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TECHNICAL REPORT

colour inside

Ultrasonics – Real-time pulse-echo systems – Test procedures to determine performance specifications

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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IEC TR 61390 has been prepared by IEC technical committee 87: Ultrasonics. It is a Technical Report.

This second edition cancels and replaces the first edition published in 1996. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) Several additional phantom designs are included in the main body of the document;
b) Several additional transducer types are included in the Scope;
c) Methods of analysis are presented in new Annex B.

The text of this Technical Report is based on the following documents:

Draft	Report on voting
87/771/DTR	87/796A/RVDTR

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Report is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

NOTE Words in **bold** in the text are defined in Clause 3.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

An ultrasonic pulse-echo scanner produces images of tissue in a **scan plane** by sweeping a narrow, pulsed beam of **ultrasound** through the section of interest and detecting the echoes generated at tissue boundaries. Furthermore, the number of ultrasonic pulse-echo scanners using plane-wave imaging technology is increasing.

Alternatively, a scanner can transmit a wide-field wave-front or several transmit-beams and record from the whole transducer array the echoes backscattered from tissue boundaries [1] [2][1]. The latter is followed by software beamforming, picking several parts of the wide beam or in this way selecting one of the simultaneously transmitted beams to obtain adequate resolution. Plane-wave techniques cannot compete with physical, transmit beam-forming for maximum depth of imaging at a given **bandwidth**, maximum resolution and minimum acoustic exposure.

Ultrasonic scanners are widely used in medical practice to produce images of many soft-tissue organs throughout the human body. A variety of transducer types is employed to operate in a transmit/receive mode for generating/receiving the ultrasonic signals.

This document describes test procedures that should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use this document to prepare their own specifications, while users should use this document to check manufacturers' specifications. The measurements can be carried out without interfering with the normal working conditions of the machine. The structures of the **test objects, test equipment** and measuring systems have not been specified in detail; rather, suitable types of overall and internal structures are described, together with typical **test objects**, in Annex A. The specific structure of a **test object** and **test equipment** should be reported, together with the results obtained using them. Similar commercial versions of these **test objects** are available.

The performance parameters selected and the corresponding methods of measurement have been chosen to provide a basis for comparison with the manufacturers' specifications and between similar types of apparatus of different makes, intended for the same kind of diagnostic application. The manufacturers' specifications should allow comparison with the results obtained from the tests described in this document. Specific values of parameters and the tolerances on them have not been recommended, since these are constantly changing. 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.

The procedures recommended in this document are in accordance with IEC 60601-1:2005. Where a diagnostic system accommodates more than one option in respect of a particular system component, for example the 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.

Data relating to measuring methods, principles and equipment that are common to two or more sections of this report are given in Annex A. Specific test procedures are given in Annex B.

The measurement of acoustic output power levels and the assessment of electrical safety are dealt with in other IEC standards; they are therefore specifically excluded from this document.

[1] Numbers in square brackets refer to the Bibliography.

ULTRASONICS – REAL-TIME PULSE-ECHO SYSTEMS –

Test procedures to determine performance specifications

1 Scope

This document describes representative methods of measuring the performance of complete real-time medical ultrasonic imaging equipment in the frequency range 0,5 MHz to 23 MHz.

NOTE The frequency range given represents, in general, the widely used range in hospitals at the date of publication; special medical applications use higher frequencies for imaging but mainly in research or pre-clinical imaging.

This document is relevant for real-time ultrasonic scanners based on the pulse-echo principle, for the types listed below:

- mechanical sector scanner;
- electronic phased array sector scanner;
- electronic linear array scanner;
- electronic curved array sector scanner;
- water-bath scanner based on any of the above four scanning mechanisms;
- plane-wave/fast imaging scanners;
- combination of several of the above methods (e.g. a linear array phased at the edge to produce a sector there to enlarge the field of view.

The methods described are based on evaluation of:

- sonograms obtained by scanning of tissue mimicking objects (phantoms);
- sonograms obtained by scanning of artificial, low- or highly reflective **target**s in suitable environments;
- parameters of the **ultrasound** field transmitted by the measured scanner.

This document does not relate to methods for measuring electrical parameters of the scanner's electronic systems.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

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

[SOURCE: IEC 61391-1:2006, 3.1]

3.2
A-mode
amplitude-modulated display
method of presentation of **A-scan** information in which the **ultrasonic transducer-target** distance is represented on one axis (normally horizontal) and the echo amplitude on the other axis

[SOURCE: IEC TR 60854:1986, 3.17, modified – Replacement of "echo information" with "**A-scan** information" and "transducer to **target** distance" with "**ultrasonic transducer-target** distance"]

3.3
acceptance testing
evaluation of system performance after delivery of a purchased or repaired system and before authorisation for payment

3.4
acoustic clutter
noise artifact in **ultrasound** images that appears as diffuse echoes overlying signals of interest

Note 1 to entry: Sources of **acoustic clutter** include sound reverberation in tissue layers, scattering from off-axis structures, **ultrasound** beam distortion, returning echoes from previously transmitted pulses and random acoustic or electronic noise

3.5
acoustic scan line
one of the component lines that form a **B-mode** image on an **ultrasound** monitor, where each line is the envelope-detected **A-scan** line, in which the echo amplitudes are converted to brightness values

[SOURCE: IEC 61391-1:2006, 3.26]

3.6
acoustic-working frequency
centre 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

[SOURCE: IEC 61391-1:2006, 3.3]

3.7
axial resolution
minimum separation along the **beam axis** of two equally scattering volumes or **target**s at a specified depth for which two distinct echo signals can be displayed

[SOURCE: IEC 61391-1:2006, 3.5]

3.8
B-scan
brightness-modulated display scan
class of data-acquisition geometry in which echo information is acquired from points lying in an ultrasonic **scan plane** containing interrogating ultrasonic beams

Note 1 to entry: **B-scan** is a colloquial term for **B-mode** scan or image.

3.9
B-mode
brightness-modulated display
method of presentation of **B-scan** information, in which a particular section through an imaged object is represented in a conformal way by the plane of the display and echo amplitude is represented by local brightness or optical density of the display

[SOURCE: IEC 61391-1:2006, 3.10, modified – Replacement of "**scan plane**" with "plane"]

3.10
backscatter coefficient
at a specified frequency, the mean acoustic power scattered by a specified object in the 180° direction with respect to the direction of the incident beam, per unit solid angle per unit volume, divided by the incident beam intensity, the mean power being obtained from different spatial realizations of the scattering volume

Note 1 to entry: The frequency dependency should be addressed at places where **backscatter coefficient** is used, if frequency influences results significantly.

Note 2 to entry: **Backscatter coefficient** is expressed in units of 1 per metre times 1 per steradian ($m^{-1}sr^{-1}$)".

[SOURCE: IEC 61391-1:2006, 3.6, modified – In the definition, addition of "at a specified frequency", and addition of two new Notes to entry]

3.11
backscatter contrast
ratio between the **backscatter coefficients** of two objects or regions

[SOURCE: IEC 61391-2:2010, 3.8]

3.12
bandwidth
difference in the most widely separated frequencies f_1 and f_2 at which the magnitude of the acoustic pressure spectrum drops 3 dB below the peak magnitude, at a specified point in the acoustic field

Note 1 to entry: **Bandwidth** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.6, modified – Replacement of "becomes" with "drops"]

3.13
beam axis
straight line that passes through the **beam centrepoints** of two planes perpendicular to the line which connects the point of maximal **pulse-pressure-squared integral** with the centre of the **external transducer aperture**

Note 1 to entry: See Figure 2 .

Note 2 to entry: The location of the first plane is the location of the plane containing the maximum **pulse-pressure-squared integral** or, alternatively, is one containing a single main lobe which is in the focal Fraunhofer zone. The location of the second plane is as far as is practicable from the first plane and parallel to the first with the same two orthogonal **scan lines** (x and y axes) used for the first plane. This alternative definition, eliminating reference to the centre of the **external transducer aperture**, is necessary when the pressure distribution among the transducer elements is not symmetric about the **external transducer aperture**.

Note 3 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, for examples:

a) in the case of a continuous wave signal, the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689:2022, 3.29.;

b) in cases where signal synchronisation with the scan frame is not available, the term **pulse-pressure-squared integral** can be replaced by **temporal average intensity**.

Note 4 to entry: Definition is modified compared to 4.2.14 of IEC 61828:2020 – "**aperture**" replaces "**surface plane**".

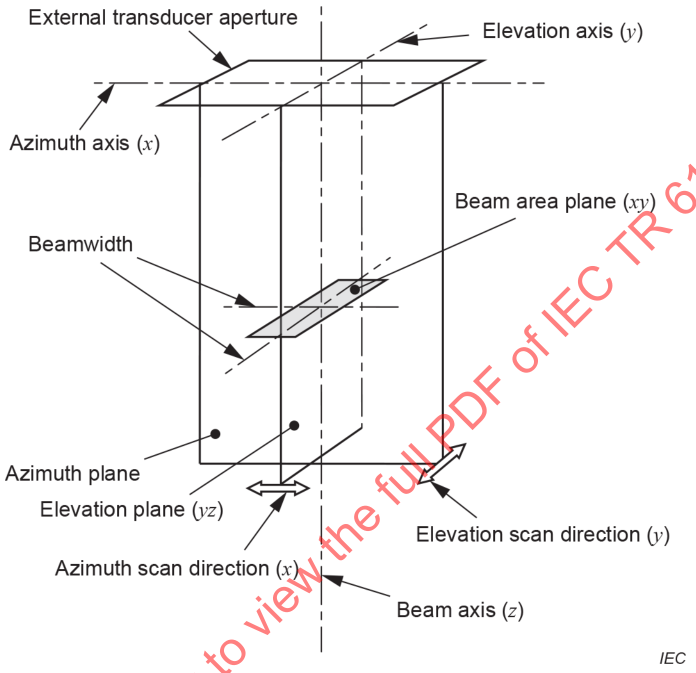


Figure 1 – Beam geometry

3.13.1
beam centrepoint
position determined by the 2D centroid of a set of **pulse-pressure-squared integrals** measured over the -6 dB beam-area in a specified plane

Note 1 to entry: Methods for determining 2D centroids are described in Annex C of IEC 61828:2020.

[SOURCE: IEC 62359:2010, 3.14]

3.13.2
external transducer aperture
part of the surface of the **ultrasonic transducer** or **ultrasonic transducer element group** assembly that emits ultrasonic radiation into the propagation medium

Note 1 to entry: This surface is assumed to be either directly in contact with the patient or in contact with a water or liquid path to the patient.

Note 2 to entry: The **ultrasonic transducer element group** is usually offset from this surface by a lens, matching layers and possibly fluid.

[SOURCE: IEC 62127-1:2007, 3.27, modified]

3.13.3
pulse-pressure-squared integral
ppsi
time integral of the square of the **instantaneous acoustic pressure** at a particular point in an acoustic field integrated over the **acoustic pulse waveform**

Note 1 to entry: The **pulse-pressure-squared integral** is expressed in pascals squared second (Pa^2s).

Note 2 to entry: Definition adapted from 3.50 of IEC 62127-1:2007.

3.14
contrast detail

3.14.1
contrast detail detectability
minimum diameter of an object, at specified control settings and range, which can be distinguished on the display with a specified level of confidence, as a function of the **backscatter contrast** of the object with respect to the background, said contrast being varied in steps over a wide range

3.14.2
contrast-detail resolution
minimum difference in echo amplitude, which can be detected for a scattering or reflecting structure of specified properties, embedded in a particular **tissue-mimicking material**

Note 1 to entry: The specified properties include shape, size or speed of sound.

3.15
dead zone
distance from the **test object scanning surface** to the nearest **test-object target** that can be unequivocally imaged

Note 1 to entry: This concept is now rarely useful unless the transducer is damaged. It was defined historically for **line targets** lying parallel to the length of linear array elements. **Dead zone** has been superseded by **proximal** and **distal working limits.**

3.15.1
proximal working limit
distance from the **test object scanning surface** to the nearest depth at which **spherical low-scattering masses** can be unequivocally detected

3.15.2
distal working limit
distance from the **test object scanning surface** to the furthest depth at which **spherical low-scattering masses** can be unequivocally detected

3.16
depth of penetration
maximum distance from the scanning surface of **tissue-mimicking material** to the embedded **test object** beyond which the **speckle pattern** echoes are no longer detectable

3.17
display curve
curve of signal level amplitude sent to the display as a function of the **linear signal**

3.18
linear signal
amplitude of the voltage generated across the transducer element, that is assumed, generally correctly, to be proportional to the integrated pressure across the element face

3.19
display frame rate
rate at which complete images are presented on the output display

3.20
display sonic contrast
display acoustic contrast
C_{DS}
relative difference between any **pixel value** in a resolved void without inclusions and the mean **pixel value** over a region in the image corresponding to background material at approximately the same depth and lateral location

$$C_{DS} = f_{NL} \times px \times R_D / R_{Dp} \text{ d} \quad (1)$$

where

R_D is the dynamic range in dB;

R_{Dp} is the dynamic range in pixel-values;

px is the difference between main- and side-lobe **maxima** in pixel-values;

f_{NL} is a correction factor for non-linear image processing; for linear image processing, f_{NL} = 1.

Note 1 to entry: **Display sonic contrast** as treated here assumes that the **display curve** is the log of the signal pressure amplitude and thus can be expressed in decibels by accounting for the **displayed dynamic range**, ignoring other nonlinear image processing in the system prior to the display. It is best to test for **display sonic contrast** using an available **display curve** most closely approximating that logarithmic relationship.

Note 2 to entry: See B.2.2.

