# **Ultrasonics — Pulse-echo scanners —**

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

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ICS 17.140.50



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# **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 (CEI 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)

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

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#### **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:



Annex ZA has been added by CENELEC.

# **Endorsement notice**

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The text of the International Standard IEC 61391-1:2006 was approved by CENELEC as a European Standard without any modification.  $\frac{1}{2}$ 

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#### 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  $[11]$ <sup>1)</sup>.

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.

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<sup>1)</sup> 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

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#### **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 180º 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** 

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#### **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.

### **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]

# **3.28**

#### **side lobe**

secondary beam, generated by an **ultrasonic transducer**, that deviates from the direction of the main beam. Usually, the intensity of the **side lobes** is significantly less than that of the central axis beam

NOTE The presence of **side lobes** may be responsible for introducing artifactual echoes into the **ultrasound** image.

#### **3.29**

#### **slice thickness**

thickness, perpendicular to the **ultrasonic scan plane** and at a stated depth in the **test object**, of that region of the **test object** from which acoustic information is displayed

#### **3.30**

#### **speckle pattern**

image pattern or texture, produced by the interference of echoes from the scattering centres in tissue or **tissue-mimicking material** 

#### **3.31**

#### **spot size**

the –6 dB width or otherwise specified width of the **PSF** or **LSF**

#### **3.32**

#### **target**

an object to be interrogated by an **ultrasound** beam

NOTE Examples of **targets** are:

a) a device specifically designed to be inserted into the ultrasonic field to serve as the object on which the radiation force is to be measured;

b) a scatterer or ensemble of scatterers giving rise to a signal within the effective ultrasonic beam;

c) a wire or a filament in a **test object**.

#### **3.33 test object**

device containing one or more groups of object configurations embedded in a **tissuemimicking material** or another medium

#### **3.34 test object scanning surface**

surface on the tissue-mimicking **test object** recommended for transducer location during a test procedure

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# **3.35**

#### **time-gain compensation**

#### **TGC**

change in amplifier gain with time, introduced to compensate for loss in echo amplitude with increasing depth due to attenuation in tissue

#### **3.36**

#### **tissue-mimicking material**

material in which the propagation velocity (speed of sound), reflecting, scattering and attenuating properties are similar to those of soft tissue for **ultrasound** in the frequency range 0,5 MHz to 15 MHz.

[See 6.4 and Annex D of IEC 61685]

#### **3.37**

#### **transmitted ultrasound field**

three-dimensional distribution of ultrasound energy emanating from the ultrasonic transducer

#### **3.38**

#### **ultrasonic scan line**

for automatic scanning systems, the beam-alignment axis either for a particular **ultrasonic transducer** element or for a single or multiple excitation of an **ultrasonic transducer** or of an **ultrasonic transducer element group** 

[IEC 61157: definition 3.27, modified]

#### **3.39**

#### **ultrasonic transducer**

device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and/or reciprocally capable of converting mechanical energy to electrical energy

[IEC 61102: definition 3.58]

NOTE For the purposes of this standard, **ultrasonic transducer** is taken to refer to a complete assembly that includes the transducer element or elements and mechanical and electrical damping and matching provisions.

#### **3.40**

#### **ultrasonic transducer element group**

group of elements of an **ultrasonic transducer** which are excited together in order to produce a single acoustic pulse

[IEC 61102: definition 3.60]

#### **3.41**

#### **ultrasound**

acoustic oscillation whose frequency is above the high-frequency limit of audible sound (conventionally 20 kHz)

[IEV 801 21-04, modified]

#### **3.42**

#### **ultrasound beam** (pulse-echo response pattern)

region adjacent to the transducer face from which an echo signal from a specified **target** may be detected for the test settings of the scanner and with the scanner operating in a non-scanning mode. This term should be distinguished from the **transmitted ultrasound field**

# **3.43**

### **voxel**

smallest spatial unit or cell size of a digitized 3-dimensional array representation of an image. Each **voxel** has an address (x, y, and z-coordinates) corresponding to its position in the array, and a specific brightness and/or color value

# **3.44**

### **working liquid**

a mixture of water and other solvent that adjusts the speed of sound to 1 540 m/s

[See also 6.4 and Annex D of IEC 61685:2001]

# **4 Symbols**

- *A surface area*
- *A*c cross-sectional area
- *a*i length of the semi-major axes for a given half  $(i = 1 or 2)$  of the ellipsoid of an ovoid object
- *b* mean of the lengths of the minor axes of the ellipsoid of an ovoid object

# *f* **acoustic working frequency**

- *k* circular wave number;( =  $2\pi / \lambda$  in which  $\lambda$  is the wavelength)
- *P* perimeter of cross-section of ovoid object
- *R* ratio of mean of measured spacings to known spacings (see 7.3.1)
- *Rx* lateral dimension calibration factor (see 7.4.2);

ratio of mean filament spacings to known spacings for the horizontal direction

- *Ry* ratio of mean filament spacings to known spacings for the vertical direction
- *r* radius of a wire or filament **target**
- *V* volume of an ovoid object
- *Z*m characteristic acoustic impedance of a wire or filament material
- *Z*w characteristic acoustic impedance of the surrounding medium (working liquid or tissue-mimicking material)
- $\varepsilon$  1- $(b/(2a))^2$  eccentricity of an ellipsoid or an ovoid object
- <sup>σ</sup> backscattering cross-section for a point-like **target**

# **5 General conditions**

The tests should be performed within the following ambient conditions:

- temperature 23 °C  $\pm$  3 °C;
- $r$  relative humidity  $45\%$  to 75 %;
- atmospheric pressure 86 kPa to 106 kPa.

This standard permits the use of test objects of various constructions. Therefore it is essential that the following data of the test object be reported. The following standard choices are recommended:

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- a) medium: either **working liquid** or **tissue-mimicking material** [6]
- b) use of coupling gel: thin layer or gel with adapted sound velocity
- c) geometry (one of the models given in Annex A, B or C, where needed with a different spacing between **targets**).

For the medium **working liquid**, the following properties are required:

- speed of sound =  $(1\,540 \pm 15)$  m/s;
- low attenuation  $(< 0.1 f dB cm^{-1} MHz^{-1})$ :
- negligible scattering (see IEC 61685).

For adjusting the speed of sound in working liquid, see [7, 8].

For the medium **tissue-mimicking material** [9], the following properties are required:

- speed of sound =  $(1\,540 \pm 15)$  m/s;
- attenuation (0,5 ± 0,05) *f* dB cm<sup>-1</sup>MHz<sup>-1</sup>) in the frequency range used in the tests;
- scattering (moderate, no value imposed).

Note: Where an ultrasound system is designed for particular applications where the mean speed of sound is different from 1 540 m/s, a medium with that design speed of sound should be employed and that change reported with the results.

For tissue-mimicking properties, see also 6.4 and Annex D of IEC 61685:2001 .

**Tissue-mimicking material** is usually protected by a thin cover. Its thickness and acoustic properties (attenuation and sound velocity) should be reported if these influence the measurement.

The transducer is usually coupled to the cover of **tissue-mimicking material** by an **acoustic coupling agent** (ultrasound gel). If the layer is thin (compared to the wavelength) its influence can be ignored. For a thick layer, for example as needed for a curved-array transducer, the sound velocity of the **acoustic coupling agent** shall be equal to  $(1.540 \pm 15)$  m/s.

Sound velocity of a medium has two different effects: if it is larger then 1 540 m/s, the axial distances in the medium are rendered proportionally shorter and the focus of the transducer moves away from the transducer. If the sound velocity is lower, the opposite occurs. The effect on the focus becomes more important for transducers with a high numeric aperture. Therefore the use of the correct sound velocity (1 540  $\pm$  15) m/s, to which ultrasonic systems are standardized) is essential in Clauses 6 and 7, dealing with geometrical distortions. In Clause 8, dealing with the **PSF**, a deviation can be tolerated for not too high numeric apertures.

In describing scanning procedures with "horizontal" and "vertical", it is assumed that a **test object** is insonated from above, and that the image on the scanner is oriented correspondingly.

# **6 Techniques for calibrating 2D-measurement systems**

### **6.1 Test methods**

To carry out the test procedures, the following items are required:

- a) tissue-mimicking **test objects** containing **targets** at accurately specified positions;
- b) tissue-mimicking **test object** containing a 3D-object of accurately specified dimensions;
- c) a tank containing degassed **working liquid**.

The specifications of these devices are given in the annexes.

#### **6.2 Instruments**

#### **6.2.1 General**

The equipment specified in this subclause has been selected to permit testing of ultrasonic scanners in clinical usage. The devices described will ensure that the data collection and analysis will be objective and reproducible.

