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INTERNATIONAL STANDARD

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AMENDMENT 1
AMENDEMENT 1

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

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

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FOREWORD

This amendment has been prepared by IEC technical committee 87: Ultrasonics.

This bilingual version (2018-04) corresponds to the monolingual English version, published in 2017-07.

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.

The French version of this amendment has not been voted upon.

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- withdrawn,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.

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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_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**

$W_{F,HM}$	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 $\lambda \le D \le 4\lambda$, 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 also varies with distance from the transducer in both the axial and the azimuthal directions. Thus, it is important that many different measurements of the **PSF** at different positions and depths be performed to obtain representative values of the system's imaging performance at specific positions along the beam axis. It is also important that the measured area be covered by a grid of the measuring points, the density of which is determined by the expected parameters and the **accuracy** of the measurement [44].

NOTE For example, determination of a focal point's position may need an axial step Δz = 5 mm; visualization of scanning lines demands an azimuthal step Δx = 0,1 mm for a conventional linear transducer of nominal frequency 3 MHz.

The following features are necessary to apply the **PSF**-analyser to the sonograph:

a) The sonograph to be tested:
   – video-signal output of live, dynamic scanning available in analog (composite) or digital (DVI-D, HDMI) form;
   – operating instructions or skilled operator to assure proper manipulation and operating adjustment;
   – record of proper evidence and registration of the measurement process, including identification of operator and all apparatus used, record of parameters preset in the measured system, record of environmental conditions, including a time stamp.

b) The basic configuration of the measurement tank:
   – The **scanning window**(s) is(are) localized in the side wall(s) of the tank.
   – The spherical-target positioning system is fixed on top of the tank, controlling movement of the target fixed in a holder.
   – Filling the tank with degassed working liquid is recommended to prevent bubble generation in the working fluid. Bubbles may mimic the point reflector and/or produce spurious reflections from the point reflector after having accumulated on it, due to surface tension.
   – Temperature should be kept in the specified range to eliminate measurement uncertainties generated by dependence of the speed of ultrasound propagation upon temperature.

c) The transducer:
   – The transducer is acoustically coupled to the **scanning window** by standard coupling ultrasound gel. The **scanning window** is covered by tough, flexible foil made of material with similar acoustic properties to the working liquid to avoid ultrasound field reflections and absorption.
   – The scanning plane is oriented in the horizontal direction and the transducer is fixed to keep the whole slice thickness below the water surface. It is important that the lateral orientation of the transducer be specified.

d) The positioning system:
   – A computer-controlled micromanipulator is used to move the target or transducer to a determined position. It is important that mechanical construction, **accuracy** and stability of the positioning system correspond with ultrasound frequency. The shorter the wavelength, the more accurate and robust the system should be to avoid systematic measuring errors.

e) The control and analysing system:
   – The software controls the video-signal acquisition, determines ROI, selects and saves the ROI frames to be used for analysis and finally maintains the complex analysis of the stored information.
   – The basic parameters used for **PSF**-analysis are the $W_{F,HM}$ (Full Width at Half Maximum, i.e. at −6 dB down from $a_{r,max}$) and the **pixel** level of noise at an area without reflections.

– The $W_{F,HM}$ depends upon the intensity of the received signal. Therefore, it is important that the receiving gain and output power be properly adjusted to utilize the whole dynamic range of the analyser.

D.5 Measuring conditions

D.5.1 General

In Figure D.1 a principal schematic of the **PSF**-analyser is introduced. The **PSF**-analyser consists of the data-acquisition components (test-tank and point-reflector parts of the schema), a linear transducer, a personal computer (PC) with video-signal input, running acquisition and analysis software. The sonograph being measured is shown with a linear transducer but the results analysis is displayed for a sector-scan transducer to illustrate transducer-type independency of the system.