3.21
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 electronically from the background under the scanner test settings

[SOURCE: IEC 61391-1:2006, 3.11, modified – Replacement of "in the display" with "from the background"]

3.22
elevational resolution
transversal resolution
for two **line-targets** parallel to the scanned plane, 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

Note 1 to entry: The plane of separation between the **targets** should be perpendicular to the beam-alignment axis.

3.23
field-of-view
area in the **scan plane** that is insonated by the **ultrasound** beam during the acquisition of echo data to produce one image frame

[SOURCE: IEC 61391-1:2006, 3.13, modified – Deletion of "ultrasonic" before "**scan plane**"]

3.24
frame rate
number of sweeps comprising the full-frame refresh rate that the ultrasonic beam makes per second through the **field-of-view**

[SOURCE: IEC 61391-1:2006, 3.14]

3.25
grey scale
range of values of image brightness, being either continuous between two extreme values or, if discontinuous, including discrete values

[SOURCE: IEC 61391-1:2006, 3.16, modified – Replacement of "including at least three discrete values" with "including discrete values"]

3.26
lateral resolution
azimuthal resolution
for two **line-targets** perpendicular to the scanned plane, 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

Note 1 to entry: The plane of separation between the **targets** should be perpendicular to the **beam axis**.

Note 2 to entry: For linear arrays the terminology is typically **azimuthal resolution**.

[SOURCE: IEC 61391-1:2006, 3.17, modified – Rewording of the definition, and addition of two Notes to entry]

3.27
line target
filament
line 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

Note 1 to entry: **Line-targets** are appropriate for 2D scanning systems.

[SOURCE: IEC 61391-1:2006, 3.19, modified – Replacement of "cylindrical reflector" with "line reflector", and "diameter is" with "scattering-surface dimensions are". Rewording of the whole definition]

3.28
low-scattering sphere
low-echo sphere
sphere of material with less backscatter than the background over the range of applicable frequencies

Note 1 to entry: The term "**low-echo sphere**" is used frequently in IEC TS 62791:2022.

3.29
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**

Note 1 to entry: The echo information is presented using an **M-mode** display.

[SOURCE: IEC 61391-1:2006, 3.21]

3.30
M-mode
time-motion mode
method of presentation of **M-scan** information in which the motion of structures along a fixed **ultrasonic beam axis** is depicted by presenting their positions on a vertical line, which moves across a display to show the variation with time of the echo

[SOURCE: IEC 61391-1:2006, 3.20, modified – Addition of "vertical"]

3.31
maximum depth of penetration
maximum depth in a tissue-mimicking **test object** of specified properties for which the ratio of data from background scatterers to data displaying only electronic noise, both derived from the digitized **B-mode** images, equals 1,4

Note 1 to entry: The phantom and noise-only images are obtained using identical system settings.

Note 2 to entry: **Maximum depth of penetration** is expressed in metres (m).

[SOURCE: IEC 61391-2:2010, 3.21, modified – Replacement of "phantom" with "**test object**", "digitalized **B-mode** image data" with "data", and "the digitized B-mode image data displaying only electronic noise" with " data displaying only electronic noise, both derived from the digitized **B-mode** images"]

3.32
nominal frequency
ultrasonic frequency of operation of an **ultrasonic transducer** or **ultrasonic transducer element group** quoted by the designer or manufacturer

[SOURCE: IEC 61157:2007, 3.16]

3.33
overall gain
basic level of gain that is uniform for the whole scan area but modified by **TGC** relative to the depth of the scan

Note 1 to entry: **Overall gain** is usually expressed in decibels (dB).

[SOURCE: IEC 61391-1:2006/AMD1:2017, 3.51, modified]

3.34
pixel value
integer value of a processed signal level or integer values of processed colour levels, provided to the display for a given **pixel**

Note 1 to entry: In a gray-scale display the **pixel value** is converted to a luminance by some, usually monotonic, function. The set of integer values representing the gray scale runs from 0 (black) to (2^M -1) (white), where M is a positive integer, commonly called the bit depth. Thus, if M = 8, the largest **pixel value** in the set is 255.

3.35
point target
point 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

Note 1 to entry: **Point targets** are appropriate for 3D scanning systems.

Note 2 to entry: The backscatter cross section of a standard **point target** should be a simple function of frequency over the range of frequencies studied.

[SOURCE: IEC 61391-1:2006, 3.24, modified – Moving "The backscatter cross section of a standard **point target** should be a simple function of frequency over the range of frequencies studied." to a Note to entry]

3.36
position recording error
display error
distance between the centre of the image of a target in an image of a **test object** and the **test object**'s correct position, as defined by the positions of the remaining **target**s or of a single reference **target**

3.37
quality assurance
QA
simple periodic testing to verify the stability of an imaging system's elementary performance

Note 1 to entry: This term is distinguished from performance evaluation, which is more rigorous testing of absolute performance, typically performed by more skilled personnel for purposes such as **acceptance testing**.

3.38
real-time B-scan
class of data acquisition and presentation in which **B-scans** are automatically and repetitively performed at **display frame rates**

Note 1 to entry: **Display frame rates** are typically greater than five per second.

3.39
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**

3.40
scan plane
acquired image plane containing the **acoustic scan line**s

[SOURCE: IEC 61391-2:2010, 3.30]

3.41
slice thickness
thickness, perpendicular to the **scan plane** and at a stated depth in the **test object**, of that region of the **test object** from which acoustic information is displayed

[SOURCE: IEC 61391-1:2006, 3.29, modified – Deletion of "ultrasonic" before "**scan plane**"]

3.42
speckle pattern
image pattern or texture produced by the interference of echoes from the scattering centres in **tissue-mimicking material**

[SOURCE: IEC 61391-1:2006, 3.30, modified – Deletion of "tissue or" before **"tissue-mimicking material"**]

3.43
target
ultrasound-reflecting object in a phantom

Note 1 to entry: Usually a **line target** or, for 3D imaging systems, possibly a **point target.**

3.44
test object
device containing one or more groups of **target** configurations embedded in a **tissue-mimicking material** or another medium

[SOURCE: IEC 61391-1:2006, 3.33, modified – Replacement of "object" with "**target**"]

3.45
test-object scanning surface
surface on a **test object,** recommended for **ultrasonic transducer** location during a test procedure

[SOURCE: IEC 61391-1:2006, 3.34, modified – Replacement of "on the tissue-mimicking **test object**" with "on a **test object**"; addition of "ultrasonic"]

3.46
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

[SOURCE: IEC 61391-1:2006, 3.35]

3.47
tissue-mimicking material
TMM
material in which the propagation velocity (speed of sound), reflection, scattering, density and other properties of interest are similar to those of the tissues of interest for the main application for which the **ultrasound** system is intended and in the frequency range specified

Note 1 to entry: The values of the above properties are usually specified and guaranteed by the manufacturer.

[SOURCE: IEC 61391-1:2006, 3.36 modified – Replacement of the end of the definition "and attenuating properties are similar to those of soft tissue for **ultrasound** in the frequency range 0,5 MHz to 15 MHz"]

3.48
transmitted ultrasound field
three-dimensional distribution of **ultrasound** pressure wave emanating from the **ultrasonic transducer**

[SOURCE: IEC 61391-1:2006, 3.37, modified – Replacement of "energy" with "pressure wave"]

3.49
ultrasonic beam axis
line fitted to points of maximum temporal-average intensity measured at increasing distances in the direction of propagation of a **transmitted ultrasound field**

3.50
ultrasonic transducer
device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and, reciprocally, of converting mechanical energy to electrical energy

Note 1 to entry: For the purposes of this document, **ultrasonic transducer** refers to a complete assembly that includes the transducer element or elements, mechanical and electrical damping and acoustic matching provisions.

[SOURCE: IEC 61391-1:2006, 3.39, modified – Replacement of "and/or" with "and"]

3.51
ultrasonic transducer element group
group of elements of an **ultrasonic transducer,** which are connected together in order to produce or receive a single acoustic pulse

Note 1 to entry: The connection of elements is intended to allow the distribution of the excitation pulse to separate elements of the group with particular elaboration (e.g. delay and/or amplification). The same conditions are valid for summed signals in receiving mode of the element group operation.

[SOURCE: IEC 61391-1:2006, 3.40 modified – Replacement of "excited" with "connected", addition of a Note to entry]

3.52
ultrasound
acoustic oscillation whose frequency is above the high-frequency limit of audible sound for humans (about 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01, modified – Addition of "for humans"]

3.53
void-detectability ratio
VDR
for a void in a specified material of homogeneous acoustic properties, a number characterizing the visibility of an image area corresponding to a void of defined diameter surrounded by **tissue-mimicking material** in the **test object**

Note 1 to entry: For a given C-plane, this number is the mean **pixel value** of the background minus that in the void, divided by the standard deviation of mean **pixel values** for numerous (n), separate areas of background equal to the void area and lying in the vicinity of the void. Ideally, **pixel values** would be converted to dB or transformed with a gray-scale curve (signal as a function of acoustic pressure) that is purely logarithmic.

[SOURCE: IEC TS 62558:2011, 3.21, modified – Addition of "for a void in a specified material of homogeneous acoustic properties"; replacement of "phantom" with "**test object**"; deletion of the equation and addition of a Note to entry]

3.53.1
detectability ratio for a single voxel
VDR_i
value of VDR for a single voxel

Note 1 to entry: For more details see 3.21.1 of IEC TS 62558:2011.

3.53.2
maximum VDR within a void
VDR_v
maximum value of VDR within a void

Note 1 to entry: For more details see 3.21.2 of IEC TS 62558:2011.

3.54
water content ratio
WCR
in a C-plane image the ratio of the number of voxels with VDR_i-values above the detection limit divided by the total number of voxels, for all voxels equidistant from/to the emitting/receiving transducer surface

Note 1 to entry: VDR_i is the value of VDR for a single voxel (see 3.21.1 of IEC TS 62558:2011).

Note 2 to entry: The term and symbol WCR refer to the apparent water content of the set of images at a given depth (an area ratio) e.g. the C-plane for adjacent images, not the water content of the phantom (a volume ratio).

4 Environmental conditions

The tests should be performed within the following ambient conditions:

- temperature: 23 °C ± 2 °C;
- relative humidity: 45 % to 75 %;
- atmospheric pressure: 86 kPa to 106 kPa.

5 Recommended equipment

To carry out all the test procedures, the following items are recommended:

a) a hydrophone (see 6.1.2);
b) an oscilloscope (6.1.3);
c) a spectrum analyser or ability to Fourier-transform recorded waveforms (6.1.4);
d) a pulse generator for the injection of acoustic pulses into the system's **ultrasonic transducer (**6.1.5**);**
e) a tissue-mimicking **test object** (6.1.6**);**
f) a tank containing degassed water (6.1.7);
g) a thermometer (≤ 0,5 °C accuracy) for water temperature measurement;
h) a high and/or low reflective **target** (reflector) (6.1.8);
i) a **target** holder and/or positioning system (6.1.9);
j) a computing system to run computer-assisted evaluation software (6.1.10);
k) software for evaluation of particular parameters (6.1.11).

Suitable specifications of these devices are given in Clause 6.

6 Test methods

6.1 Instruments

6.1.1 General

The instruments have been selected to permit testing of real-time ultrasonic scanners, performing as in clinical usage or set to obtain optimal measuring conditions for a particular measured parameter and, with the exception of 6.1.5, without needing electronic signals to be input to the complete scanner system [3].

NOTE IEC technical reports can contain recommendations but not requirements; however, readers are warned that tests sometimes do not work satisfactorily, if equipment and procedures other than those recommended are used.

6.1.2 Hydrophones

A hydrophone with a piezoelectric element of less than 1 mm diameter and with a flat frequency response (±3 dB) in the whole measured frequency range is recommended. A second hydrophone can be used to trigger an oscilloscope, if the ultrasonic pulses (in a scanning beam that cannot be stopped) are to be detected for examination by the first hydrophone.

NOTE Additional information on the use of hydrophones is available in IEC 62127-2.

6.1.3 Oscilloscope or other transient recorder

An oscilloscope of a suitable frequency **bandwidth** and minimum sensitivity of 5 mV/div is recommended. The suitable frequency range is determined by the maximum **ultrasound** frequency to be measured. The frequency range should be more than double the maximum frequency to be measured according to the Nyquist criterion. The transient recorder (DSO) should have a minimum resolution of 10 bit; better is 12 bit.

6.1.4 Spectrum analyzer

A spectrum analyzer of a suitable frequency **bandwidth** and dynamic range of at least 60 dB is recommended. The suitable frequency range is determined by the maximum **ultrasound** frequency to be measured. The frequency range should be more than double the maximum frequency to be measured according to the Nyquist criterion. The ability to Fourier-transform recorded waveforms is recommended.

6.1.5 Pulse generator

A pulse generator and **ultrasonic transducer** of **acoustic working frequency** similar to that of the scanning system's **ultrasonic transducer** under test are recommended. This generator allows the injection of regular bursts of **ultrasound** into the scanning system's **ultrasonic transducer**.

6.1.6 Tissue-mimicking test objects

Tissue-mimicking **test objects** are recommended, which contain structures that allow the following equipment features to be measured:

a) **axial resolution**, **lateral resolution**, **elevational resolution**, **contrast-detail resolution**;
b) low-scattering spherical mass detectability or cylindrical void detectability;
c) display sonic contrast
d) **dead zone** or, better, **proximal** and **distal working limit**;
e) scan **slice thickness**;
f) **depth of penetration**;
g) **displayed dynamic rang**e;
h) **display error** or **position recording error**;
i) measurement system accuracy;
j) **M-mode** calibration;
k) beam shape
l) Uniformity degradation.

Measurement procedures are described in 6.3.