#### **6.2.2 Digitizers**

While some spatial measurements can be made with long-existing digital callipers, for more generally applicable, objective, reproducible data, the **ultrasound** images obtained for testing should be digitally encoded. Many modern **ultrasound** imaging devices produce digital images from the scan converter that can be used for these measurements and are most closely representative of the displayed images. Such measurements can be employed well by hospitalbased users with some digital measurement expertise. For spatial measurements this procedure is directly applicable. For **PSF** and **LSF** measures it is necessary, however, to have a characteristic curve of linear echo amplitude at the transducer as a function of the digital image values or to create a sparse representation of that curve by use of calibrated reflectors as described in 7.2.1.2 of [19]. In some systems, rf scan-line data are available. Such data are more accurate for precision measurements in which the linear signal amplitude is important. Measurements made with rf data should be clearly indicated as such and the level at which they came from the system documented. For those machines that do not produce digital images, a frame grabber may be used to acquire and digitize **ultrasound** images. This digitizer requires adequate spatial resolution (at least 512 × 512 **pixels**) and sufficient **grey scale** (at least 256 grey shades). Also, adequate image analysis software should be used to perform the simple measurements described below on the digital **ultrasound** images of the **test objects**. The digitizer shall exhibit a linearity producing spatial uncertainty of <1 % over 75 % of the image dimension measured, signal level (grey scale) linearity <3 % of full range and signal level stability over a year of <5 % of full range.

The digital imaging software should allow the user to be able to place the cursor at any location on the screen and obtain the pixel address (i.e. row, column coordinates). This will allow the user to calibrate the digital image to actual distances recorded in the **ultrasound** images. Once the digitizer is calibrated, digitized ultrasound images can be subjected to more sophisticated software analysis than that which is possible directly on the ultrasound display. The digital imaging software should allow the reading of the grey value at any pixel address.

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To calibrate the digital image pixel distance (i.e. calibrate the digitizer relative to the **ultrasound** imaging system):

- a) Scan an image of a **test object** containing appropriate **working liquid**. Make a note of the magnification level for this image and make all subsequent measurements and comparisons with the same level of magnification.
- b) Measure the known distances between the positions of two wires or filaments at a distance of about 75 % of the screen size with the electronic callipers to confirm that the calliper measured distance corresponds to the actual distance. The measurement should be performed for a pair of wires or filaments connected by a vertical line and for a pair of wires or filaments connected by a horizontal line. In case deviations are found the scanner should be adjusted before proceeding further. If adjustment is not possible the actual distances shall be used in d).
- c) Digitize the scanned image and use the imaging software to measure the distances in pixels between pairs of wires or filaments by obtaining the pixel address of each wire or filament location, and subtracting to obtain the distances in pixels. Repeat for several different locations, checking both vertical and horizontal distances.
- d) Measure the distance in pixels for various positions of wires, using various directions of the connecting line with respect to the vertical. Divide each distance by the actual distance in mm. Average these ratios; this average ratio is the pixels per millimetre calibration for your digitizer. Once this calibration has been performed, this ratio can be used to compute relative distances in all subsequent digitized images for the particular scanner and magnification used.

See [10].

#### **6.2.3 Tissue-mimicking test objects**

Tissue-mimicking **test objects** shall contain structures that allow the following types of measurement to be made:

- a) linear;
- b) curvilinear;
- c) circumferential;
- d) area;
- e) volume;
- f) image distortion;
- g) **M-mode** calibration.

Examples of tissue-mimicking **test objects** are given in Annex B.

#### **6.3 Test settings**

#### **6.3.1 General**

The many combinations of scanner settings and transducers make it impracticable to carry out tests for all of them. Tests are therefore carried out for each **ultrasonic transducer**. with two settings, one which provides a complete image and one which provides the highest resolution of the **test objects.** The focusing of the ultrasonic beam should be extended over as large a range as possible, to achieve the best resolution over all visible **targets**.

The **test object**, containing an array of filaments as in Figure A.1, is used for the procedures described below.

# **6.3.2 Display settings (focus, brilliance, contrast)**

The focus is made sharp and the brilliance and contrast controls are turned to their lowest positions. The brilliance is now increased until the echo-free zone at the side of the image becomes the minimum perceptible shade of grey. The contrast control is then increased to make the image contain the greatest range of grey shades possible. The focus is then checked for sharpness. If it requires further adjustment, the whole procedure is repeated.

# **6.3.3 Sensitivity settings (frequency, suppression, output power, gain, TGC, ATGC)**

- a) The **nominal frequency** of the **ultrasonic transducer** is noted.
- b) If there is a suppression- or reject-control, it is adjusted to allow the smallest possible signals to be displayed.
- c) The output power and **gain** are adjusted to present the images of the **target** filaments as the smallest visible points on the display.
- d) The **time-gain compensation (TGC)** controls are arranged to present the images of the **target** with equal brilliance over the image. For scanning in **working liquid** the TGC slope should be close to zero

# **6.3.4 Final optimisation**

A final optimisation of the image may be carried out by a small change in the suppression level, **gain** or output power.

When **automatic time-gain compensation (ATGC)** is an option in a scanner, tests should be carried out in this mode of operation. The **test object** is imaged with **ATGC** enabled, the image being optimised using any control which still functions manually, e.g. the overall **gain** or output power.

# **6.3.5 Recording system**

The digital acquisition of **ultrasound** images allows for objective measurements and also allows the images to be saved for comparison at a later date. A major advantage of digital recording is that images are not subjected to the degradation that occurs with either photographic or video recording systems.

# **6.4 Test parameters**

# **6.4.1 General**

Techniques are described in this standard for the following types of measurement:

- − linear;
- − curvilinear;
- − circumferential;
- − area;
- − volume;
- display and recording distortion;
- − **M-mode** calibration.

Transmitted intensity should be low enough to avoid pulse distortion due to non-linear propagation (see IEC 61102). A list of all factors influencing the operation of the scanner for example transducer, frequency, sensitivity control settings, focusing, image processing option shall be made. These data are to be recorded in sufficient detail so as to allow the test to be repeated exactly at a later date by another operator and shall accompany the measuring results.

#### **6.4.2 Measurement accuracy (linear, curvilinear, circumferential, area)**

To assess the accuracy of the measurement system of a scanner, the wires or filaments in the **test object** shown in Figure A.1 or Figure A.2 are imaged with the sensitivity adjusted to make the displayed echoes as sharp as possible. If the test object is sealed, a coupling agent shall be used. An **ultrasound** image is obtained and digitized of the set of filament **targets** situated at the middle of the typical working range for the **ultrasonic transducer** assembly being used. Other factors that may affect the value of the resolution are also noted, for example the image processing options of the scan converter or focusing. The procedure is repeated for the other **ultrasonic transducers** of the scanner.

Measurements are made in straight lines on the screen of lengths approximately equal to 75 % of the displayed range. Using image analysis software, a linear brightness profile is obtained along each dimension. Distances are measured "from peak to peak" of the wire or filament brightness profiles. (In case the measuring results are noisy, the position of a peak value is replaced by the midpoint between the –3 dB points and that action noted.) These measurements are carried out along at least a vertical and a horizontal line in Figures A.1, and A.2 and, when possible, along near-vertical directions in the **field-of-view**. The average percentage error is tabulated for each length in each direction. The process is repeated for the available display scales.

To evaluate the accuracy of measurements of curved lines and cross-sectional areas, closed figures having an area approximately 0,75 of the **field-of-view** are traced centrally on the display. The circumferences and areas are measured and the percentage errors calculated. The tracing is done point-to-point, so that a polygon-shaped region is traced. The circumference and area of the polygon are measured. Additional measurements are made with two smaller figures (areas 0,1 and 0,25 of the **field-of-view**) located at the top and bottom of the display. This process is repeated for the available scales of the display.

For rigorous testing, sources of variability should be evaluated. This holds true for both shortterm and long-term variation in measurement and analysis procedure. Short-term testing (same-day) should be repeated multiple times from setup to final analysis. In manual testing, an operator should repeat the tests over a short period of time and then the tests should be repeated by several operators.

#### **6.4.3 Display and recording of image distortion**

Scan the two-dimensional, regular array of filaments of the **test object** shown in Figure A.2, so that their echoes are seen with equal brilliance throughout the **field-of-view**. Select wires or filaments located horizontally and vertically from the centre throughout the **field-of-view**. Measure on the digitized image the distance from the centre of each wire or filament to the centre of a reference wire or filament located at approximately the centre of the **field-of-view**. Calculate and tabulate the percentage errors.

Observe the directly viewed image of the array of filaments to check that any distortion (i.e. failing orthogonality) of dimensions in the display is less than 3 %.