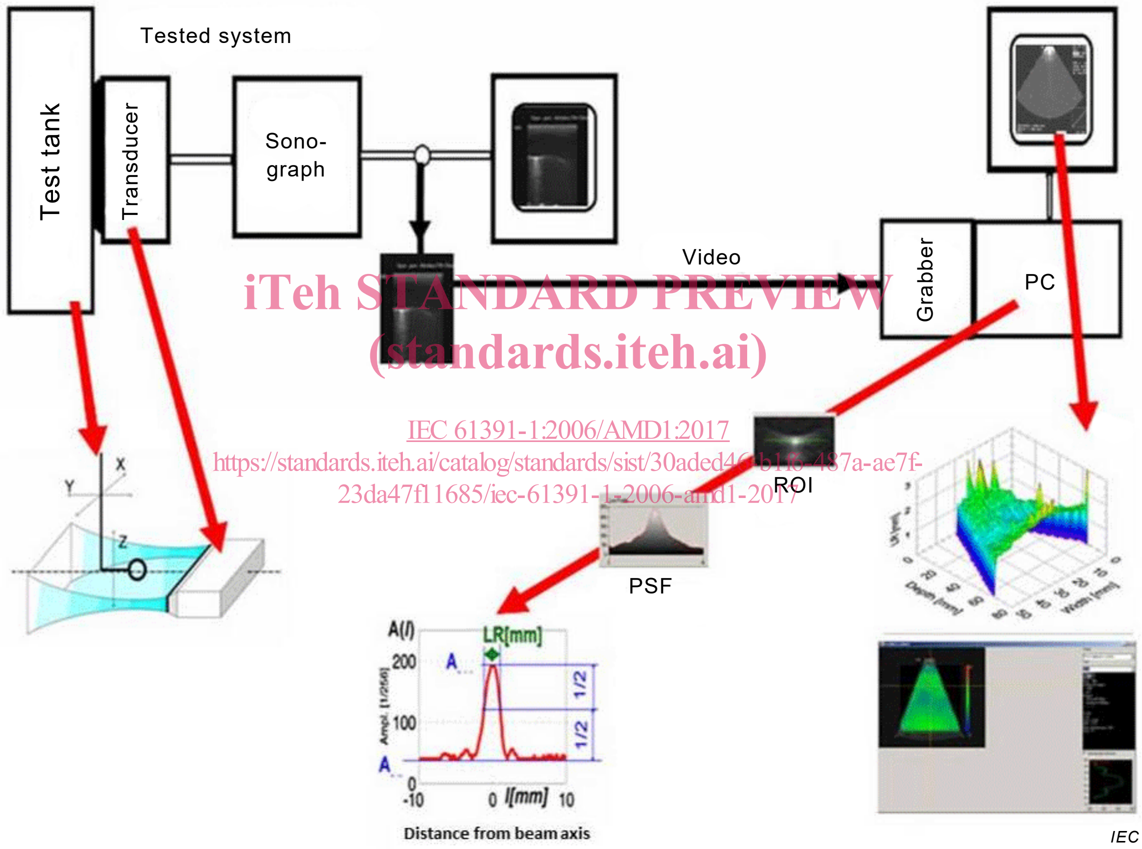

Figure D.1 – Principal schematic of the PSF-analyser function

D.5.2 Sonograph

D.5.2.1 General

Sonographs are equipped with a large set of different control functions to ensure optimal handling of received ultrasound signals to create the best image. These control functions affect remarkably the measurement results because the method evaluates the signal after it has passed through a whole imaging system. Therefore, it is important that all the adjustments and settings be carefully documented in the measuring protocol to be available for use for repeated measurements.

D.5.2.2 The amplitude transfer-characteristic adjustment

The sonograph receiver employs a logarithmic amplifier to compress a very wide range of received signal amplitudes (more than 100 dB). It is important that all the other additional, nonlinear, so-called pre-processing and post-processing functions be switched off or adjusted to linear working regions to avoid further nonlinear distortions of the signal. This requirement includes functions dedicated to eliminating different types of noise either by scan-sequences correlation or averaging or cutting off low-level signals.

It is important that the amplified signal-peak amplitude limitation due to low amplifier dynamic range be eliminated to assure correct measurement of the FWHM-function. Therefore, it is also important that the widest dynamic range accessible by the measuring system be selected, except in the case when the gain of the sonograph is not sufficient to achieve full dynamic range for the $A_{\mathrm{r,max}}$.

D.5.2.3 The look-up table setting

The relation of the grey-scale level to the digitalized amplitude of the signal is derived from a look-up table (LUT) or Gamma curve. If possible to assure a pure logarithmic characteristic of the system, only a most linear LUT should be used. It is important that all the settings be documented in the measuring protocol, to be recorded for use during further periodical measurements. A method to find the most linear LUT should be part of the measuring software.