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

6.1.7 Tank and degassed water

A tank of degassed water is recommended for the hydrophone measurements (see 6.3.2) and/or scanning of high/low reflective **target**s. The inner walls of the tank should be equipped with slabs of material suitable for absorbing incident **ultrasound** at the **acoustic working frequency** and preventing significant reflection, to avoid interference with the signals essential for measurements in progress.

6.1.8 High or low reflective target

A reflector of a proper material, size and shape should be placed into the **tank,** to be imaged by the measured scanner.

6.1.9 Target holder and/or positioning system

A mechanism should be provided to keep the **target** in the desired place or to move it on a specified trajectory in the tank.

6.1.10 Computing system to run computer-assisted evaluation software

A computing system should be provided that is suitable for inputting digital- and/or analog-image-signal elaboration and fulfilling technical specifications compatible with the evaluating software.

6.1.11 Software to evaluate quality parameters

Manufacturers should provide software that is designed to analyse the digital or digitalised output of image information by the scanner being measured, as necessary to evaluate quality parameters.

6.2 Test settings

6.2.1 General

The many combinations of scanner settings and **ultrasonic transducers** make it impossible to carry out tests for all of them. Tests are therefore carried out for specified settings, and for each **ultrasonic transducer.** The specified settings should be similar to the settings employed in the clinical examinations for which the **ultrasonic transducer** is most commonly used or should set the tested scanner to conditions needed for a particular test. Simulation of an examination, where deep penetration is the goal, is usually desirable. The scanner should be set using the procedures outlined below, which are similar to those that would be used to optimise scanning conditions for average soft-tissue structures. The focusing of the ultrasonic beam should be extended over as large a range as possible, to achieve the best average resolution over all visible **target**s. The soft tissue-mimicking **test object** (see Figure A.1, Figure A.2 and Figure A.3) should be used for the procedures of 6.3.2 to 6.3.5. Initially, the **test object** should be imaged using scanner settings typical for imaging tissue.

The highly reflective **target**s should entail different combinations of settings compared to the soft **target**s or **tissue-mimicking materials**. The basic rule for the setting is using the largest dynamic range (lowest contrast) and combination of transmitted power and **overall gain** to avoid signal-amplitude limitation. Detailed settings of all the scanner's parameter settings should correspond with the particular type of parameter(s) being measured. The use of highly reflective **target**s results in more accurate and reproducible parameters, although sonograph settings can differ from ones used for medical imaging.

6.2.2 Display settings (focus, brilliance, contrast)

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

6.2.3 Sensitivity settings (frequency, suppression, output power, overall gain, TGC, automatic TGC)

6.2.3.1 Settings for lowly reflective targets

a) If there is a suppression or reject control, it should be adjusted to allow the smallest possible signals to be displayed.

b) Maximum **overall gain** and transmitted power should be used for measurement of maximum penetration. Then the gain should be decreased, if electronic noise obscures echo signals or either gain or power should be decreased to avoid saturation of the received signal to assure best results of the spatial resolution measurement.

c) The near gain level of the **time-gain compensation** (**TGC**) controls should be altered to display the echo signals in the first 1 cm or 2 cm range of the **test object** as a mid-grey shade.

d) The slope of the **TGC** controls should be adjusted to set the signals from intermediate range to a mid-grey shade.

e) The **nominal frequency** of the scanner's **ultrasonic transducer** and all the pre- and post-processing functions of the scanner, adjusted for the measurement, should be noted.

6.2.3.2 Settings for highly reflective targets

a) Use of largest dynamic range of the scanner's amplifier is important to avoid amplitude-signal limitation, as well as low output power and suitable **overall gain** and **TGC** adjustment.

b) All pre- and post-process parameters should be set according to required conditions of the measurement. In most cases the non-linear operations should be eliminated to obtain raw data.

c) The **nominal frequency** of the scanner's **ultrasonic transducer** and all the pre- and post-processing functions of the scanner, adjusted for the measurement, should be noted, as well as the identification data of the measured scanner and transducer.

6.2.4 Final optimisation

A final optimisation of the image can be carried out by a small change in the suppression level, **overall gain** or output power. When automatic gain control (AGC) is an option in a scanner, tests should be carried out in this mode of operation. The **test object** should be imaged with AGC, the image being optimised using any control that still functions manually, e.g., the **overall gain** or output power.

6.2.5 Recording system

A record of the final image should be made for comparison at a later date. Images are usually recorded digitally within the system for transfer to a PACs system or as a digital file for incorporation in the exam report and patient file. Digitally stored images give the best results to reproduce all the details and parameters recorded together with the picture. If possible DICOM storage of the images is recommended as it allows a unified comparison of data without the problem of unknown video-output curves or the storage-system's influence showing in the results. For all 3D-evaluations (and statistical evaluation of data), it is necessary to store a set of images or a video-sequence. For later evaluation, the most important precaution is to avoid any lossy compression in the storage process.

For systems with an integrated monitor, no image output and no internal screen capture, it can be necessary to use external cameras to evaluate the system. Any camera systems used should allow turning off automated gain settings and providing linear presentation of brightness. Ideally the resolution of the camera system should be high enough to resolve the pixels in the image. The advantage of using cameras for image storage is that the interface to the evaluation software is completely independent of the **ultrasound** system's image output options. However, camera adjustment and settings become necessary for every system tested. When using cameras to evaluate the screen image, great care should be given to avoid monitor reflections that influence the test results.

In cases without built-in digital image recording, where the monitor is connected to the system via a cable and a standard video interface plug, it is possible to use video digitizers. In the case of digital monitors, frame-grabbers might possibly be used. Some of the same cautions as with photography apply.

6.3 Tested quantities / parameters and procedures

6.3.1 General

Techniques are described, in this document, which can be used for measuring the following scanner parameters:

- acoustic working-frequency bandwidth (6.3.2);

- **axial resolution** (6.3.3.2),**lateral resolution** (6.3.3.3), **elevational resolution** (6.3.3.4), **temporal resolution** (6.3.3.5) and **contrast-detail resolution** (6.3.4);
- **low-scattering spherical mass or cylindrical void** (6.3.5);
- **display sonic contrast** (6.3.5.5**)**
- **proximal** and **distal working limits** or **dead zone** (6.3.6);
- **slice thickness** (6.3.7);
- **depth of penetration** (6.3.8);
- **displayed dynamic range** (6.3.9);
- **display error** or **position recording error** (6.3.10);
- measurement system accuracy (6.3.11);
- **M-mode** calibration (6.3.12);
- beam shape (6.3.13);
- dead element (6.3.14);
- dynamic focus(foci) position(s) in azimuthal and elevational planes (A.3.9);
- side-lobes level and direction in azimuthal and elevational scanning planes (Annex A);
- techniques for measuring other parameters of interest can be found in referenced publications, e.g.:
  - linearity of the image geometry with regard to area [6];
  - uniformity of sensitivity in IEC TS62558:2011 and IEC TS 62736:2016.

A calibrated transmit-power or receiver-amplification control is recommended in some of the following tests. If the scanner controls are uncalibrated, they should be calibrated, using a step **test object** containing surfaces of known relative reflectivity (Figure A.1).

6.3.2 Acoustic working-frequency bandwidth

The **acoustic-working-frequency bandwidth** of a scanner's **transmitted ultrasound field** is a parameter of great significance to its performance, since it is related to the spatial resolution in the image and to the rate of attenuation of the beam in its passage through tissue. This **acoustic-working-frequency bandwidth** can be measured by detecting with a hydrophone the transmitted ultrasonic pulse in the focal region in degassed water and then analysing the signal with a spectrum analyzer or by Fourier transformation of the recorded waveform. Care should be taken to ensure that the pulse waveform is not distorted by electronic factors such as capacitive loading of the signal or reflections in the cable. Where necessary, a driver amplifier should be connected between the hydrophone and the analyzer. The transmitted intensity should be low enough to avoid pulse distortion due to non-linear propagation (see IEC 62127-1:2007). If this is not possible, the distance between the **ultrasonic transducer** and hydrophone in water should be recorded.

6.3.3 Resolution

6.3.3.1 General

The approaches to determining the spatial resolutions are considered to be compatible with the commonly employed clinical practice of optimising the resolution in localised regions of the image or over the whole image, using controls to adjust the transmitted power, the **overall gain** together with the **TGC** and dynamic focusing at several depths. They are also reasonably compatible with the use of controls that can only influence resolution of large areas of the image. If automatic gain control is an option, the resolution should be obtained at a range of depths through the **field-of-view** using this option.

6.3.3.2 Axial resolution

Two **line targets** are resolved in the axial direction in a **B-mode** display when two separate echoes can be distinguished along the direction parallel to the axis of the scanning beam. A method for measuring **axial resolution** involves noting the minimum separation for the distinct imaging of two **line target**s in a material of low backscatter cross-section. A suitable **test object** comprises two reflecting **line targets** (or **filament**s) placed at a small angle to each other as shown in Figure A.2. This measurement should be carried out at the threshold detection sensitivity and also at 10 dB and 20 dB higher levels.

The **axial resolution** measurement should be repeated at a few depths throughout the **depth of penetration** achievable for the **ultrasonic transducer** assembly being used.

A recording should be taken of the image of the **line target**s situated at the middle of the typical **depth of penetration** for the **ultrasonic transducer** assembly being assessed. Other factors that can affect the value of the resolution are the image processing options of the scan converter or focusing, for examples. The procedure is repeated for each **ultrasonic transducer** of the scanner. The final output of this test procedure should be a table of **axial resolution** versus depth. A list of all other factors influencing the operation of the scanner should accompany this table, e.g., **ultrasonic transducer** type, **nominal frequency**, sensitivity control settings, focusing, image processing option. These data should be recorded in sufficient detail to allow the test to be repeated exactly at a later date by another operator.

The 3D **grey scale** map provided for the 3D-thread phantom (see Figure A.12 and Figure A.16) will allow evaluation of the **axial resolution** at the position of any of the threads.

The PSF-mapping method referenced in [3] and [6] offers the **axial resolution** as a parameter in a PSF-map**.** This parameter is derived from the frontal edge of the PSF at the **beam axis** in the direction toward the transducer and can be mapped over the whole scanned area or measured at a few points of interest.

6.3.3.3 Lateral resolution

Two **target**s are resolved in the lateral (also termed azimuthal) direction in a **B-mode** display when two separate echoes can be observed in a direction perpendicular to the scanning **beam axis** and in the **scan plane**. In practice, the **lateral resolution** can be taken to be equal to the lateral length of the displayed spot size from a single **target**. This length should be measured between the points at which the signal level is just discernible above the background level. Additional measurements should also be made for sensitivity levels 10 dB and 20 dB above the detection threshold. The **lateral resolution** should be determined using a **test object** of the design shown in Figure A.3. The **line targets** (or **filament**s) are scanned with the **ultrasonic transducer** assembly on the top surface. A record should be taken of the image of the set of **line targets** situated at the middle of the typical working range for the **ultrasonic transducer** assembly being used. Other factors that can affect the value of the resolution should also be noted, for example the image processing options of the scan converter or focusing. The procedure should be repeated for each other **ultrasonic transducer** of the scanner. Sufficient data should be recorded to allow another operator to repeat the test at a later date.

Another form of the **lateral resolution** evaluation can be determined from the point-spread-function (PSF) distribution over the scanned area by computing the full-width at half-maximum (FWHM) and full width at 1/10 maximum of PSF values recorded in the azimuthal plane as a **lateral resolution** in a PSF-map [3] [6].

The same can be done using the line-spread-function (LSF) of the 3D-thread phantom (see Figure A.12 and Figure A.13)

6.3.3.4 Elevational resolution

Resolution in elevational directions can be approximated as the FWHM of a set of maximum amplitudes of received signals reflected by a point reflector, according to the point-reflector's vertical position at the measured point of the image. The reflector passes through the scanning plane perpendicularly; the set of data forms a point-spread-function profile from which the distance between the reflector positions generating half of the maximum reflected amplitude and the shape of the side-lobes (if any) can be computed. This process can also be used to estimate a scan-thickness value at any point of the scanning area [4] (see 6.3.7).

The same evaluation can be performed by using the 3D-grayscale data derived from the line-spread-function the LSF of the 3D thread-phantom (see Figure A.12 and Figure A.13).

6.3.3.5 Temporal resolution

Temporal resolution is an important parameter in clinical applications when imaging moving organs and structures. The temporal resolution of M-, 2D-B- and 4D-**B-modes** should be estimated using a moving reflector in a measuring tank. The temporal resolution could be derived from the cine-loop in the measured sonographic unit. The temporal resolution is determined by the **ultrasound** scanner's **frame rate**, output-**display frame rate** and by functions of the noise reduction technique.

6.3.4 Contrast-detail resolution

The capability of a scanner to detect a mass (**target**) is known to depend on the contrast and size of the mass. An evaluation of **target** detectability as a function of size and contrast is known as the **contrast detail** or **contrast-detail detectability** test. **Contrast-detail** analysis allows the evaluation of an **ultrasound** scanner in terms of the minimum detectable diameter of a disc-shaped **target** as a function of the contrast of the **target** to the surrounding background **tissue-mimicking material.** The minimum detectable diameter of a disc of known contrast should be the minimum resolution of the scanner at that contrast.

One form of the **contrast-detail test object** consists of a matrix of **tissue-mimicking material**, with a row of embedded conical **targets** [5] [6] (see Figure A.5). Each cone has a different **backscatter contrast** with respect to the background material. The axes of the cones are parallel to each other and perpendicular to the **scan plane.** For an **ultrasonic transducer** positioned on the **test-object scanning surface** with the **scan plane** parallel to the front face of the **test object**, each cone appears essentially as a cylinder with its axis perpendicular to this plane, and its tomographic image appears as a disc, whose diameter varies from 0 mm to 20 mm, over a length of 10 cm, depending on which cross-section of the cone is imaged. The **contrast detail** measurement should be carried out with the sensitivity and display controls in calibrated positions. A **contrast-detail resolution** curve should be obtained by plotting **target** contrast versus threshold detection diameter. This curve is specific for a particular scanner, the **ultrasonic transducer** used for the test, and the depth of the object.