#### **6.4.4 M-mode calibration**

#### **6.4.4.1 General**

An **M-mode** facility exists on most real-time scanners. A partial assessment of its performance can be carried out using the **test objects** described in Annex A.

#### **6.4.4.2 Spatial measurements (scrolling A-scan line)**

Performing an **M-mode** scan with the **ultrasound beam** directed at wires or filaments in a resolution **test object**, as described earlier for the **B-mode**, enables the measurement errors of a system to be ascertained.

Distortions of the display or record are checked and recorded using the array of **target** filaments in the **test object** as is done for a **B-mode** image.

The accuracy of the time-axis calibration of the **M-mode** trace can be checked by injecting bursts of **ultrasound** into the **ultrasonic transducer** using an external pulse generator and transducer at accurately known intervals, for example 1 ms bursts at 200 ms intervals.

Measurement checks should be carried out for the digitized image of the **M-mode** trace on the display screen. The errors in measurement should be less than 3 %.

#### **6.4.4.3 Tissue-thickness M-mode**

For tissue-thickness **M-mode**, the system measures changes in relative thickness of moving tissue. Thus, evaluation of the accuracy of these measurements requires a tissue-like phantom that can be compressed and relaxed at pre-determined positions, and the ability to compare the compressed and relaxed thicknesses with the **M-mode** readings. Also, it should be possible to compress and relax the phantom at different rates. A deformable sponge phantom might be useful for this measurement. It is important to have the ability to test the synthetic **M-mode** at various depths, so the phantom should allow for re-positioning the transducer for different **target-**to-transducer distances. Also, the test should be repeated for each of the **M-mode** sweep speeds.

#### **7 Methods for calibrating 3D-measurement systems**

#### **7.1 General**

Three-dimensional (3D) imaging systems exist which are only used for visualization, while others include measurement capabilities. Since 3D-reconstruction of volumes is achieved in different ways, it is important to examine the volume reconstruction method and its associated problems, and evaluate the accuracy of the reconstructed images. This discussion is limited to measurement of dimensional accuracy of reconstruction. Measurement of 3D-system resolution will be discussed in document IEC 61391-2 dealing with system resolution and sensitivity.

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#### **7.2 Types of 3D-reconstruction methods**

#### **7.2.1 General**

True 3D-imaging requires that the imaging system assemble data in a 3-dimensional **voxel** matrix. This matrix is usually composed of data from a stack of ultrasonic **scan planes** that contain the **target** volume. The 3D-imaging system stores the information as a 3-dimensional matrix. The spatial density of data-matrix points depends on the number of **ultrasonic scan lines** within each ultrasonic **scan plane**, the pulse length, and the number and spacing of ultrasonic **scan planes** that make up the elevational (depth) dimension. The manner in which the volume of interest is scanned is important, since reconstruction accuracy will depend on how well physical distances are preserved. The distance between successive ultrasonic **scan planes** should be constant, but it should be less than the elevational resolution (**slice thickness**) of the **ultrasonic transducer**. Otherwise, interpolation of adjacent ultrasonic **scan planes** will be included in the reconstructed volume. This interpolation can lead to errors in the dimensions of the reconstructed volumes.

Once the 3D-matrix is constructed, data may be obtained along any dimension within that volume. For example, if multiple images of xy-**ultrasonic scan-plane** data are collected to form a 3D-volume, the resulting 3D-matrix can be "sliced" normal to the y-axis in the xz plane, producing C-scan slices from the resulting data. Also, the resulting 3D-reconstruction can be rotated in space, so as to be viewed and measured from angles that were not available in the original ultrasonic **scan planes**.

[See [11, 12] for reviews of 3D-scanning techniques.]

3D-volume-matrix acquisition and reconstruction are performed in two basic ways:

- a) reconstruction by external positioning;
- b) sequential reconstruction.

Each method has its own characteristics, strengths, and problems.

#### **7.2.2 3D-volume reconstruction methods**

#### **7.2.2.1 External positioning methods**

Reconstruction methods for 3D-volume by external positioning methods use a reference point and a coordinate reference frame, and all dimensions and positions within the 3D-volume matrix are recorded with respect to the reference coordinates. In these types of systems there is usually a scanning framework, into which the scanning volume is inserted, and the transducer is usually motorized and rides on a rail at a constant speed. Other forms of rigid support may be used that restrain the **ultrasonic transducer** to maintain its 3D-coordinates accurately. This type of reconstruction method is the most accurate and reliable, but is subject to some problems due to initial positioning of the **ultrasonic transducer**'s support frame, motor speed deviations, or changes in the positioning system during the data-collection phase. A variant of external positioning systems exists, in which the transducer is guided manually and its position and direction are sensed with respect to a reference coordinate system.

[See [13].]

### **7.2.2.2 Sequential positioning methods**

Sequential positioning and reconstruction methods use different techniques but are usually based on attachment of subsequent **scan planes** to the 3D-matrix based on the position of the previous plane. One such method uses the rate of change of image speckle in at least one dimension [14, 15]. This encoding involves several assumptions that are not always valid. One assumption is that the motion is either a purely linear sweep or a purely angular sweep. In some commercial implementations, a simple, uniform, linear sweep speed is assumed. Tests are therefore important to demonstrate the capabilities and limitations of the measurements under laboratory conditions. Problems occur if the transducer is not moved at a uniform speed, or if the transducer angle shifts from its previous orientation. The reconstruction scheme, in most cases, cannot compensate for these shifts in reference plane orientation, and the reconstructed volume will contain inaccuracies.

#### **7.3 Test parameters associated with reconstruction problems**

#### **7.3.1 Reconstruction by external positioning**

For reconstruction by external positioning-system testing, either water-based or tissuemimicking-based **test objects** may be used.

Test parameters: From the reconstructed volume, measure the reconstructed lengths in all three Cartesian coordinate directions and compare with the physical object dimensions along the same coordinate directions. Check the **ultrasonic transducer** orientation with respect to frame and point of reference; speed of motor; distance between ultrasonic **scan planes**; and Cartesian dimensions of reconstructed volume. Procedures for measuring the following parameters are described below.

- a) linear dimensions;
- b) areas;
- c) perimeters of areas;
- d) volumes.

#### **7.3.2 Sequential plane reconstruction systems**

Systems in which 3D-spatial encoding is based on the image speckle require a **test object** with relatively uniform speckle backscatter and structures to allow tests of the accuracy and precision of the registration. With certain **ultrasound** systems not only should the accuracy of measurements over long distances be tested, but also the uniformity of the distance scale. Many sequential encoding systems require additional tests due to imprecise position encoding. When such imprecision exists, the direction in an image can be distorted by local jumps or retardation of recorded position in the direction of scanning.

Test parameters: from the reconstructed volume, measure the reconstructed lengths in all three Cartesian coordinates and compare with the physical object dimensions along these same coordinates. Procedures for measuring the following parameters are described below.

- a) linear dimensions (axes);
- b) areas;
- c) perimeter of areas;
- d) volumes.

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#### **7.3.3 Test instruments (phantoms) for evaluation of 3D-reconstruction accuracy**

#### **7.3.3.1 Filament phantom (water-filled)**

For the reconstruction method by external positioning, a filament **test object**, filled with **working liquid** as described in Annex A, Figure A.1 or Figure A.2, may be used. Since the system does not depend on speckle correlation to place the ultrasonic **scan planes** into the 3D-matrix, the filament matrix is a useful structure for testing reconstruction accuracy. For each of the rows of filaments, the distance  $r$  from the image location of a filament to a reference filament is measured and plotted against the known distance *r*' in the phantom. The maximum and r.m.s. deviations of the measured filament positions from the linear regression lines of *r* on *r*' are measured, as well as the slopes of the fitted lines.

If the volume measurement algorithm of the system under test can work with sharp corners and flat surfaces, the accuracy of measurement of well-defined volumes are best tested with a filament **test object** as in Figure A.1 or A.2.

#### **7.3.3.2 Tissue-mimicking phantom**

A second **test object** that can be used to test both types of systems is shown in Annex B. Figures B.1 to B.4 show different views of ovoid-shaped **tissue-mimicking material** structures with minimal specular boundaries, set in a **tissue-mimicking material** matrix. Such a **test object** is volumetric and the **targets** are defined in the image by differences in **backscatter contrast**. Only the **grey scale** texture and average signal level define the borders This reliance on volumetric backscatter rather than specular reflectors or **point targets** allows evaluation of image formation, display and measurement aspects of the ultrasound system's reconstruction of volumetric **target**s imaged in the body.