D.5.2.4 The measured gain adjustment

The sonograph's receiver gain is controlled in two parts: the **overall gain** (G_{o}) and the **time-gain compensation** (**TGC**) functions. Their adjustment prior to measurement should be as follows: The **TGC** is adjusted first. The basic condition is to adjust the **TGC** to be constant within the whole range of the scanned depth. The basic condition of the **TGC** adjustment is its independence from the depth parameter (elimination of the function). Then the G_{o} is increased to just obtain little visible thermal noise of the system in an echo-free area on the screen, e.g. when the transducer is energized when coupled to the air. It is important that the G_{o} be decreased or a smaller reflector used, if the $A_{\mathrm{r,max}}$ amplitude limitation occurs.

Some sonographs utilize an **ATGC** (automatic time gain compensation) function. It is important that this function be disabled for gain (sensitivity) dependence from depth and focal-points localization from MER-profile assessments.

D.5.3 Measuring tank

D.5.3.1 General

The measuring tank serves as a holder of the volume of homogenous non-reflecting medium – the working liquid – in which the point reflector is moving by the precise, computer-controlled electromechanical system. An appropriate **scanning window** allows effective acoustic connection between the working liquid inside the tank and the active part of the measured transducer. The size of the measuring tank should be appropriate to the size of largest scanned area expected.

D.5.3.2 Working liquid

It is important that the working liquid used in the tank be degassed to avoid collection of bubbles at the point reflector [45]. It is also important that the temperature be recorded for the measurements to be based on accurate values of speed of sound, which significantly affects reading geometry of the scan. However, measurements based on reading the echo intensity are not remarkably affected by working liquid temperature because temperature dependence of both the reflectivity and the water absorption are negligible in this case.

The accuracy of the distance calculations is determined by the accuracy of knowledge of ultrasound speed of propagation in the working liquid. The coefficient of speed of ultrasound in pure water as a function of temperature is approximately 4 $ms^{-1}°C^{-1}$ in the temperature range 10 °C to 30 °C. According to the distance calculation from the echo delay, a change of temperature of ±1 °C results in error of ±0,15 % of the measured distance value. A calculation giving the temperature error compensation is possible by use of an expression given by [46] or another by [47].

D.5.3.3 Reflections

Due to low ultrasound absorption of the working liquid and high reflectivity of the tank walls and relatively small size of the measuring tank, many multiple reflections are generated in the scanned area. These multiple reflections may be eliminated by a simple system of absorbers and reflector shielding because a pulsed signal is generated and only a small ROI surrounding and close to the reflector is analysed in the sonogram.

D.5.3.4 Scanning windows

The ultrasound signal is transferred between transducer and reflector via the **scanning window**. The window works as an acoustic coupler between the active surface of the transducer and the working liquid. The window is closed with flexible foil made of material with similar acoustic properties to the working liquid to assure effective transfer of the ultrasound signal and elimination of ultrasound-signal reflections and absorption. The transducer is attached to the foil with use of conventional coupling gel so that the whole active surface of the transducer is in acoustic contact with the working liquid. Proper shape of the window is needed to assure effective contact of different types of transducers. The measured transducer holder is part of the **scanning window**. Its design should ensure adjustment of the scanning plane to be parallel to the xz-plane of the target positioning system and stable transducer positions during measurement.

D.5.4 Target

D.5.4.1 General

The target system is composed of the sphere reflector, the reflector holder and the reflector positioning system.

D.5.4.2 Reflector

In contrast to C.4 and Figure C.4, the point reflector is not the flat end of a wire but a sphere made of steel or similar highly reflective material. The reflector is fixed to a positioning system with use of a holder made of tiny, hard wire. The sphere reflection is independent of the incident angle of irradiation.

The diameter D of the rigid metallic reflector is critical for the method used but should be kept within a range $\lambda < D < 4\lambda$ according to [42]. Use of a reflector of $D < \lambda$ is possible, but the reflected signal amplitude will not be strong enough for low-sensitivity systems. Therefore decrease of the target diameter, D, may be employed when too-sensitive sonographs limit high amplitude of signals, even if the **overall gain** G_o and output power are adjusted to minimum levels (see D.5.2.4).

If $D > 4\lambda$, values and variations of the $W_{F,HM}$ increase to an erroneous extent in both the lateral and the elevational directions.

The reflections from any inner structure of the sphere and multiple reflections in the sphere and/or sphere resonances [48] [49] are eliminated in the received-signal evaluation process. They do not affect the measurement results. The **PSF**-mapping method evaluates reflections of a transmitted ultrasound wave from a point-reflector surface and working-liquid boundary only (Figure D.2). It is important that the sphere reflector be made of a highly reflective