6.3.5 Non- or minimally-scattering region detectability

6.3.5.1 Volume distribution of low-scattering spheres or cylindrical voids

A qualitative test, which can contribute to the assessment of performance of a clinical scanner, is one which demonstrates the ability of the scanner to image non-scattering **spheres** embedded in a background of scattering material (see Figure A.6).

The material of the low echo spheres or cylinders should be the same as that of the scattering material with the scattering centres removed or replaced with a lower density of scatterers. The **target**s should be imaged with the sensitivity and display controls in calibrated positions. The spheres should be located at all depths over the working range of each **ultrasonic transducer** assembly. The minimum size of **target** that can be detected at each depth should be tabulated if there are multiple **target** sizes. The overall combined effect of many factors will be demonstrated. On smaller **targets**, the effects of the main lobe of the beam on **azimuthal** (lateral) and **elevational resolution** are seen and, in the case of spherical **target**s, the effects of **axial resolution.** On larger **target**s, detectability is determined more by side- and grating-lobes and other signal clutter [7] from the beam formation and multiple scattering.

6.3.5.2 Randomly positioned, embedded low-echo spheres

A sophisticated but increasingly fast and inexpensive means for testing the imaging performance of an **ultrasound** pulse-echo scanner is to quantify the degree to which and depth ranges over which small, **low-echo spheres** are distinguished from the surrounding soft tissue, as described in IEC TS 62791:2015. It is reasonable to assume that the smaller the **low-echo sphere** that can be detected at some position, the better the resolution of the scanner, i.e., the better it will allow detection of an abnormal object, such as a tumour and delineate its boundary.

There are three components of spatial resolution defined in pulse-echo **ultrasound** (see 6.3.3), *viz*, **axial resolution** (parallel to the local pulse propagation direction), **lateral resolution** (perpendicular to the local pulse propagation direction and parallel to the **scan plane**), and **elevational resolution** (perpendicular to the local pulse propagation direction and also to the **scan plane**). Thus, all three components ideally are given equal weight in measuring detectability. **Axial resolution** usually – *but not always* – is better than **azimuthal** and **elevational resolutions**. A sphere has no preferred orientation and is the best for a single **target** shape; all three components of resolution are then weighted equally irrespective of the beam's incident direction. Further, the incident beam's propagation direction will vary considerably in the case of convex and phased arrays and with modern compounding (see IEC 62791:2015, Figure A.7). Tests with spheres of a uniform size and known contrast tell the user that spherical masses of that size and contrast can be seen, with the contrast- and proximal and distal detectability limits as displayed on a curve of measured contrast as a function of depth. In the body, a user is rarely trying to delineate cylindrical objects lying along the axis of the beam.

6.3.5.3 Quasi-spherical voids in foam

Random quasi-spherical void phantoms can use foams saturated with degassed saline solution devoid of acoustic scatterers and with a random distribution of size, position and shape of the individual pores. Saline water with adjusted concentration of saline can be used to ensure that the speed of sound is (1 540 ± 10) ms^{-1} at 20 °C. Pores with diameters below the resolution limit of an **ultrasound** system will be interpreted as tissue. Pores with sizes resolved by the scanner and thus "visible" will be seen as quasi-spherical voids. In an optical image (Figure 2) spatial uniformity of void distribution is seen as reasonably high. Most of the voids in this selected image are quasi-spherical. While exceptions abound, as long as they are statistically well distributed, they should not disturb this evaluation, which is purely based on the statistical distribution of gray levels at a given distance from the transducer [8].

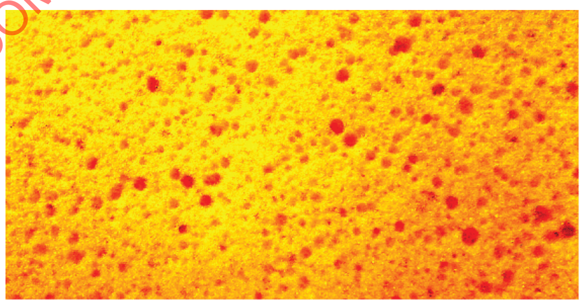


Figure 2 – Reticulated foam with random voids

Independence of scanning geometry and scanner orientation and a simultaneous evaluation for a complete range of void sizes by using statistical methods is the great advantage of the random-void approach. It would be helpful, if the statistics of a standardized foam were measured and reported.

Besides selecting the foam and the concentration of the saline solution to obtain body-equivalence for sound velocity, absorption and backscatter, the foam is chosen so that the diameters of the largest voids do not greatly exceed the lowest resolution of interest. This results in a higher percentage of smaller voids in the phantom, thus improving the statistical evaluation. Size, position and even shape of the individual pores may be random, although the statistical distribution in an adequately large region will nevertheless allow generating information characterising the visibility of small voids.

Void-detection capability can be assessed using random-void phantoms and calculating the percentage of void-area in an image in relation to the total area of a region of interest for a given distance from the transducer. This factor is equivalent to **water content ratio (WCR**). The better the resolution the greater is the number of visible voids, resulting in a higher percentage of voxels being identified as part of the water-filled voids (hence **WCR**). Evaluating this number for individual surfaces equidistant from the transducer (i.e. C-planes for linear arrays and cylindrical surfaces for curved and phased arrays) allows the creation of depth-dependent information.

The signal from a foam pore or void appears in an **ultrasound** image as a dark area (or spot) with gray-level corresponding to the noise level. The amplitude of this signal depends on the void size and spatial resolution. The signal amplitude from the void is also influenced by the noise from side- and grating- lobes and other **acoustic clutter**, which increases this amplitude. The effect appears in an **ultrasound** image as reduced image contrast. Void "contrast" depends upon resolution in a given depth and upon side-lobes noise, if any exists.

With a void phantom it is not possible to distinguish directly from a void's image the reason for contrast reduction – reduced resolution or side-lobes noise. Side lobes, if they exist, can appear in all directions from a transducer. From this point of view the uniformity test for arrays is necessary but not sufficient.

The relevant information for the clinician is the void visibility, represented by the **void-detection ratio** (see 6.3.5.4 and IEC TS62558) and the minimum size of void that is still detectable.

A test procedure for a phantom using random-void foam is described in Clause B.1.

6.3.5.4 Cylindrical voids

A design described in IEC TS 62558:2011 and shown in Figure A.8 and Figure A.9 uses sliced **tissue-mimicking material** (**TMM**) arranged as alternating "cyst-slices" and "attenuation-slices". It allows measurement along all three axes of the ultrasonic beam (axial, azimuthal and elevational) to determine the **void-detectability ratio** and its dependence on the depth in the generated image from a transducer. The basis of the design concept and measurement method, originated by J.Satrapa but not published, is anechoic, artificial cysts, representing e.g. idealized pancreatic ducts in the human body, and the measurement of the **void-detectability ratio** inside the images of these artificial cysts. The images of the artificial cysts should appear anechoic, except for debris floating in the water. The measurement of **void-detectability ratio** quantifies the diagnostic **ultrasound** system's ability to properly represent these objects. Increased artefactual signals appearing within images of these artificial cysts indicate a degradation of certain image parameters. A certain level of artefactual signals should be expected for any **ultrasound** system, due to the emitted beam-shape and the transducer-receive characteristics. Any increase in these artefactual signals can be caused e.g. by grating- and side-lobes and other **acoustic clutter** that can be increased due, for example, to partial or total depolarisation of elements, delamination between transducer elements and lens, dropping the transducer or corrosion. The advantage of the cylindrical voids arranged in defined layers is shown best with linear transducers. Having several adjacent C-planes providing identical void diameters allows combination of these layers to improve the statistical evaluation of the voids – which is inherently necessary due to the noisy speckle character of **ultrasound** images and the limited range of angles at which the voids can be optimally imaged to obtain better statistics.

6.3.5.5 Display sonic contrast

Possible advantages of foam- and cylindrical-void phantoms are the reflecting properties of water-filled voids. Very large water- or saline-filled voids arguably reflect 60 dB less than the foam material used in [8]. This is not achievable in typical gel-based phantoms. A probe having side- and grating-lobes entails reduced "contrast" of large voids. For probes with very small levels of side-lobes, only grating-lobes and other **acoustic clutter** are evident in large voids at a level theoretically as much as 40 dB less than in the sponge material [8].

The quality of probes of identical design can differ because of defects from their manufacture, use or repair. It is important to differentiate differences in design properties from quality within the design. High-quality probes produce images of a random-void phantom (RVP) with large **display sonic contrast**.

6.3.6 Dead zone and proximal and distal working limits

The **dead zone** was defined when ring-down of the transducer or recovery of the receiver electronics from the transmit pulse obscured display of objects close to the transducer. **Proximal** and **distal working limits** are recommended instead. Another cause of a proximal **dead zone** is poor sensitivity due to poor resolution. This last type of sensitivity loss near the transducer is not fully tested with **line targets** lying parallel to the length of linear array elements. It is a good test for **line targets** lying in that orientation within the body, but does not reveal the **dead zone** for imaging **point targets** or resolving other **targets** with gradients in the elevational direction in the body. To avoid confusion with the older definitions of **dead zone** the concepts **proximal** and **distal working limits** are recommended. Key **target**s of imaging concern for rapid interpretation without requiring 3D imaging are **spherical low-scattering masses** of appropriate size and spatial density, and random distribution. These **targets** also can be quasi-spherical over a wide range of sizes, as in a sponge, for low cost but with less ability to standardize or interpret clinically. To obtain precise and reproducible **proximal** and **distal working limits,** multiple slices should be analyzed quantitatively; viewing of multiple slices in a cine loop at ~5 frames/s should give reasonably reproducible visual limits. Most efficient quantitative analysis algorithms require scanning at uniform speed.

The **dead zone** has been determined historically by scanning the array of **line targets** from the top of the **test object** shown in Figure A.3. An estimate of the **dead zone** was obtained by noting the most superficial **line target** that could be resolved from the transmission pulse signal. The distance from the top surface to that **line target** was then noted. With a linear array, this procedure should be carried out in one scan; with a sector scanner, each **line target** should be examined in turn by locating it at the centre of the **field-of-view.** A hard copy or digital record of the image of the **line target** just outside the **dead zone** is recommended for a record of the test. **Point targets** can also be used with true 3D scanning when point-like **target**s are of more clinical interest.

6.3.7 Slice thickness

The **slice thickness** should be determined by scanning the thin sheet of scattering targets shown in Figure A.4 [9]. The maximum displayed range should be considered as being divided into five consecutive equal-sized sections. The **scan plane** should be placed to intersect the sheet of **targets** along a line parallel to the **test-object scanning surface** and should also be perpendicular to the **test-object scanning surface** as shown in Figure A.4. To measure the **slice thickness** in the middle of the first section, the line of intersection of the **scan plane** and the **target** sheet should be arranged at that depth. The thickness of the image of the sheet of **target**s should be measured and the **slice thickness** calculated at the centre of this first section. The procedure should be repeated for the four other sections. The **slice thickness** at each depth should be measured with the sensitivity and display controls in calibrated positions.

A different expression of the **slice thickness** in any point of the scanned area can be determined from the PSF distribution over the scanned area by computing the 10 dB decrease of PSF maximum-level values recorded in the elevational plane IEC 61391-1:2006.

6.3.8 Depth of penetration

With the scanner sensitivity set up as described earlier (see 6.2), the soft tissue-mimicking **test object** (see Figure A.1) should be scanned through the **test-object scanning surface,** so that the **ultrasound** passes through scattering **tissue-mimicking material.** The **maximum depth of penetration** should be the depth at which the **speckle pattern** of echoes is no longer detectable in the image. If electronic noise appears in the image at depths less than that at which the **speckle pattern** is not detected, the **maximum depth of penetration** should be taken to be the depth at which the image of the scattering region cannot be distinguished from the electronic noise.

6.3.9 Displayed dynamic range

To determine the **displayed dynamic range** of the scanner, the steps in the soft tissue-mimicking **test object** (see Figure A.1) should be scanned, using the sensitivity set up described in 6.2. Scanned through the low attenuation material, the step should be noted, at which the echoes are just saturated in the image. At the same depth as this step, the position in the scattering material where the echoes are just detectable should also be noted and the number of high attenuation steps through which the beam passed to reach this position counted. Using the known attenuation difference per step between the low- and high attenuation material, the **displayed dynamic range** should be calculated. It should be noted that the accuracy obtained with this technique is limited by the attenuation per step in the **test object** and on the dynamic range of the scattering material but it is a practical technique. To reduce error in this measurement due to beam focusing, the focus should be arranged to be at the greatest depth possible. With a sector scanner, the **ultrasonic transducer** should be moved laterally to place the central line of the **field-of-view** perpendicular to the steps at which the just-saturated and just-detectable echoes are determined. 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 **target**s.

For greater accuracy, the acoustic-injection technique [10] should be used, whereby the transmitted ultrasonic pulse is detected by an independent **ultrasonic transducer** that is then excited to emit a series of ultrasonic pulses. This series of pulses should be detected by the scanning **ultrasonic transducer** and presented on the display screen [10]. The size of the ultrasonic pulses detected by the scanning **ultrasonic transducer** can be altered by the excitation circuitry of the independent **ultrasonic transducer**. The **displayed dynamic range**, which covers the range of signal size from those just saturated to those just detectable, can therefore be measured.