#### **7.4 Test methods for measurement of 3D-reconstruction accuracy**

#### **7.4.1 General**

These methods are for 3D-measurements with conventional 2D-scanners as well as 3Dscanners. For high quality 3D-imaging and testing thereof, the separation of the recorded image planes should be less than the width of the ultrasonic **scan plane** thickness at its focus, ideally, less than one half the elevational (ultrasonic **scan plane**) focal width. If controls for scan-plane separation are provided, such settings should be employed.

#### **7.4.2 Measurement methods and accuracy using the filament test object**

Volumetric measurements from two orthogonal 2D-images: 3D-measurements are often made with simple 2D-imaging systems by acquisition of two orthogonal views of a roughly spherical object, measurement of the three major axes of the object, and calculation of the spherical or ellipsoidal volume by appropriate equations therefore or by the ultrasound system. Either volumetric calculation method can be tested on one of the images from the stack of the previous paragraph by measuring the diameters of the assumed sphere passing through four or more filaments in the phantom and then repeating the measurements on the same or adjacent image, assuming that the two were acquired at 90-degree angles to each other. The calculation of the sphere with cross-section equal to the circle measured is then calculated, compared with the volume of the assumed sphere, and the error computed.

Tests for correction of angulation of scan plane in the elevational direction and for verification of the measurement algorithm from a 3D-sweep parallel to filaments: Perform a 3D-scan with the central acquired image planes normal to the filaments and the scan direction parallel to the filaments, i.e., with the transducer in View B of Figure A.1. If the system allows rotation of the transducer in an arc in the elevational direction, perform the scan in that way and, if possible, display the reconstructed volume with all the reconstructed images normal to the filaments. If that reformatting is not an option in a sector scanner, correct the separation of the filaments for the known viewing angle. If not already so done in the same way in 6.4.2, perform the measurements of 6.4.2 on the first, middle and last image of the 3D-set and document their errors and variances. The ratios of mean filament spacings to known spacings for the horizontal and vertical directions are referred to as the lateral- and longitudinal-dimension calibration factors, *Rx* and *Ry* respectively. Check that the mean spacings of groups of filaments that should have the same spacings are the same in each of the image planes within 1 %.

#### See [16].

For calibration of the **ultrasonic scan-plane** separation in 3D-imaging and for assessing distortion of images reconstructed (from a volume data set) with one axis in the **ultrasonic scan-plane**'s thickness direction, the transducer is moved or rotated slowly in the elevational (ultrasonic **scan-plane**'s thickness) direction normal to the filaments. That is, the transducer is moved from left to right (Transducer View A) on Figure A.1. This motion is performed in accordance with directions for this type of 3D-scanning as provided by the **ultrasound** system manufacturer. Often only a linear translation or a sector sweep is allowed but it is instructive to deviate from the instructions to see the amount of error generated.

For each of the rows of filaments from this second scan (View A), display reconstructed images that are perpendicular to the filaments. Calculate and report the maximum and r.m.s. deviations of:

- a) the measured filament spacings from their known values;
- b) the measured filament positions for the fitted lines;
- c) the slopes of the fitted lines from the expected values.

To evaluate the accuracy of curved lines and cross-sectional areas, closed figures are traced centrally on the display of curves and areas covering approximately 0,75 of the field-of-view. The lengths, circumferences and areas are measured and the percentages of measured-toknown areas calculated. Volume measurements are tested in these data with the sweep direction orthogonal to the filaments. Mark a known area, *A*, in the reconstructed image that is perpendicular to the filaments. Mark an **ultrasound** system-indicated length *L*' along the filaments for the third dimension of a 3D-volume enclosed by the filaments. For Figure A.1 this volume would be a cylindrical rod. Compare the measured volume  $A' \times L'$  with the known

volume A  $\times$  *L'*/ $R_x$ , where  $R_x$  is the lateral-dimension calibration factor from the second paragraph of this subclause. Further examples of measurements with filament **test objects** are given in [16].

#### **7.4.3 Measurement accuracy using volumetric targets in a backscattering object phantom (Figure B.1) with a 2D-scanner**

#### **7.4.3.1 General**

In these measurements, the transducer is rotated and tilted to find a circular cross-section of each of the **targets** in the 3D-**test object** that can be fully imaged in one view. For each **target**, move and adjust the image plane to find the minor axis, the largest diameter where the object still appears circular. The calliper markers are placed on the ends of the largest vertical (axial)

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diameter, *b*y, obtainable through that circular cross-section and the value is noted on the calliper read-out. A horizontal (lateral) diameter,  $b<sub>h</sub>$ , is measured in a similar way. The average of those two diameter measures is labelled *b*.

Rotate the transducer through 90° and find and measure the longest dimension of the ellipsoid, referred to as *a*, where *a* is the sum of the lengths of each half of the egg,  $a_1 + a_2$ . These procedures are repeated for the smaller 3D-object, if possible. The results obtained are tabulated in Table 2. Compare the measured values with the known values of the diameters given in Table 1.

#### **7.4.3.2 Perimeters**

Using an image of a cross-section of an ovoid **target**, begin to measure at a desired point on the perimeter of the **target** to be measured. Calliper markers are placed all along the selected image of the 3D-object until the starting point is reached. On average, the separation of the calliper markers should be no more than 1/20 of the estimated length of the perimeter except when an ellipse, or at least a curved line, fit is performed by the **ultrasound** system. The

equation for the perimeter [17] of each of the two half-ellipses is approximately:

$$
P = \frac{\pi}{\sqrt{2}} \left[ a_i^2 + \left( \frac{b}{2} \right)^2 \right]^{1/2}
$$
 (1)

where

 $a_{\mathsf{i}}$  is either  $a_{\mathsf{1}}$  or  $a_{\mathsf{2}}$ , the semi-major axes for a given half of the ellipsoid;

*b* is the mean minor axis of the ellipsoid.

The perimeter of the entire egg-shaped object is the sum of the perimeters of the two halves. The perimeter of the circular cross-section is 2π*b.* See Table 1 for expected values for the two objects in Figures B.1 and B.2.

#### **7.4.3.3 Areas**

On virtually all machines, a value for the enclosed (cross-sectional) area is calculated from the same measurement points defined in the perimeter measurements (see 7.4.3.2).

The measured area values should be compared against the known areas for the 3D-object cross-sections. In the largest elliptical and circular cross-sections, respectively, the areas are [17]

$$
A_c = 0.79 \ b \ (a_1 + a_2) = \pi \ b \ (a_1 + a_2) / 4 \ and \quad A_c = 0.79 \ b^2 = \pi \ b^2 / 4
$$

The surface area of the ellipsoids is given by:

$$
A = 2 \pi \left(\frac{b}{2}\right)^2 + \pi a_1 \left(\frac{b}{2 \varepsilon_1}\right) \arcsin \varepsilon_1 + \pi a_2 \left(\frac{b}{2 \varepsilon_2}\right) \arcsin \varepsilon_2 \tag{2}
$$

where

 $\varepsilon_1$  is the eccentricity  $(1 - (b/(2a_1))^2)$ ;

 $\varepsilon_2$  is the eccentricity  $(1 - (b/(2a_2))^2)$ .

See Table 1 for expected values for the two objects in Figure B.1.

#### **7.4.3.4 Volumes**

Volume measurements or relative measurements of objects of consistent shape can be made by measuring maximum linear dimensions on three orthogonal axes. In the case of 3Dellipsoidal objects [17], the actual volume is given as:

$$
V = 0.52 \left( a_1 + a_2 \right) b^2 = \frac{4}{3} \pi \frac{\left( a_1 + a_2 \right)}{2} \left( \frac{b}{2} \right)^2 \tag{3}
$$

The volume can be determined by measuring individually the two lengths, *a* and *b*, where  $a = a_1 + a_2$ . Averaging two perpendicular measures of *b* is appropriate. These measurements can be made from two image planes, with the transducer rotated 90º between them. Note this calculation method is essentially correct only for volumes approximating two half-ellipsoids with circular cross-sections. (For estimating the volume of any mass that resembles an ellipsoid with orthogonal axes *a, b*, and *c*, equation 3 would have *V* = 0,52*abc*). See Table 1 for expected values for the two objects in Figure B.3.

For applicability to other shapes and probably increased accuracy, a series of images is obtained from equally spaced ultrasonic **scan planes**. For high accuracy, the separation of the ultrasonic **scan planes** should be less than the width of the ultrasonic **scan-plane** thickness at its focus, ideally, less than half that focal width. In the conceptually simplest calculation, the volume is estimated by considering it to be composed of a number of cylinders of base area equal to that measured in a ultrasonic **scan plane** and height equal to the separation of the planes, i.e., multiply the cross-sectional area of the 3D-object in each plane by the scan separation and add these volumes for each slice. This calculation can be tedious by hand. More sophisticated volume-measurement algorithms are implemented on most 3D crosssection imaging systems and should be tested.

