-volume scanning probes based on a combination of the above types.

The **PSF**-measuring system is not a tissue-mimicking object. It is dedicated to performing accurate, stable and reliable measurements under conditions appropriate to achieving these measurements of parameters, some of which may be obtained by use of sophisticated electronic measurements of the scanner's electronic system and some by **PSF**-mapping analysis only [43].

The following data are acquired and are analysed using the method:

a) the ROI digital image stored for the scanned-plane axis in each point of the **measuring grid**;
b) the echo-signal amplitude distribution over the measured area;
c) the distribution of the parameter $W_{\mathrm{F,HM}}$ which is Full-Width-at-Half-Maximum (FWHM) of the **point-spread function** (**PSF**) in the azimuthal direction over the measured area;
d) the distribution of the parameter $W_{\mathrm{H,HM}}$ Half-Width-at-Half-Maximum (HWHM) of the **point-spread function** (**PSF**) in the axial direction over the measured area;
e) the peak echo-amplitude received $a_{\mathrm{r,max}}(x,y,z)$ at each y_{k} step of the target position in the elevation (transversal) direction;
f) the (x,y,z) coordinates set for stored position of the point reflector generating $a_{\mathrm{r,max}}(x,y,z)$ from MER in each point of the **measuring grid** (position in centre of ultrasound beam).

Data analysis derives the following ultrasound scanner parameters and functions:

1) focal areas in both the azimuth and the elevation directions;
2) visualization of the distribution of ultrasound scanning lines;
3) manufacturer's preloaded **TGC** function;
4) width (elevation) of the scanning plane over the depth of scan;
5) side-lobes signal-level distribution in the scan plane;
6) amplification uniformity in the azimuth direction;
7) scan geometry linearity and **accuracy**.

D.3 Environmental conditions

The most temperature-sensitive parameters are those assessing geometry of the sonogram and related calculations. The temperature-dependent deviations may be compensated mathematically from known working-liquid temperature and thermal coefficient of speed of sound.

Water condensation on electronic system components should be avoided.

D.4 General requirements of the method

Ultrasound waves produce a **PSF**-signal that is neither singular nor isotropic. Furthermore, the ultrasound **PSF** can be asymmetrical, having different axial and lateral dimensions, and it