6.3.10 Display error or position recording error

A two-dimensional regular array of **line target**s in the **test object** shown in Figure A.3 should be scanned so that their echoes are present throughout the **field-of-view.** The coupling agent should have a velocity of sound of (1 535 ±15) m s^{-1} to avoid beam deviation due to refraction. **Line targets** located horizontally and vertically from the centre throughout the **field-of-view** should be selected. The distance of each **line target** from the centre of the **field-of-view** should be measured on a film or other hardcopy image. The percentage errors should then be calculated and tabulated. The directly viewed image of the array of **line targets** should be observed to check that any distortion of dimensions in the displayed image is less than 10 %.

6.3.11 Measurement system accuracy

To assess the accuracy of the measurement system of a scanner, the **line targets** in the **test object** shown in Figure A.3 should be imaged with the sensitivity adjusted to make the displayed echoes as sharp as possible. Measurements should be made in straight lines on the screen of lengths approximately equal to 0,75 of the displayed range. These measurements should be carried out in both horizontal and vertical directions in the **field-of-view.** The average percentage error should be tabulated for each length in each direction. The process should be repeated for the available display scales. To evaluate the accuracy of measurements of curved lines and cross-sectional areas, closed figures should be traced centrally on the display of an area approximately 0,75 of the **field-of-view.** The circumferences and areas should be measured and the percentage errors calculated. Additional measurements should be made with the two smaller areas (0,1 and 0,25 of the **field-of-view**) located at the top and bottom of the display. This process should be repeated for the available scales of the display.

The **measurement system accuracy** can be assessed with use of a point reflector and an accurate **target**-positioning system. A difference between the speed of sound used in the scanner to calculate the distance and the speed of sound in degassed water, including influence of the water temperature, should be taken into account for the accurate calculation. Comparing a map of real positions of the **point target**, determined by the accurate positioning system, to imaged positions of the points in the scanned area yields information about inaccuracies in the image. The **target** positioning system can be precisely manufactured and therefore be suitable to use for very high frequencies of **ultrasound**.

6.3.12 M-mode calibration

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. Performing an **M-mode** scan with the **ultrasound** beam directed at **line targets** in a resolution **test object** (see Figure A.2), as described earlier for the **B-mode**, should enable the **axial resolution** to be measured. The **dead zone** can also be measured for this mode of operation with the multi-purpose **test object** (see Figure A.3). The **contrast-detail resolution** can be noted using the **contrast-resolution test object** (see Figure A.5). The minimum detectable cone cross-section for each type of scattering material in the cones should also be noted.

The **maximum depth of penetration** should be measured by noting the range in the soft-**tissue-mimicking material** (see Figure A.1) for which echo signals are detected. The **displayed dynamic range** of the scanner can be calculated, as in the **B-mode** imaging case, by noting the positions of the just-saturated echoes and just-detectable echoes in the step wedge of the soft tissue-mimicking **test object (**see Figure A.1)**.** The scanning beam should be moved azimuthally to detect these echoes. The acoustic injection technique described in 6.3.9 can also be used to measure the **displayed dynamic range** of the **M-mode**.

Distortions of the display accuracy and of the measuring system should be checked and recorded using the array of **line targets** in the multi-purpose **test object** (see Figure A.3), as 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 **ultrasonic transducer** at accurately known intervals, for example 1 ms bursts at 200 ms intervals. Measurement checks should be carried out for the **M-mode** trace on both the display screen and the strip-chart recorder.

6.3.13 Beam shape

Problems with resolution and contrast in **ultrasound** imaging systems originate from pulse-shape and beam-shape. With modern transmit- and receive-electronics pulse-shape is generally well optimized. Reduced contrast and resolution are generally due to beam-shape, e.g., side- and grating-lobes. For medical **ultrasound** imaging, 3D-void phantoms allow a sensitive measurement of contrast using VDR-measurements as described in IEC TS 62558. For servicing and improvement of design, it is of interest to obtain information on the cause for inadequate visibility of some voids – i.e. on the beam shape.

Beam-shape, as revealed by the point-spread function (PSF), can be measured using a small spherical reflector to scan the total volume IEC 61391-1:2006, possibly even taking into account body-equivalent damping. However, using **tissue-equivalent material** for this task is not feasible as the back-reflection from the tissue-equivalent surroundings e.g., from side- and grating-lobes, would obscure the smaller back-reflected amplitudes from the main beam. The procedures described in the cited IEC 61391-1:2006 and IEC TS62558 are designed for laboratory use and are too elaborate for in-field measurements.

It is also possible to assess the beam shape by means of sound field measurements according to IEC 62127-1:2007.

A first, quick check in the field can be achieved by measuring the line-spread function (LSF) [6]. Use of a 3D-crossed-thread phantom (see Figure A.10) will provide preliminary information concerning the beam profile and side- and grating-lobe amplitudes.

The procedure makes use of the same acquisition tools and software as the void test described in IEC TS62558, while replacing the phantom for the **void-detection ratio** by the thread phantom and then selecting custom thread-evaluation software. The test procedures are described in Annex B.

6.3.14 Uniformity-degradation (element or channel) test

A simple, fast and effective method to detect defective element(s) or channel(s) in a multi-element electronic transducer uses a highly reflective (metallic) object narrow enough to be positioned just in front of one element of the transducer array; coupling gel is not necessary. When the element works, multiple reflections inside the object form an echogenic tail at the examined element position and direction of the beam in the sonogram. If the reflector is positioned in front of a dead element, then the multiple reflections disappear. The width of the aperture and the position(s) of the focus(foci) can be recognized from the image. The method is not sensitive enough for phased array transducers. Simple metallic objects like a narrow coin, **line target** or paperclip can be used as the reflector (see [3]). Other and more precise methods for the detection of dead elements are described in IEC TS 62736:2016, 9.2.

Annex A
(informative)

Test objects and tissue-mimicking material

A.1 Test object structures

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 to be satisfactory in practice.

Each **test object** (Figure A.1 to Figure A.11) is designed to be scanned directly in water or 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** filling the **test object.** The acoustic properties of the material should be given by the manufacturer to allow correction of test results, if necessary, because of its non-tissue-equivalent properties, for example, in the **depth of penetration** measurements or transducer **dead zone.** The size of the window should be sufficient to allow all **ultrasonic transducers** to be used in all recommended orientations to the internal structures.

Suitable **target**s for the **test object** are wires of stainless steel (type 316) with a diameter of 0,15 mm. These **line targets** are sufficiently thin, so that echoes from them are not elongated by internal reverberations. They should be located in each **test object** to within ±0,25 mm of their specified locations. Nylon or ultra-dense polyethylene **filament**s in the **test object** shown in Figure A.3 and Figure A.11 are used to reduce the effect of shadowing. They are typically 0,1 mm in diameter.

A.2 Tissue-mimicking materials

Several types of **tissue-mimicking materials** have been described in references [12] [13]. They are commonly based on graphite or aluminium oxide micro-particles, glass microbeads and/or plastic particles in gelatin or agarose gel [11] [13] with additional chemicals to improve their stability, to adjust the speed of sound (SOS) and to prevent bacterial growth. The specifications of any **test object** used should be obtained from the manufacturer and, in particular, information on stability and **line-target** resonance frequency should be sought [14] [15].

The attenuation and scattering of the **tissue-mimicking material** is controlled mainly by the amount of graphite and glass microbeads in the system. A low attenuation material should contain no graphite, and will therefore have a negligible attenuation coefficient. The high attenuation coefficient should be (0,7 ± 0,05) dB cm^{-1} MHz^{-1} with a temperature coefficient of less than 0,02 dB cm^{-1} MHz^{-1} $^{\circ}C^{-1}$. The velocity of sound in the **tissue-mimicking material** should be (1 535 ± 15) m s^{-1} and have a temperature coefficient of less than 3 m s^{-1} $^{\circ}C^{-1}$. Tests should be performed at (23 ± 3) °C. For resolution tests with high dynamic range, as in beam profile measurements, a material with tissue mimicking attenuation and speed of sound, but very low backscatter is desirable [15].

A.3 Description of test objects

A.3.1 Soft tissue-mimicking test object

Tissue-mimicking material with high attenuation is described in A.2. Gelatin or agarose gel is commonly used as the low attenuation material that contains no scattering centres (see Figure A.1).

Dimensions in millimetres

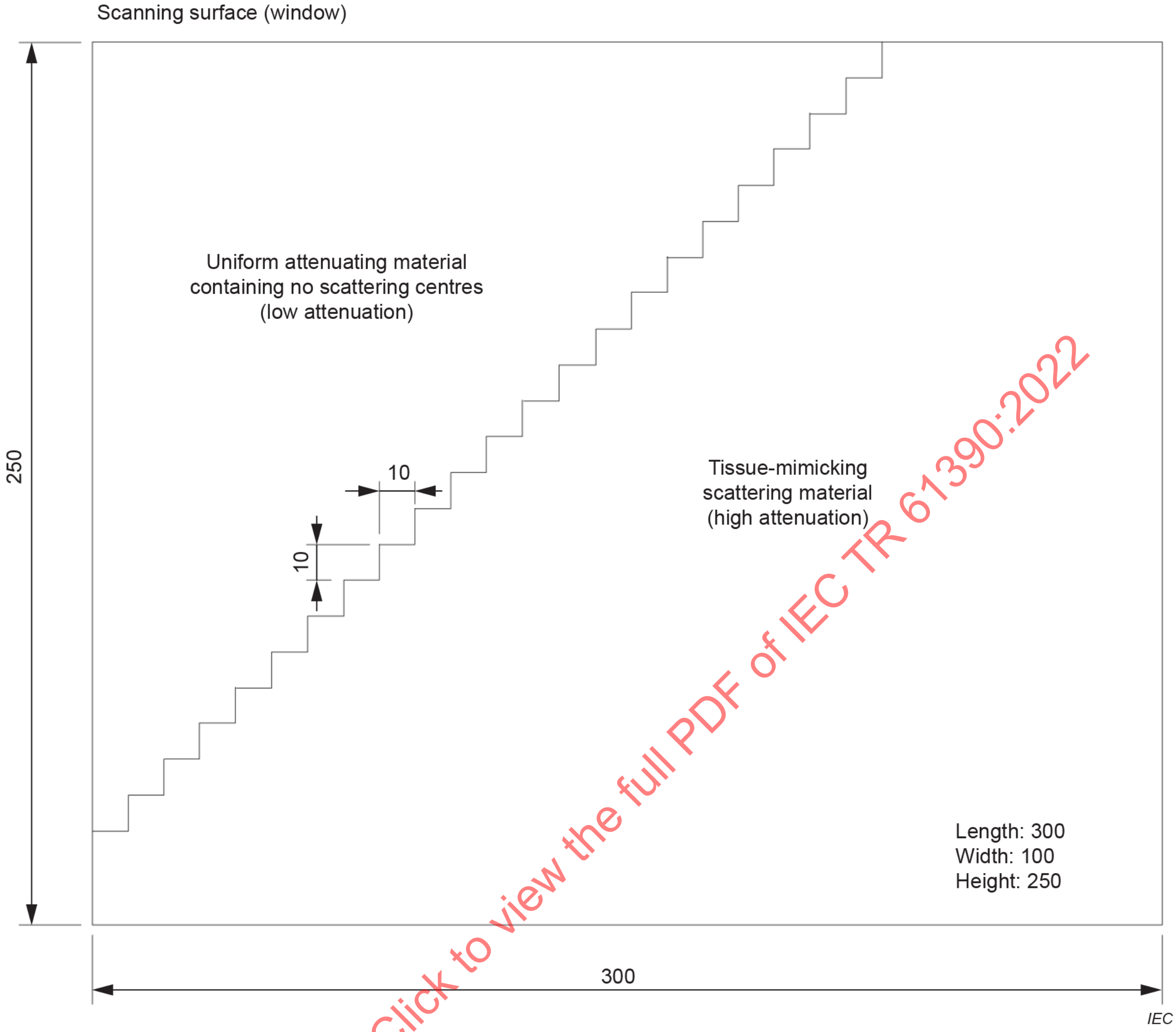


Figure A.1 – Soft tissue-mimicking test object

A.3.2 Axial resolution test object

Two nylon **filaments** of typical diameter 0,1 mm are arranged to lie in the same vertical plane and at an angle to each other as shown in Figure A.2. The **filaments** can be supported over a range of depths in low ultrasonic scattering material. Degassed aqueous solution with its speed of sound adjusted to (1 540+/-10) m s^{-1} is a suitable material. Alcohol, glycerol or table salt are suitable for adjusting the speed of sound.