	<b>Half the</b> perimeter <sup>a</sup>	<b>Perimeter</b>	Area	Surface area	Volume
	cm	cm	cm <sup>2</sup>	cm <sup>2</sup>	cm <sup>3</sup>
Small object					
Long half	3,01	6,02	3,82	14,51	4,58
Short half	1,65	3,31	1,70	9,94	2,04
Total	4,66	9,32	5,51	24,45	6,61
Cross-section	2,83	5,65	2,54		
Large object					
Long half	5,35	10,7	16,5	63,6	55,0
Short half	4,16	8,3	11,0	69,9	36,6
Total	9,5	19,0	27,5	133,6	91,6
Cross-section	7,9	15,7	19,6		
The perimeters and half-perimeters here are calculated from the exact elliptical integrals, rather than from Equation 1.					
a Half the perimeter is a test of curved path length					

**Table 1 – Expected values for the two ellipsoidal objects in Figure B.3** 



#### **Table 2 – Suggested table of reported values**

Enter the measurement then that measurement as a percent of the expected value from Table 1. This form should be filled out for each of the measurement algorithms under study. It is instructive to fill out all or parts of the table from values calculated from the linear dimensions,  $a_1$ ,  $a_2$ , and *b*, using equations 1, 2 and 3, as well as from any other measurement method provided on the imaging system. Similar measurements are performed in 3D-fetal biometry [18]. This table may also be used for curved line, area and volume measurements from the filament test objects.

### **8 Measurement of point-spread and line-spread functions (high-contrast spot size)**

#### **8.1 General**

High-contrast resolution characteristics of most imaging systems can be characterized by measurement of the **point-spread function (PSF)**, which is the characteristic response of the imaging system to a high-contrast **point target** or the similar **line-spread function (LSF)**. For most optical systems, the **PSF** is singular, symmetric and isotropic. Thus, a measurement of the **PSF** usually is sufficient to characterize the system's impulse response.

Unlike optical imaging systems, **ultrasound** produces a **PSF** and **LSF** that is neither singular nor isotropic. Further, the **ultrasound PSF** and **LSF** are asymmetrical, having different axial and lateral dimensions, and they also vary with distance from the transducer (i.e. depth in the image). Thus, many different measurements of the **PSF** and **LSF** at different positions and depths must be performed to obtain representative values of the system's imaging performance at specific positions along the beam axis.

An individual **PSF** or **LSF** cannot be used as the system's impulse response. Due to changes in the **PSF** and **LSF** with depth, there are different levels of resolution, depending on the position within the **ultrasound** scan.

Another complication arises from the way **ultrasound** behaves with high-contrast **targets** versus low-contrast **targets**. At high contrast, **ultrasound** can image very small structures, such as thin wires, filaments or the tip of a needle, or an air microbubble. Each of these will produce a characteristic smear that is associated with the **PSF** or **LSF**. For low-contrast **targets**, such as tissue, however, **ultrasound** images do not produce images of individual point **targets**, but rather, form a grey **speckle pattern** that appears as a grainy background, whose characteristics arise from the coherent nature of the **ultrasound beam**. A measurement of the dimensions of the PSF for an ultrasound system at a given depth describes the highcontrast resolution of the system at that depth. For low-contrast resolution measurements,

a tissue-mimicking phantom is used, and the contrast-detail performance is sometimes measured. In this document, only the high-contrast behaviour of the **ultrasound PSF** or **LSF** will be measured. Low-contrast measurements will be described in another standard (See future IEC 61391-2).

In this document **PSF** and **LSF** are measured at two levels: FWHM (full width at half maximum), i.e. at –6 dB from the maximum, and at –20 dB. This requires that the relation between grey level and signal intensity be known (see 8.4.5).

NOTE Resolution on a two-target phantom (axial, lateral, or elevational) can be approximated from the PSF or LSF by adding two PSF- or LSF-curves as functions of distance between them and identifying the separation where there is a dip in the combined curves of –6 dB. Rigorously, the rf signal at each point in the PSF or LSF, and for each assumed target, must be summed to more accurately simulate the two-target response.

#### **8.2 Test methods**

To carry out the test procedures, the following items are required:

- a) **test objects,** as described in Annex A and Annex C, containing **targets** at accurately specified positions;
- b) a tank containing degassed liquid;
- c) digitized images, as described in 6.2.2 and 6.3.5.

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

#### **8.3 Instruments**

#### **8.3.1 General**

The instruments specified in this subclause have been selected to permit testing of real-time ultrasonic scanners without requiring electronic signals to be output from or input to the scanners.

#### **8.3.2 Test object and tank**

A **test object** should contain structures that allow the following machine features to be measured:

- a) **axial resolution**;
- b) **lateral resolution**;
- c) scan **slice thickness**;

Examples of **test objects** are given in Annexes A and C.

A tank of degassed **working liquid** is required. Under circumstances that allow a deviation of the speed of sound (see 5) the **working liquid** can be replaced by water to facilitate handling.

#### **8.3.3 Image digitizer**

An image digitizer as described in 6.2.2 is required.

#### **8.4 Test settings**

#### **8.4.1 General**

The many combinations of scanner settings and transducers make it impossible to carry out tests for all of them. Tests are therefore carried out for specified settings and for each transducer. The scanner is set up using the procedures outlined below. The focusing of the ultrasonic beam should be extended over as large a range as possible i.e. to achieve the best average resolution over all visible **targets**.

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#### **8.4.2 Display settings (focus, brilliance, contrast)**

The focus is made sharp and the brilliance and contrast controls are turned to their lowest positions. The brilliance is now increased until the echo-free zone at the side of the image becomes the minimum perceptible shade of grey by observing the grey-shade bar on the display. The contrast control is then increased to make the image contain the greatest range of grey shades possible. The focus is then checked for sharpness; if it requires further adjustment, the whole procedure is repeated. If the system allows multiple focal zones, activate all of them for the desired range of measurements.

#### **8.4.3 Sensitivity settings (frequency, suppression, output power, gain, TGC, ATGC)**

- a) The **nominal frequency** of the scanner's transducer is noted.
- b) If there is a suppression or reject control, it is adjusted to allow the smallest possible signals to be displayed.
- c) The output power and **gain** are set to the minimum values consistent with displaying an adequate image.
- d) The **ATGC** controls are adjusted to remove the **ATGC.**
- e) The overall **gain** control is increased until the signal from the **target** is clearly visualized on the display.

#### **8.4.4 Recording system**

Digitized images will be used, as described in 6.2.2 and 6.3.5.

#### **8.4.5 Calibration of system characteristic curve**

A well-established method for calibrating the system characteristic curve (output signal as a function of acoustic-pressure signal at the transducer) is with planar boundaries of graded reflectivity [19, 20]. A simple, calibration phantom provides specular reflectors located parallel to each other and normal to the intended path of the **ultrasound beam** at different ranges from the transducer position in a **tissue-mimicking material**. At each range at least two reflectors are provided, with different reflectivities.

In its simplest form one plate has a 10 dB lower reflection coefficient than the other. This is achieved by constructing one plate of 342 stainless steel and the other of plexiglas. The steel is located on each step of one staircase (A), and the plexiglas on each step of another, adjacent staircase (B). At usual diagnostic frequencies, the first step is 1 cm below the surface followed by two additional steps at 2 cm and 5 cm depth. These steps are followed by two steps, one at 10 cm depth and another at 18 cm depth. The space above the steps is filled with **tissue-mimicking material**. The speed of sound,  $c$ , the density,  $\rho$ , and the attenuation coefficient slope,  $\alpha f$  (where  $\alpha$  is the attenuation coefficient at the working frequency,  $f$ ) of this **tissue-mimicking material** shall be as follows:  $c = (1.540 \pm 6)$  m/s;  $\rho = (1.05 \pm 0.05)$  g/cm<sup>3</sup>;  $\alpha$ /*f* = (0.5 ± 0.05) dB cm<sup>-1</sup>MHz<sup>-1</sup>.

Echo signals due to backscatter in the **tissue-mimicking material** should be at least 20 dB weaker than the echo signal from the weakest reflecting interface at all frequencies in the tested waveforms.

In use to calibrate a system's sensitivity control, gain or output, this phantom is imaged at a range at or beyond the transducer's focal zone and at a gain where the weaker reflector, on staircase B, is approximately 6 dB above the electronic noise level. If signal levels are too high, choose a deeper step and reduce the TGC as much as possible. Signal levels (10 dB apart) are recorded from the steps at that range on staircases A and B, respectively. Then the system's sensitivity control is increased until the signal from the step on staircase B (plate B) is equal to the signal level from the step on staircase A (plate A) at the previous control setting. Thus, the signal from plate A is now 10 dB above that for plate B at the first setting. By repeating this process, the entire signal dynamic range can be calibrated in 10-dB steps. By recording settings of the system's sensitivity control, this control is thus calibrated relatively as well. Interpolation of those control settings will allow calibration of signal changes at finer increments.