The volume of the low scattering material should typically be a cube of side length 20 cm. (see 6.3.3.2 and Figure A.2)

Dimensions in millimetres

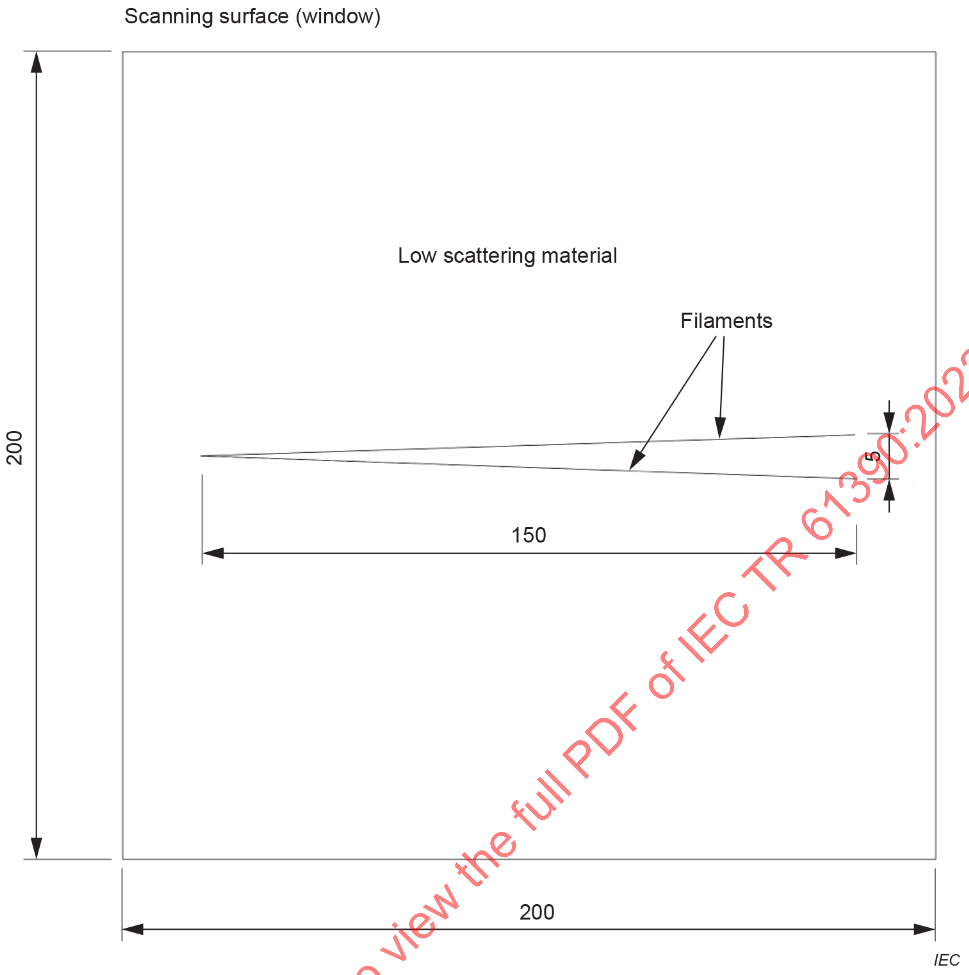


Figure A.2 – Axial resolution test object

[see also Figure C.2 in IEC 61391-1:2006]

A.3.3 Multi-purpose resolution test object

This **test object** is filled with material of low or tissue-mimicking attenuation and furnished with stainless-steel **line targets** or thin nylon or other polymer mono**filament**s as specified in A.1 (see Figure A.3). The array of **line target**s for measuring the **dead zone** (see 6.3.6) is located at depths that increase in 0,5 mm steps, starting at the **test-object scanning surface.** The array of **line target**s for **axial** and **lateral resolution** measurements (see 6.3.3.2 and 6.3.3.3) is arranged to make an angle of 60° with the **test-object scanning surface.** The sheet of scatterers for slice-thickness measurement (see 6.3.7) makes an angle of 75° with the **test-object scanning surface**. Suitable material for this sheet of scatterers will have a **backscatter coefficient** more than 50 dB higher than that of the background material and the sheet will be less than 0,2 mm thick for depths less than 4 cm and less than 0,4 mm thick at depths greater than 4 cm. The calculation of **slice thickness** is illustrated in Figure A.4.

Dimensions in millimetres

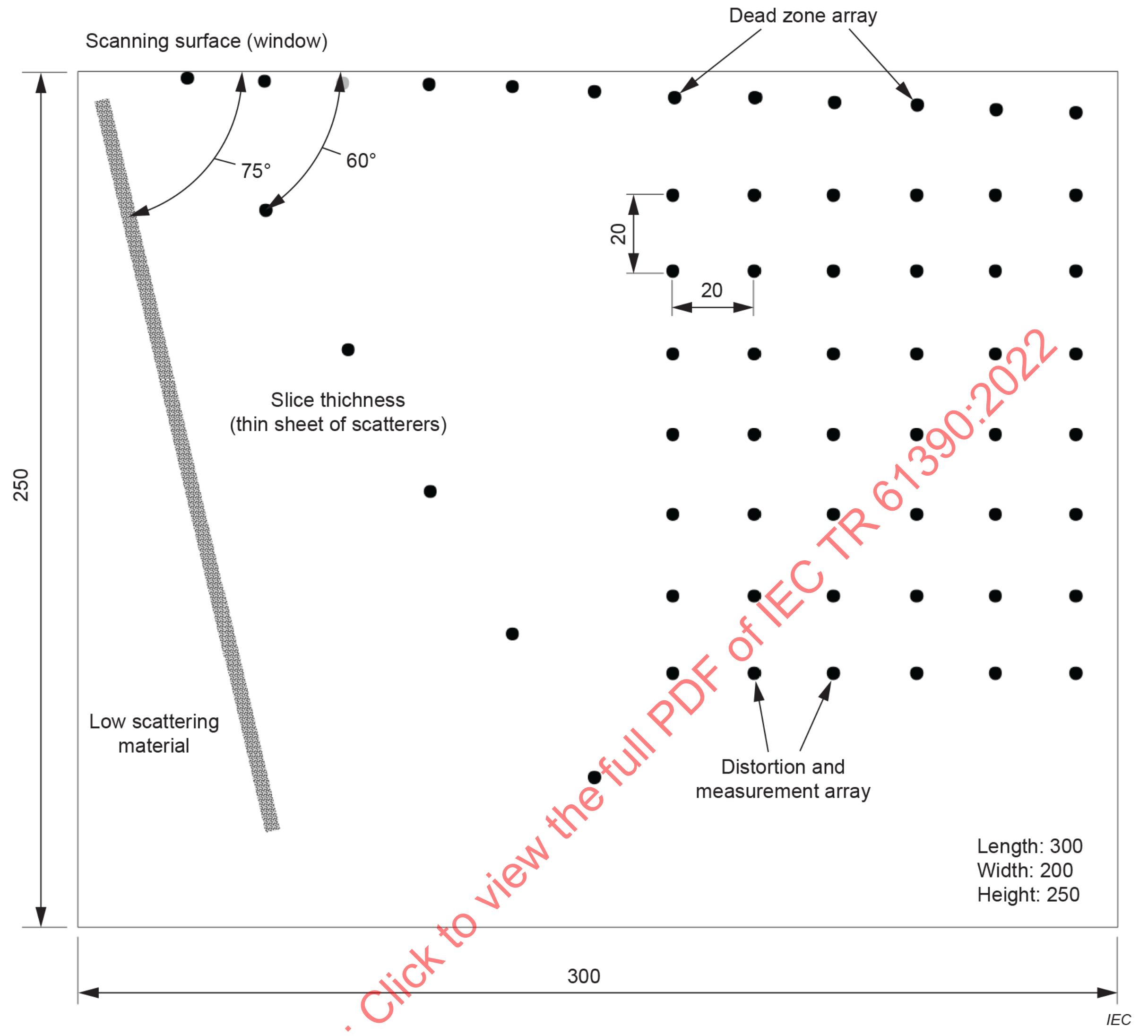


Figure A.3 – Multi-purpose resolution test object

Dimensions in millimetres

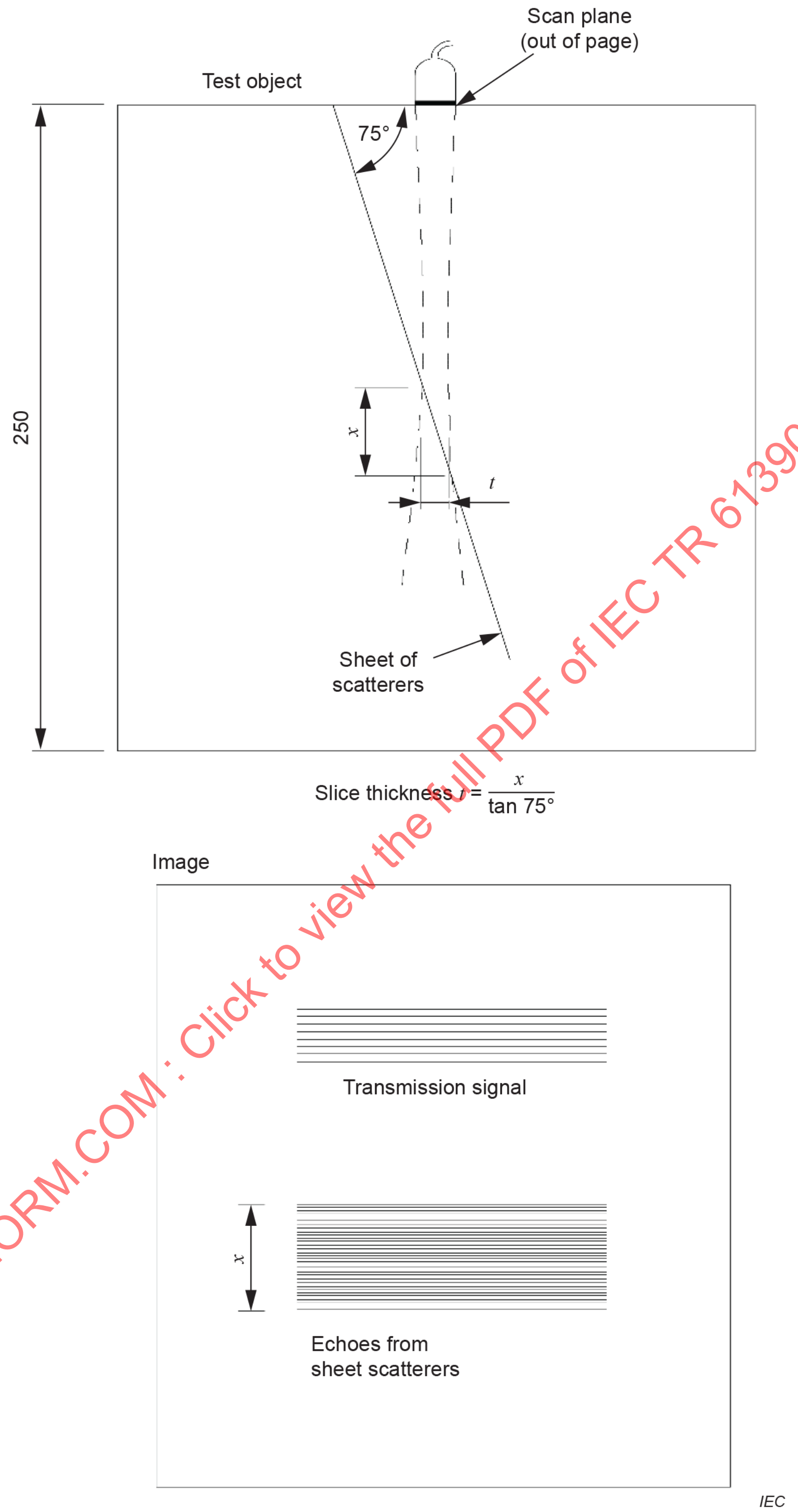


Figure A.4 – Slice-thickness measurement and calculation

[see also Figure C.5 in IEC 61391-1:2006]

A.3.4 Contrast test objects

One possible design of contrast **test object** consists of cones of **tissue-mimicking material** embedded in another **tissue-mimicking material** of different scattering cross-section [5] [6] (see 6.3.4 and Figure A.5). The scattering cross-sections of the materials within the cones provide a known progression from strong to weak scattering, while that of the embedding material is uniform and typically intermediate between those of the extreme cones. This type of contrast resolution **test object** with stepped rather than tapered cylinders**,** is commercially available.

An approximation to a complete, contrast-detail phantom [17] [18] as a function of depth is also commercially available. Reproducing the cylinders of various contrasts, sloping slowly in depth, but at additional sizes and closer and deeper would make a complete contrast-detail phantom, requiring separate sweeps for lateral (azimuthal) and elevational contrast-detail analysis.

Dimensions in millimetres

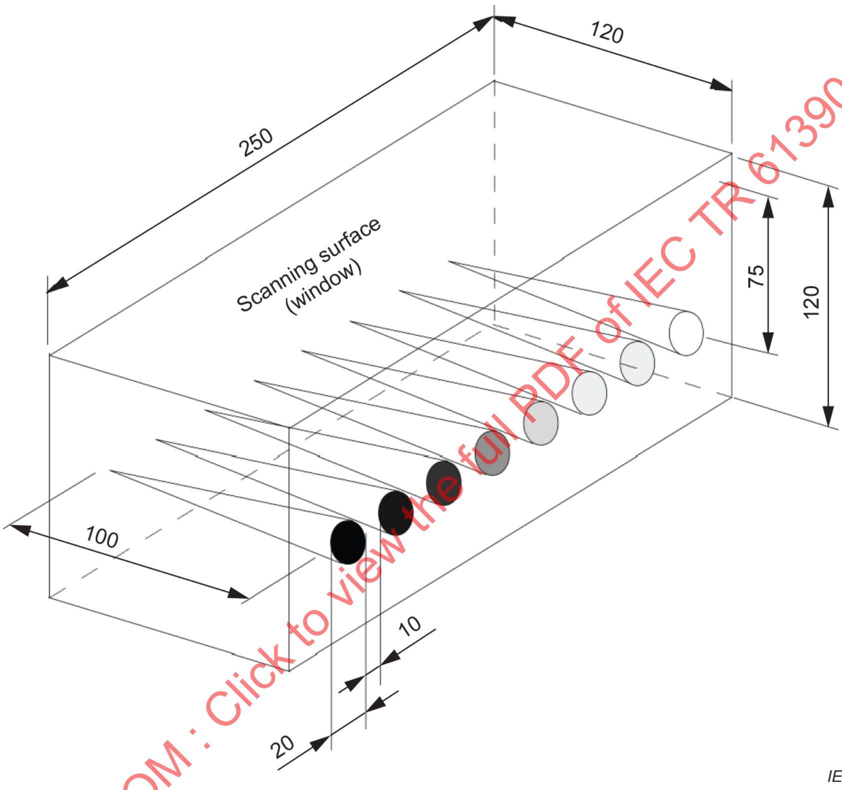


Figure A.5 – Contrast test object

A.3.5 Low-scattering sphere void test object

This **test object** is an arrangement of spheres of different size and non-scattering material, suitable for the basic objectives outlined in 6.3.5.1. Typically, the **test object** would be a cube of side length 15 cm. An example of a suitable **test object** is one containing gelatin spheres of diameters 1,00 mm, 1,25 mm, 1,59 mm and 2,00 mm embedded in graphite-loaded gelatin material at different depths (see Figure A.6). The sphere sizes are arranged in a volume doubling sequence.

Dimensions in millimetres

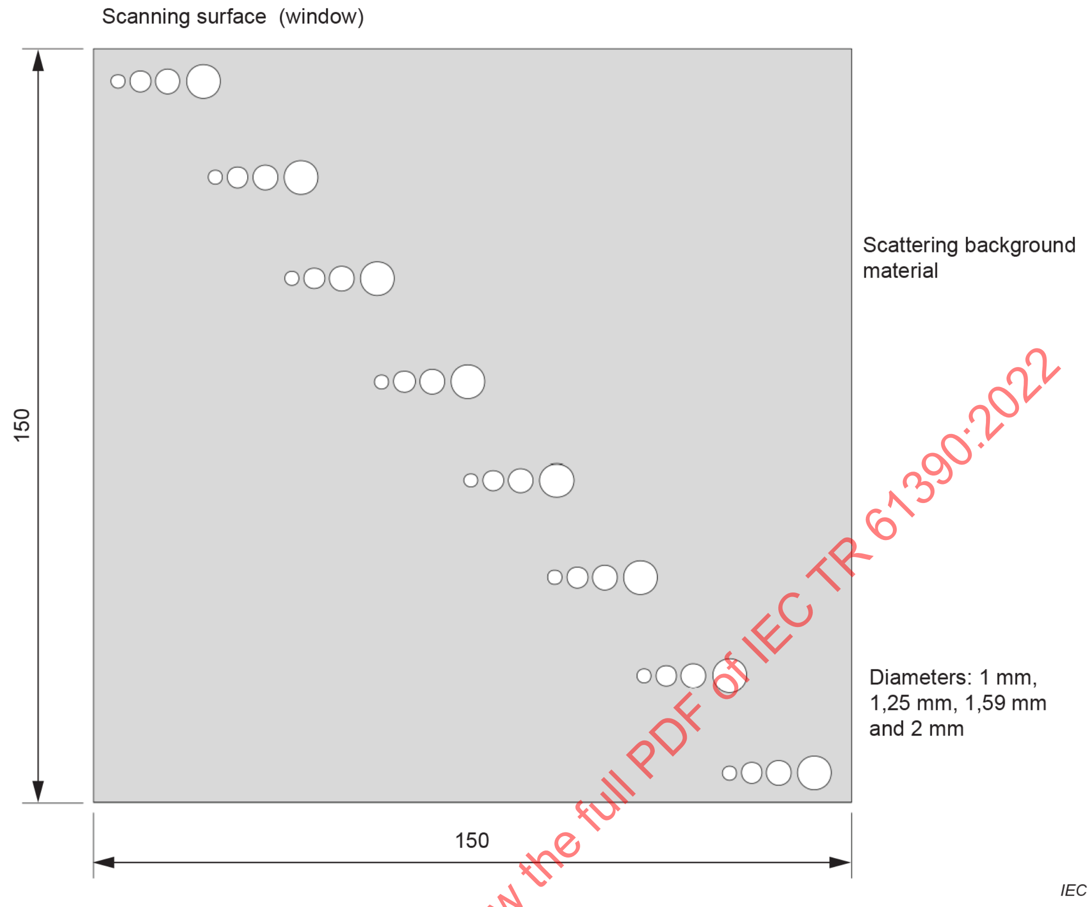
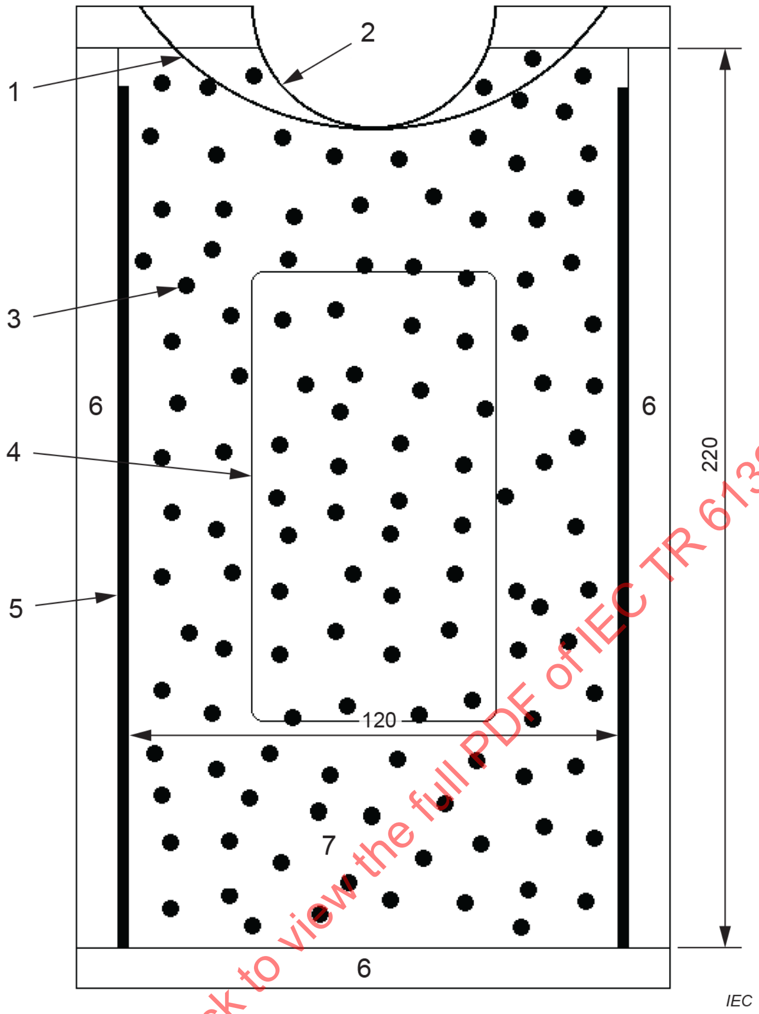


Figure A.6 – Non-scattering spheres test object

A.3.6 Randomly positioned, embedded low-echo spheres phantom

Another design discussed in 6.3.5.2 utilises a phantom with a spatially random distribution of low-echo spherical inclusions; it is suitable for measuring inclusion (lesion) signal-to-noise ratio in a given depth interval in the frequency range 2 MHz to 15 MHz. Figure A.7 illustrates a relatively sophisticated design of such a phantom containing **low-echo spheres**, which meets the technical specifications of IEC TS 62791:2015. In Figure A.7 the ends of a conical scanning window are depicted at the top of the phantom to accommodate curved arrays. The flat scanning window accommodates linear arrays, phased arrays and flat 2-D arrays. The parallel plate-glass rectangles provide – via total internal reflection – for extension of the image outside of the volume occupied by **tissue-mimicking material** (**TMM**). A flat alumina reflector can replace one of the plate-glass reflectors. The alumina reflector has a slightly rough surface, giving rise to diffuse echoes at its surface.

Dimensions in millimetres



Key

1 7-cm radius of curvature scan window at **TMM** boundary

2 3-cm radius of curvature scan window at **TMM** boundary

3 anechoic sphere

4 6-cm x 11-cm flat scanning window

5 plate-glass reflector

6 1-cm thick acrylic plate

7 background material with speed of sound = 1 540 m s^{-1}, attenuation coefficient = 0,5 dB cm^{-1}MHz^{-1} and one 4-mm diameter, anechoic sphere per mL

Figure A.7 – End view of the phantom applicable for 2 MHz to 7 MHz showing the spatially random distribution of 4-mm diameter spheres

A.3.7 Cylindrical-void phantom

A design described in IEC TS 62558:2011 and discussed in 6.3.5.4 used sliced **tissue-mimicking material** (**TMM**) arranged as alternating "cyst-slices" and "attenuation-slices". An example phantom was housed in a tight plastic box with external dimensions: height 22 cm × length 15 cm × width 8 cm. The body of the phantom consisted of alternating layers of polyurethane foam (attenuation slices and void slices), each with a thickness of 5 mm. Each second layer (the void slices) contains artificial cylindrical voids, which were cut into the foam (see Figure A.8 and Figure A.9). Foam and voids were soaked with degassed 7 % (by weight) saline solution. The concentration of the saline solution was adjusted, so that the speed of sound of the soaked foam was (1 540 ± 10) m s^{-1} at 20 °C. The backscattering level for both foams immersed in saline solution was the same. The packet of slices had a height of approximately 18 cm. After filling the phantom with saline solution, it was necessary to remove retained air bubbles by connecting to a vacuum chamber or pump. The phantom was completely sealed with a 0,25 mm polyurethane foil over the first void slice. The foil was used as a coupling window with area (11 × 5,5) cm^2; it had negligible attenuation.

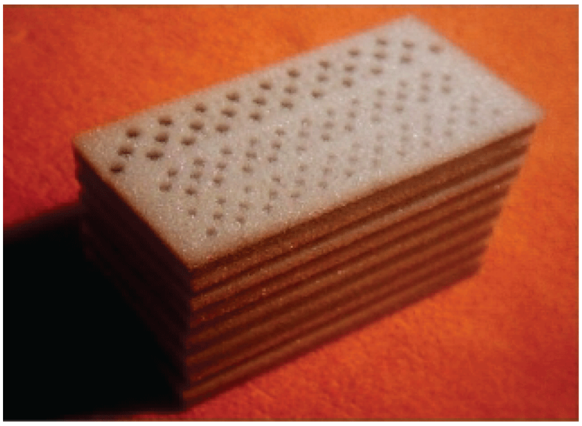


Figure A.8a) Package of TMM slices containing alternating void slices and attenuation slices of polyurethane foam

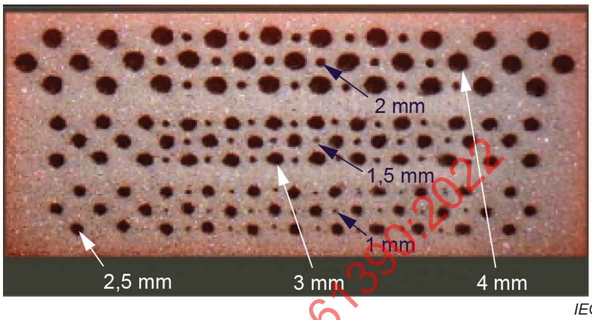
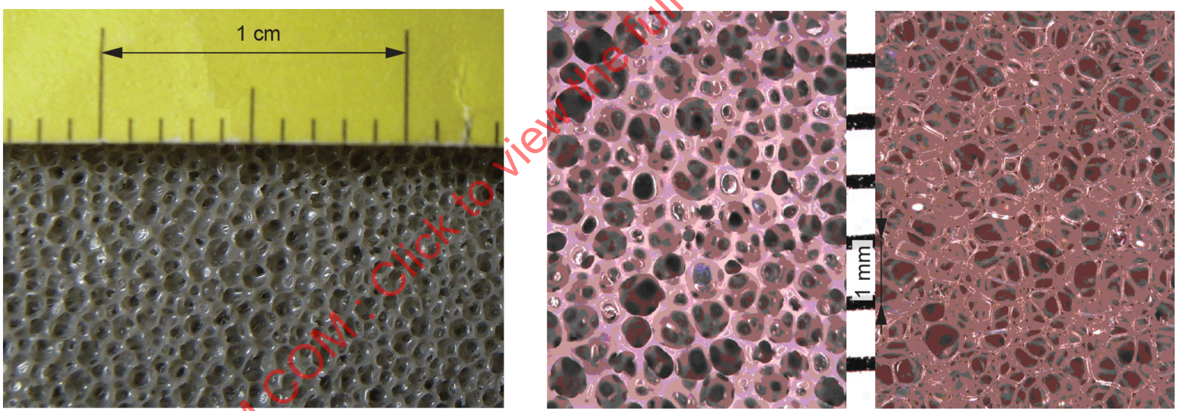


Figure A.8b) Holes of different diameters in the void slices allow the use of the phantom with different ultrasound frequencies (1 MHz to 15 MHz)

Figure A.8 – Essential components of Satrapa's cylindical-void phantom



Left: Cross section through the foam

Middle: Enlarged view of the foam of the attenuation-slices

Right: Enlarged view of foam of the void-slices

Figure A.9 – Structures of foams

The density of voids and void sizes in cylindrical-void phantoms are too small for determination of **water content ratio** (**WCR**). The random-void phantom (RVP) is much more suitable for **WCR**-processing [8].

The measurement procedure allows a reliable and reproducible determination of the visibility limits of small voids, an important image parameter of an **ultrasound** diagnostic system over the time of use by applying dedicated acquisition, processing and documentation software.

A.3.8 Edinburgh pipe phantom

The ability to measure the imaging performance of preclinical and clinical **ultrasound** scanners is important but difficult to achieve objectively. The Edinburgh pipe phantom was originally developed to assess the imaging performance of clinical scanners up to 15 MHz. It comprises a series of anechoic cylinders with diameters ranging from 0,4 mm to 8 mm formed at a 40^0 angle to the horizontal in agar-based **tissue-mimicking material** [19]. Measurement of the characteristics of the scanner/transducer combination is achieved by plotting the range of depth over which each pipe can be visualised in the **scan plane** as a function of the reciprocal of the diameter of each pipe. Usually 5 or 6 pipes can be visualised per transducer. In addition, the low contrast penetration is also measured and forms the intercept of the curve with the y-axis up to 55 MHz.