Another method for constructing the phantom is used to produce weaker signals lying more within the linear range of most diagnostic **ultrasound** systems. This method should be compared against the primary method for accuracy. The secondary method is to fabricate the steps on one staircase from high-density polyethylene (LB-861) and the steps on the other staircase from low-density polyethylene  $(NA-117)^2$ ). The high-density material has an impedance of 2,33 x 10<sup>6</sup> kgm<sup>-2</sup>s<sup>-1</sup>, while the impedance of the low-density material is 1,79 x  $10^6$  kgm<sup>-2</sup>s<sup>-1</sup> [21]. The reflection coefficients of these interfaces should differ by 10 dB in a tissue-mimicking gel. More staircases with steps having other reflection coefficients can be employed to produce even weaker echoes and finer gradations, e.g., [22]. However, these also shall be calibrated against the primary method. With low echogenicities, the temperature of the medium becomes critical and shall be controlled sufficiently precisely to maintain the relative echogenicity within ±0,5 dB.

Even more convenient, when available, is electrical signal injection, either directly, or by acoustically coupling another transducer, with a calibrated transmitter and receiver to the transducer under test [23]. Connectors for direct injection are expensive and system-specific, while acoustic coupling must be performed carefully. However, if referenced to the primary method above, signal injection can be used in practice.

**Point targets** for **PSF** measurements: A second acoustic approach is based on **target**s of different sizes and should also be referenced to the primary method above. As scattering cross-section increases with frequency, this type of **target** emphasizes the high-frequency part of the signal from the scanner. However, the same emphasis occurs for signals from distributions of small scatterers, so it is not unrealistic to test a scanner in this way.

Theory indicates that, for **targets** much smaller than the wavelength, **targets** of all diameters have the same frequency dependence. Hence, it is possible to make a series of reflectors with well-defined scattering ratios. A series of sphere diameters increasing by 26 %, such as, in microns,  $10 - 12,6 - 15,87 - 20 - 25,2 - 31,75 - 40 - 50,4 - 63,5$  and 80 would give reflectivities in steps of 6 dB, spanning a range of 54 dB. This approach has been implemented with dense distributions of small scattering particles, but practicalities of implementation are not well documented for individual particles.

 $\overline{\phantom{a}}$ 

<sup>2)</sup> Both materials are available from USI Corporation, Marlboro, MA, among others. They are examples of suitable products available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products.

Similarly, a series of flat-ended wires can provide calibrated reflectivities. Here the ratio of diameters should be  $\sqrt{2}$  = 1,41, to obtain a step of 6 dB. For 5 MHz, diameters in the range 200  $\mu$  to 1 600  $\mu$  could span a range of 36 dB with a precision of circa 1 dB.

#### **8.5 Test parameters**

#### **8.5.1 General**

To measure **point**- or **line-spread functions**, an appropriate **target** is scanned in a test tank. A standard point **target** is the tip of a flat-ended wire viewed on end; a standard line **target** is a filament or wire, typically lying normal to the direction of ultrasound propagation. The dimensions of the **point-spread function** (**PSF**) in each of the three directions are measured for complete, detailed system-performance evaluation, usually in a developmental-, production, or research setting. **Line-spread functions** (**LSF**s) are employed in the field and should be used in specifications to be tested in the field. **LSF**s are recommended over **resolution,** as measured with multiple **targets**, because fewer targets are required and spatial spreadfunction measurements are required at many locations in the **field-of-view** and are dependent on a system's focal- and frequency-settings. Actual **resolution** with target pairs is sometimes preferred for visual measurements and when non-linear signal processing, such as signal differentiation may be employed. **PSF** and **LSF** measurement on a line normal to and through the **ultrasound beam axis** are closely related to the imaging system's high-contrast **resolution** and to each other when scanned in a direction along the same line at the same depth in a phantom. **PSF, LSF** and **resolution** each can be derived from a full set of measurements of the other, if the characteristic curve of the ultrasound system is calibrated. See the definition of **spot size**, used in this standard to relate to the width of a **PSF** or **LSF** in a way more self-explanatory to those not familiar with the spread-function terminology.

**PSF**s and **LSF**s currently yield relative measurements. Quantitative measurements indicating the sensitivity of the imaging system to a specified or standard **point target** or point pressure source can be obtained [24-28] but experience with these techniques is too limited for standardization at this time. These measurements are closely related to the high-contrast **axial resolution** and axial **LSF** of the imaging system for a specific position along the beam (i.e. depth in a phantom).

For all such measures, the sensitivity and angulation of the scanner is adjusted so that the maximum signal from the **target** is clearly visualized during each test.

If a **line target** is used, oriented perpendicularly to the ultrasonic **scan plane**, the crosssection of the line with the ultrasonic **scan plane** constitutes the **lateral line-spread function**, but this configuration has two limitations:

- a) the **line-spread function** can only be measured in the ultrasonic **scan plane**;
- b) the intensity is sensitive to the orientation of the ultrasonic beam perpendicularly to the **line target**.

To overcome this limitation a spherical **target** has been used. However, now interference between ultrasonic paths inside the sphere leads to complicated patterns of angular scattering [24] unless the sphere is extremely small and a relatively weak reflector.

An alternative **test object** for the measurement of resolution is a single filament (or wire) mounted vertically (in the direction of the ultrasound beam) on a micromanipulator which allows the filament to be moved through the **field-of-view** (Figure C.3). This permits the **spot size** to be measured at any point in the **field-of-view**. It also removes the problem, encountered with an array of **targets**, of aligning all filaments perpendicularly to the beam at the same time to record a maximum signal from each.

When the point is much smaller than the wavelength (or than the diameter of the ultrasonic beam at the position of the **target** for measured transducers of large f-numbers), the **pointspread function** is measured independently of the properties of the **target**. Note that the response width from the **PSF** (from a **point target**) and the **LSF** (from a line **target)** are approximately equal. It has been shown that scattering strength depends smoothly on angle and frequency, and means of constructing **targets** have been proposed [25]. Figure C.4 gives two simpler alternatives.

From the theory of the scattering by the front plane (equation 3 of [25].), the value for the backscattering cross section*,*σ*,* is found:

$$
\sigma = \left[\frac{k r^2}{2} \left(\frac{Z_m - Z_w}{Z_m + Z_w}\right)\right]^2\tag{4}
$$

where

- *k* is the circular wave number;  $(= 2 \pi / \lambda)$  in which  $\lambda$  is the wavelength in the medium)
- *r* is the radius of the wire;
- $Z_{\rm m}$  is the characteristic acoustic impedance of the wire material;
- $Z_w$  is the characteristic acoustic impedance of the surrounding medium (water).

Scattering is proportional to the square of the frequency and the fourth power of diameter (as long as the diameter of the **target** is so small that no phase differences between various parts of the **target** occur). At small angles the influence of the angle between front plane and the direction of the beam is small [25]. At larger angles observed scattering is diminished. Making the **target** small decreases the influence of the angle.

At oblique incidence of the **ultrasound** on the front end of the wire the scattering strength decreases. The consequence is that for a sector scanner, reorientation of transducer or **target** is necessary, in case quantitative measurements of reflected intensities in various parts of the field are to be compared. Quantitative measurements of beam width remain possible without reorientation.

Figure C.4 shows a sketch of two **point targets** made from dental wire (diameter 0,24 mm). The left **target** is intended for pulsed **ultrasound**; echoes from the wire tip and the supporting tube are received separated in time. The supporting tube (outer diameter 1,0 mm) provides mechanical stability. The right **target** is intended for CW **ultrasound**; the tip of the wire is the only feature inside the **ultrasound beam** (grey) which gives backscattering.

#### **8.5.2 Axial PSF and LSF dimensions and axial resolution**

#### **8.5.2.1 General**

The dimensions of the **PSF** or **LSF** in the axial direction should be measured at different depths. An appropriate phantom for **PSF** is shown in Figure C.3 or C.4, the latter being required when reverberations from the support wire are obtrusive. **LSF** is measured with a

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phantom as depicted in Figure A.1, A.2 or C.1 and axial resolution with the phantom of Figure C.2. Measurements can be made in increments of less than 1/3 of the axial **field-of-view** for a total depth depending on the transducer's imaging range. Sources of variability should be identified and documented, as indicated in 6.4.2. Axial resolution at a specific depth can be obtained as the minimum separation 1) of the two filaments in Figure C.2 that are distinguishable before the two filaments first blur together; and 2) quantitatively, at which there is at least a 6 dB drop in the signal between the two filaments.

#### **8.5.2.2 Procedure – axial dimensions**

Align the transducer for maximum signal from the **target**(s). Alignment with the beam normal to any filament **target** is particularly critical. Set the system sensitivity controls so that all the **targets** are clearly visualized, but are not saturated. Make several **B-mode** images or image volumes of the **target** or phantom and digitize the best image. On some phantoms there is a scan window parallel to contained filament **target**s. Make sure that the **ultrasonic transducer** is well seated on the surface. When the transducer's face is curved, the central **scan line** should be normal to the scan window and the **ultrasound beam**s should be normal to the filaments.

For **PSF** measurements, a 2D-scan is required for the **point target** in each measured location, unless alignment with the central axis or central plane of the beam or image plane has been accomplished. For **LSF** or **PSF** an image of the **test object** is obtained which contains the imaged targets for the entire depth range of the **ultrasonic transducer**. Use image-processing software to plot a brightness profile in the vertical direction for many successive **scan lines** covering an imaged **target**, moving laterally from left to right, until the maximum amplitude profile of the **target** is obtained. For this maximum amplitude of the **target**, at least, the fullwidth-at-half-maximum (FWHM) and the –20 dB width are measured and recorded for the given filament depth. Now, measure the axial response width for all the imaged-**target** positions (depths) in the phantom image. Once all the axial response widths are obtained, plot the FWHM or –20 dB width versus depth in the phantom image. This plot shows the variation in axial **PSF** or **LSF** for the imaging system with depth. For most systems, there will be only a small variation in axial **PSF** or **LSF** with depth.

Profile length (**PSF** or **LSF**) at a relative signal level near the expected axial clutter level or clutter level at a certain number of wavelengths is also most illuminating, if artefacts in the phantom allow that measurement.

#### **8.5.3 Lateral PSF- and LSF-width and lateral resolution**

#### **8.5.3.1 General**

The dimensions of the **PSF** or **LSF** in the lateral direction correspond to the high-contrast **lateral resolution** of the imaging system for a specific position along the beam (i.e. several depths in the phantom). An appropriate phantom for **PSF** is shown in Figure C.3 or C.4, the latter being required when reverberations from the support wire are obtrusive. **LSF** is measured with a phantom as depicted in Figure A.1, A.2 or C.1. Multi-**target** lateral resolution measurements are rarely required and are not addressed here. Measurements can be made over the total axial imaging range of the **ultrasonic transducer** in increments of less than 1/7 of the axial **field-of-view** along a generally central axis and at a distance from a lateral edge of the image of 1/8 of the image width. For volumetric imaging systems in which **PSF** might be

dependent on elevational position in the volume (as for a linear array scanned in an enclosed housing), make a measurement at a distance from an elevational edge of the image of 1/8 of the volume thickness and in a corner of the volume at a distance from a lateral edge and an elevational edge of the image of 1/8 of the volume width and thickness, respectively, Sources of variability should be identified and documented, as indicated in 6.4.2.

#### **8.5.3.2 Procedure – lateral dimensions**

Align the transducer for maximum signal from the **target**(s). Alignment with the beam normal to any filament **target** is particularly critical. Set the system sensitivity controls as described in 8.5.2.2. Make several **B-mode** images or image volumes of the **target** or phantom and digitize the best image. Make sure that the **ultrasonic transducer** is well seated on any scanning surface of the **test object**, so that the transducer face is perpendicular to the **test object**'s surface.

For **PSF** measurements, a 2D-scan is required for the point **target** in each measured location, unless alignment with the central axis or central plane of the beam or image plane has been accomplished. For **LSF** or **PSF**, an image of the **test object** is obtained which contains the imaged **target**s for the entire depth range of the **ultrasonic transducer**. Use the image processing software to plot a brightness profile in the horizontal direction for many successive **scan lines** covering an imaged **point target**, moving vertically from top to bottom (above and below the filament cross-section image), until the maximum amplitude profile of the **target** is obtained. For this maximum amplitude of the **target**, as a minimum, the full-width-at-halfmaximum (FWHM) and the –20 dB width are measured and recorded for the given filament depth. Profile width at a relative signal level near the expected transducer clutter level or clutter level at a certain linear or angular beam width, is also most illuminating, if artefacts in the phantom allow that measurement.

Now measure the maximum lateral-response width versus depth for all the imaged **PSF** positions (depths) in the phantom image. Once all the lateral-response widths are obtained, plot the FWHM or –20 dB width versus depth in the phantom image. This plot shows the variation in lateral **PSF or LSF** (lateral **spot size)** for the imaging system with depth. For most systems, the **lateral resolution** varies much more with depth than the **axial resolution**.

NOTE The use of the **test object** described in Figure A.2 may be inadequate for some **ultrasonic transducers** which produce such large **side lobes** that they interfere with those of neighbouring filament images. For this case, a **test object** such as that described in Figure A.1 may be used. For that **test object**, the lines of **targets** are angled, so that individual **targets** are rarely positioned along the same horizontal line. A better **test object** is described in Figure C.1, where all filament **targets** are positioned individually, so that there are no laterally neighbouring **targets**. Finally, a single filament (or wire) on a micromanipulator, similar to that described in Figure C.3 but normal to the ultrasound beam, may be used.

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

For simple measurements in the field, the **slice thickness** is determined by scanning the thin sheet of scattering **targets** shown in Figure C.5. The **slice thickness** (the same as the elevational spot-size resolution) at each depth should be measured with the sensitivity and display controls in calibrated positions. Consider the maximum displayed range as being divided into five consecutive equal-sized sections. Place the plane of scan to intersect the sheet of **targets** along a line parallel to the top surface of the **test object**. The ultrasonic

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**scan plane** should also be perpendicular to the **test-object scanning surface**. To measure the **slice thickness** in the middle of the first section, arrange for the line of intersection of the ultrasonic **scan plane** and the **target** sheet to be at that depth. Using visual measurements or image-analysis software, measure the vertical thickness of the image of the sheet of **targets** and calculate the **slice thickness** at the centre of this first section, as illustrated in Figure C.5. Repeat the procedure for the four other sections. With image-analysis software, the width of the image can be measured at any desired level, e.g., FWHM, FWTM, (–6 dB, –20 dB) or clutter below that of the peak of the sheet signal.

For elevational **PSF** with a **point target** as described in Figures C.3 or C.4 or **LSF** using a horizontal wire similar to Figure C.3 or the filament phantom in Figures A.1, A.2 or C.1, a **B-mode** image is made. The **target** is moved perpendicularly to the ultrasonic **scan plane** (or *vice versa*) until the maximum amplitude of the **target** is obtained. The movement is then executed sequentially in two opposite directions along a line perpendicular to the ultrasonic **scan plane**, until two times a certain decrease in intensity is obtained repeatably twice. For example, at FWHM and FWTM (–6 dB and –20 dB), the clutter level and other desired levels may be obtained. The distance between the points on both sides of the ultrasonic **scan plane** is the **elevational resolution** at the measured level of, e.g. –6 dB, or –20 dB.

Measurements can be made over the total axial imaging range of the **ultrasonic transducer** in increments of less than 1/7 of the axial **field-of-view** along a generally central axis and at a distance from a lateral edge of the image of 1/8 of the image width. For volumetric imaging systems in which **PSF** might be dependent on elevational position in the volume (as for a linear array scanned in an enclosed housing), make a measurement at a distance, from an elevational edge of the image, of 1/8 of the volume thickness and in a corner of the volume, at a distance from a lateral edge and an elevational edge of the image, of 1/8 of the volume width and thickness, respectively, Sources of variability should be identified and documented, as indicated in 6.4.2.

Optionally the measurement of **elevational resolution** can be facilitated by using an array of equal **point targets**, placed on a line that makes an oblique angle with the **scan plane**. The **target**s should be placed at such a distance that their images are spaced with a greater distance than the **lateral resolution** of the scanner at that depth. When the **target** placed in the centre has a backscattering cross-section at the required level below that of the other **target**s, the measurement can be executed by obtaining images of equal intensity.

#### **Annex A**  (normative)

# **Test objects – Calibration of 2D-spatial measurement systems**

NOTE The **test objects** and materials described in this annex are derived from those described in several national reports and draft standards. The **test objects** have been restricted to those that have been demonstrated in practice.

#### **A.1 Test object structures**

Figures A.1 and A.2 contain sets of parallel filaments serving as or approximating **line targets**. The filaments are also parallel to the top surface, which serves usually as the scan window. The figures show two possible arrangements of the cross section perpendicular to the filaments. Figure A.2 has the advantage over A.1 of a more regular structure, but more risk of hiding a **target** by **target**s on top of it.

The scales of the test objects shown are for general abdominal imaging at 2 MHz – 5 MHz centre frequencies. The distances between filaments in a row are 2 cm. Accuracy of filament placement should be ±0,2 mm. For higher-frequency imaging, a finer, 1 cm, filament spacing, overall dimensions equal to 1/3 of the those shown in Figures A.1 and A.2, and  $\pm 0.1$  mm placement accuracy are required.

For this standard each **test object** (Figures A.1 and A.2) is designed to be scanned directly in **working liquid**. . Nylon filaments in the objects are used to reduce the effect of shadowing. They are typically 0,078 mm in diameter (8X fly-fishing tippet). The tank should be sufficiently large to allow all transducers to be used in all required orientations to the internal structures.

Alternatively, the structures in Figures A.1 and A.2 may be immersed in **tissue-mimicking material** and scanned through an acoustic window of suitable material, such as polythene. A suitable window material should prevent the loss of water from the **tissue-mimicking material**. With **tissue-mimicking material** of typical backscatter, wires rather than nylon filaments should be used for the structures to give stronger echoes. Suitable wires for the **test object** are of stainless steel (type 316) with a diameter of 0,15 mm. These wires are sufficiently thin so that echoes from them are not elongated by internal reverberations at all but the highest diagnostic frequencies. They should be located in each **test object** to within ±0,4 mm.

These structures are designed with parallel filaments, as in most commercially available phantoms originally designed for calibrating 2D-imagers. They may be employed for 3Dimaging system calibration, two dimensions at a time, by rotating the scanhead 90 degrees about an axis normal to the filaments and lying centrally in the phantom and the imaged volume. A more general use of phantom motion has been published recently [29]. Numerous papers have been published since 1990 on filament phantoms for single view calibration of 3Dimaging and image-guided therapy systems [30].

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The calibration of **test objects** depends on the sound velocity of the medium (**working liquid** or **tissue mimicking material**). Sound velocity depends on temperature. With non- enclosed liquids, the change of composition by evaporation (e.g. of alcohol) should be considered. The stated margin in sound velocity (1 540  $\pm$  15) m/s contributes  $\pm$ 1 % uncertainty to measuring results. In view of variations in sound velocity in the body, this uncertainty is acceptable.

# **A.2 Test object diagrams**







An imaginary ellipse is shown for curved-line length measurements, such as a perimeter.

**Figure A.2 – Regular 2D-array of nylon filaments** 

# **Annex B**

(normative)

#### **Test objects – Measurement and calibration of 3D-image reconstruction accuracy**

### **B.1 Working-liquid-filled filament phantom**

The phantoms described in Annex A (Figures A.1 and A.2) are appropriate for 3D as well as 2D measurements.

#### **B.2 Tissue-mimicking filament phantom**

A suitable phantom for a filament **test object** containing a backscattering background is shown (Figure A.1) for 2D- and 3D-distance measurement and image-distortion assessment. For 3Dimaging, the scanhead is moved in the elevational (ultrasonic **scan- plane** thickness) direction from left to right on this figure to assess position registration in the **slice thickness** direction. The relative positions of all filaments are maintained within  $\pm 0.2$  mm at all locations. For arc length, perimeter, area and volume measurements the imaginary ellipse (or imaginary elliptical rod),  $a = \pm 2.7$  cm,  $b = \pm 3$  cm, is shown in Figure A.2. The area and circumference (perimeter) of the ellipse are  $\pi$  a b = 25,4 cm<sup>2</sup> and approximately  $\sqrt{2} \pi (a^2 + b^2)^{1/2}$  = 17,9 cm, respectively. Circular area and perimeter measurements and cylindrical rod volume and surface area measurements may be made easily on Figure A.1 and rectangular ones on Figure A.2. Volumes and surface areas of rods are, respectively, the cross-sectional area times the length and two times the cross-sectional area plus the perimeter times the length.

#### **B.3 Tissue-mimicking ovoid target test object**

Specification for 3D-, speckle-defined (egg-shaped) objects:

- Attenuation coefficient equal to that of the background material  $\pm$  0,2 dB cm<sup>-1</sup> MHz<sup>-1</sup>.
- Speed of sound equal to that of the background material  $\pm 6$  m s<sup>-1</sup> [9, 31].
- The egg-shaped objects have a **backscatter coefficient**  $-10$  dB  $\pm$  2 dB relative to that of the standard background material, whose backscattter coefficient at 3 MHz is  $3 \times 10^{-4}$  cm<sup>-1</sup>  $sr^{-1}$   $\pm$  6 dB (with an approximately  $r^4$  dependence from 1 MHz to 15 MHz).

#### **B.4 Spatial measurements from backscatter-defined objects**

A suitable **test object** for spatial measurements of backscatter-defined objects is shown in Figures B.1 to B.4. This **test object** is referred to as the 3D-egg **test object** because the measured geometries consist of two half-ellipsoids of revolution (oblate spheroids) joined end to end.

The side view (Figure B.1) shows the long-axis views of the two ellipsoids. A composite of two cross-sectional views is shown in Figure B.2 and projections are illustrated in Figures B.3 and B.4.

NOTE Alternatively, for practical purposes in the hospital, in which a standard phantom is not available, the 3Dobject shapes may be constructed of a low -attenuation material, such as open pore reticulated foam [6, 32] and immersed in saline or other fluid, such that the 3D-objects and the fluid meet the above speed-of-sound criteria, the differential attenuation of 0,5 dB cm<sup>-1</sup>MHz<sup>-1</sup>, and the backscatter coefficient of the 3D-objects (egg) at 3 MHz of 3 x 10<sup>-5</sup> cm<sup>-1</sup>  $sr^{-1}$  ± 16 dB (with an  $f^2$  to  $f^4$  dependence from 1 MHz to 7 MHz).

# **B.5 Test object diagrams**



**Figure B.1 – Tissue mimicking ovoid target phantom** 



**Figure B.2 – Composite of two cross-sectional views of test object shown in Figure B.1** 



**Figure B.3 – Projection view from top of test object shown in Figure B.1** 



**Figure B.4 – Projection view from end window of test object shown in Figure B.1** 

#### **Annex C**  (normative)

# **Test objects – Measurement of point-spread function response**

NOTE The **test objects** and materials described in this annex are derived from those described in several national reports and draft standards. The **test objects** have been restricted to those which have been demonstrated in practice.

### **C.1 Test object structures**

For this standard each **test object** (Figures A.1, A.2 and C.1 to C.5) is designed to be scanned directly in **working liquid**. Nylon filaments in the objects are used to reduce the effect of shadowing. They are typically 0,1 mm in diameter. The tank should be sufficiently large to allow all transducers to be used in all required orientations to the internal structures. Under some conditions (see 5) the **working liquid** may be replaced by water.

Alternatively, any of the mentioned structures may be immersed in **tissue-mimicking material** and scanned through an acoustic window of suitable material, such as polythene. A suitable window material should prevent the loss of water from **tissue-mimicking material**. Wires rather than nylon filaments should be used for the structures in the **tissue-mimicking material** to give stronger echoes. Suitable wires for the **test object** are of stainless steel (type 316) with a diameter of 0,15 mm. These wires are sufficiently thin so that echoes from them are not elongated by internal reverberations. They should be located in each **test object** to within  $\pm$ 0,2 mm.

# **C.2 Array of filaments in water (Figure C.1)**

The two-dimensional array of filaments is supported in a frame. The wires or filaments are as specified in A.1.

# **C.3 Axial resolution test object (Figure C.2)**

Two nylon filaments of typical diameter 0,1 mm are arranged to lie in the same vertical plane (Figure C.2) and at an angle to each other. The filaments can be supported over a range of depths. The volume of the liquid-filled tank should typically be a cube of side length equal to 20 cm.

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

The filament is mounted on a micromanipulator (see Figure C.3) which allows it to be moved throughout the **field-of-view** of the scanner. The filament is as specified in A.1. An alternative is to use a fine metal wire mounted as shown in Figure C.4. The diameter of the metal wire shall be much smaller than the beamwidth of the investigated transducer and smaller than  $\lambda/2$ for low-*f*-number transducers.

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# **C.5 Scanner slice thickness test object (Figure C.5)**

- a) A sheet of scatterers makes an angle of 75° to the top surface [33]. Suitable material for the sheet of scatterers has a **backscatter coefficient** more than 50 dB higher than that of the background material and the sheet is less than 0,4 mm thick.
- b) The method of calculating the scan **slice thickness** from the image is discussed in 8.5.4.



**Figure C.1 – Filament test object for measuring the LSF** 



**Figure C.2 – Axial resolution test object** 



**Figure C.3 – Movable single filament in water** 









**Figure C.5 – Slice thickness measurement and calculation** 

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### **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.



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