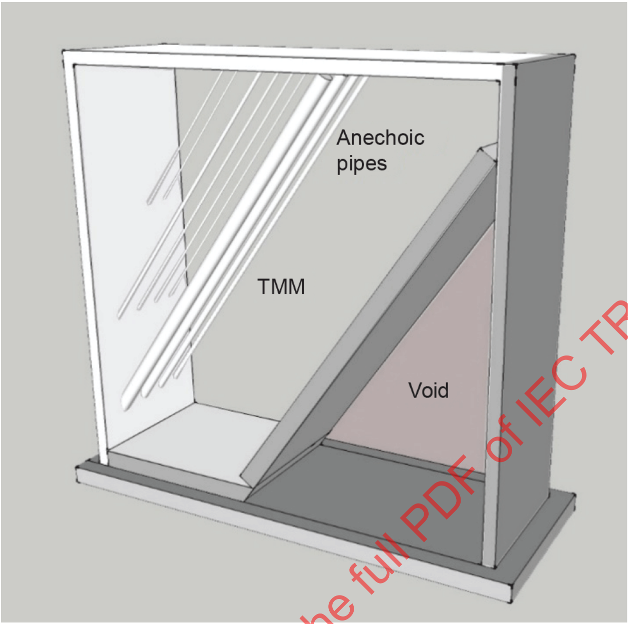
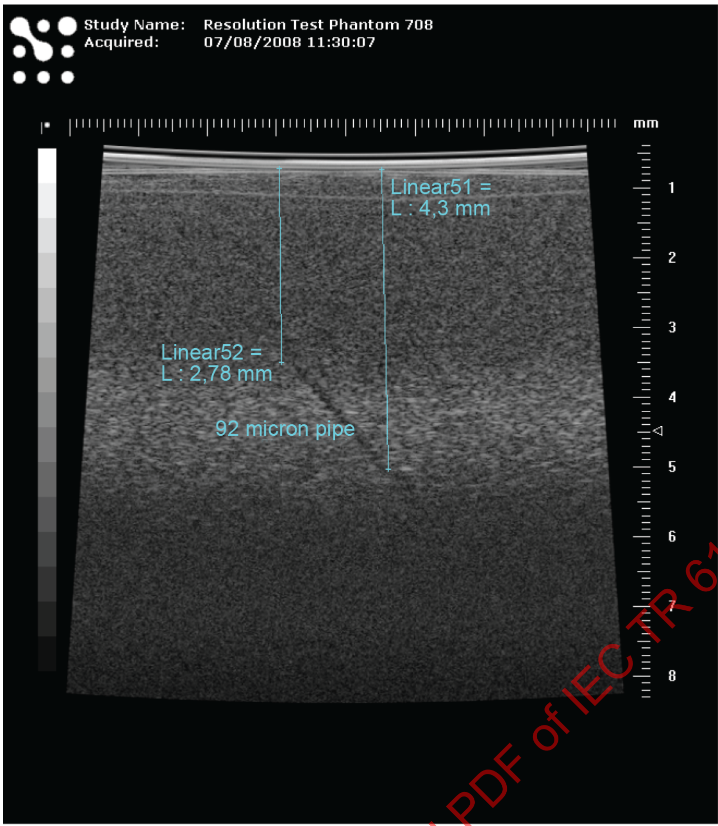


Figure A.10 – Schematic of Edinburgh pipe phantom showing anechoic pipes within the tissue mimicking material

This design enables the measurement of key imaging characteristics (resolution integral R, depth of field L_R and characteristic resolution D_R) which can be calculated from the curve. The resolution integral R is the area under the curve. L_R defines a region of optimum imaging and D_R is characteristic of the resolution within the depth of field, and $R = L_R/D_R$. These parameters were initially demonstrated to characterise transducers with centre frequencies from about 2,5 MHz to 15 MHz [20]. Further development of the Edinburgh Pipe Phantom resulted in the characterisation of echo-endoscopes [21]. intravascular **ultrasound** scanners with centre frequencies up to 45 MHz [22] and preclinical scanners with frequencies up to at least 50 MHz [23]. Characterisation of transducers with centre frequencies above 15 MHz was achieved by moulding a series of anechoic pipe structures (diameters ranging from 0,045 mm to 1,5 mm) into blocks of agar-based **tissue-mimicking material**. For preclinical imaging, measurements of R, L_R and D_R for 5 single-element and 9 linear-array transducers (centre frequencies 15 to 55 MHz) have been reported; values of R ranged from 18 to 72 for single-element transducers and from 49 to 58 for linear-array transducers. A review of over 350 clinical probes and 14 preclinical probes demonstrated that the resolution integral is able to characterise **ultrasound** imaging transducers with different levels of performance [24].

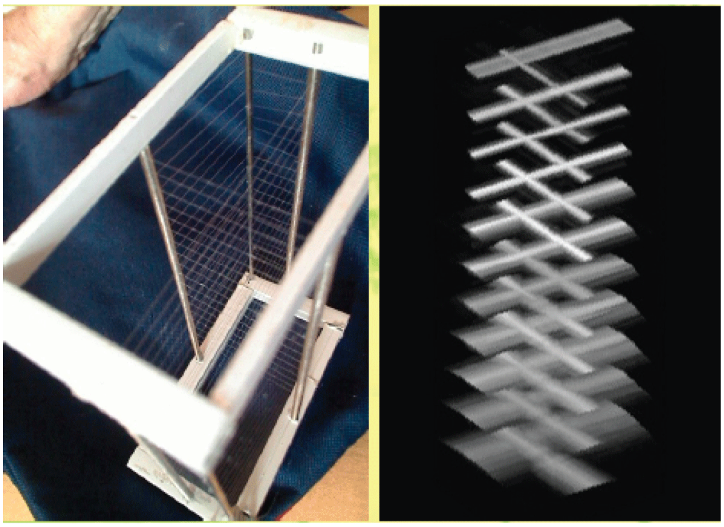


IEC

Figure A.11 – Image from a preclinical ultrasound scanner operating at 55 MHz showing the length over which a 92-micron pipe can be visualised in the scan plane

A.3.9 Crossed-threads phantom

In one design of the 3D-thread phantom discussed in 6.3.13, orthogonal nylon threads are alternately positioned in the azimuthal and elevational directions (see Figure A.12, left image) [25]. This design allows measurement of **filament**s at different depths with one single 3D-acquisition. In Figure A.13 beam profiles calculated from the single-**filament** images are shown. Two sweeps are recommended to measure both the elevational and azimuthal line-spread functions (LSFs) [6] along the full length of the array. In Figure A.13 beam profiles (LSFs) calculated from the single-filament images are shown. In another design, one set of threads is placed at 45° to the other set (Figure A.14). Aligning the transducer normal to one set of threads and sweeping it in the azimuthal direction will allow acquisition of azimuthal LSFs and a coherent summation of elevational and azimuthal LSFs along the full length of linear and curved arrays. Scanning at a fixed or known rate is not necessary, as the position along the array will be recorded in the positions of the threads in the image [25].

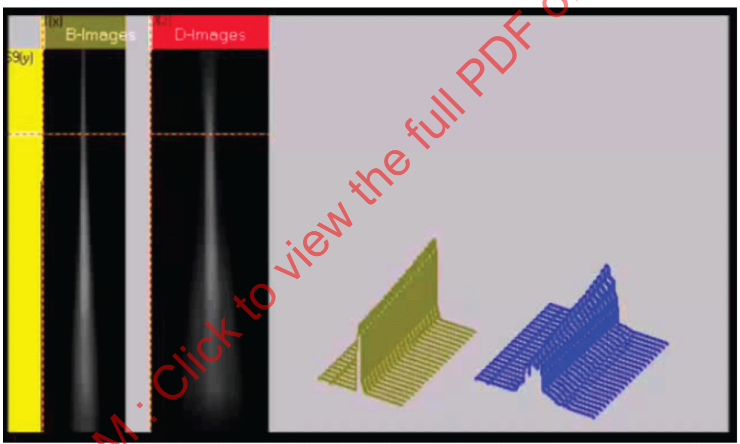


IEC

Left: Thread insert with intermittent threads stretched at right angles

Right: 3D-gray-scale image of the 3D-thread phantom

Figure A.12 – 3D-thread phantom



IEC

Left to right: Gray-scale image of lateral-beam cross-section;

gray-scale image of elevational-beam cross-section;

lateral-beam profile along the filament in elevational direction (yellow);

elevational-beam profile along the filament in lateral direction (blue)

Figure A.13 – Beam profiles calculated from the single-filament images

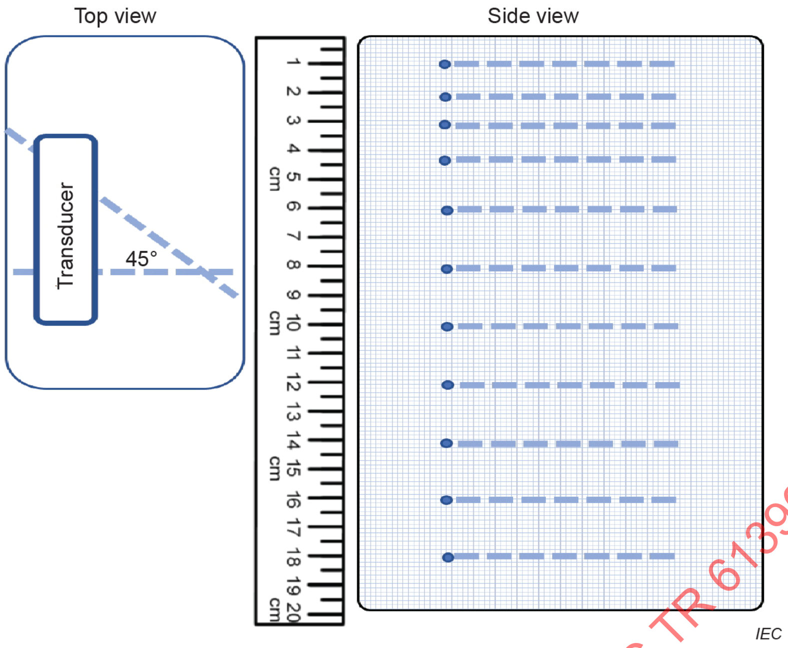


Figure A.14 – Thread groups with threads stretched at 45° angles to each other

Such 3D-thread phantoms are sensitive even to minor changes to the transducer, particularly the lens, when they might not yet show as significant reductions in **target** visibility. Thus, they can be used also to perform stability checks, if an initial test was performed earlier, preferably on delivery of the probe. Early detection and documentation of deterioration should significantly improve system availability [25].

Even if the tests are performed in water where they do not take frequency-dependent absorption into account, they are able to show when elevational or azimuthal focussing do not coincide. They could even be used to reconfigure probe lenses to optimize some scanners' performance.

The following different presentations of beam shape show the details of side-lobes and grating lobes (Figure A.15 and Figure A.16) [25].

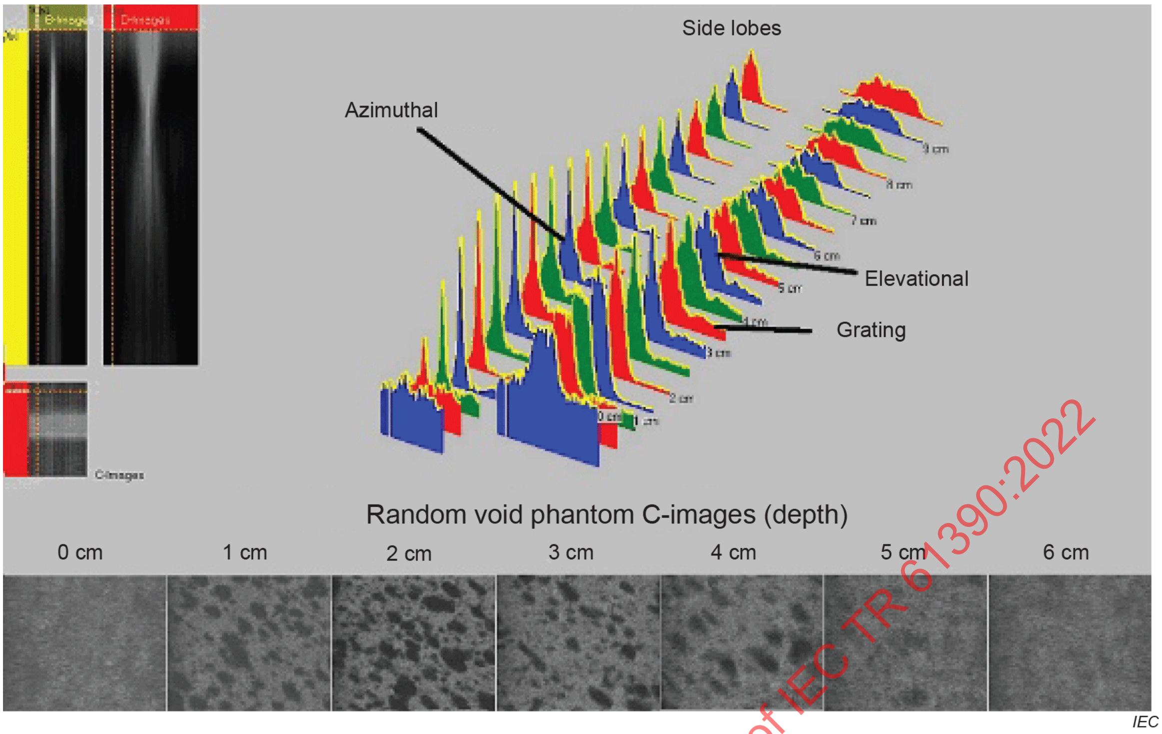
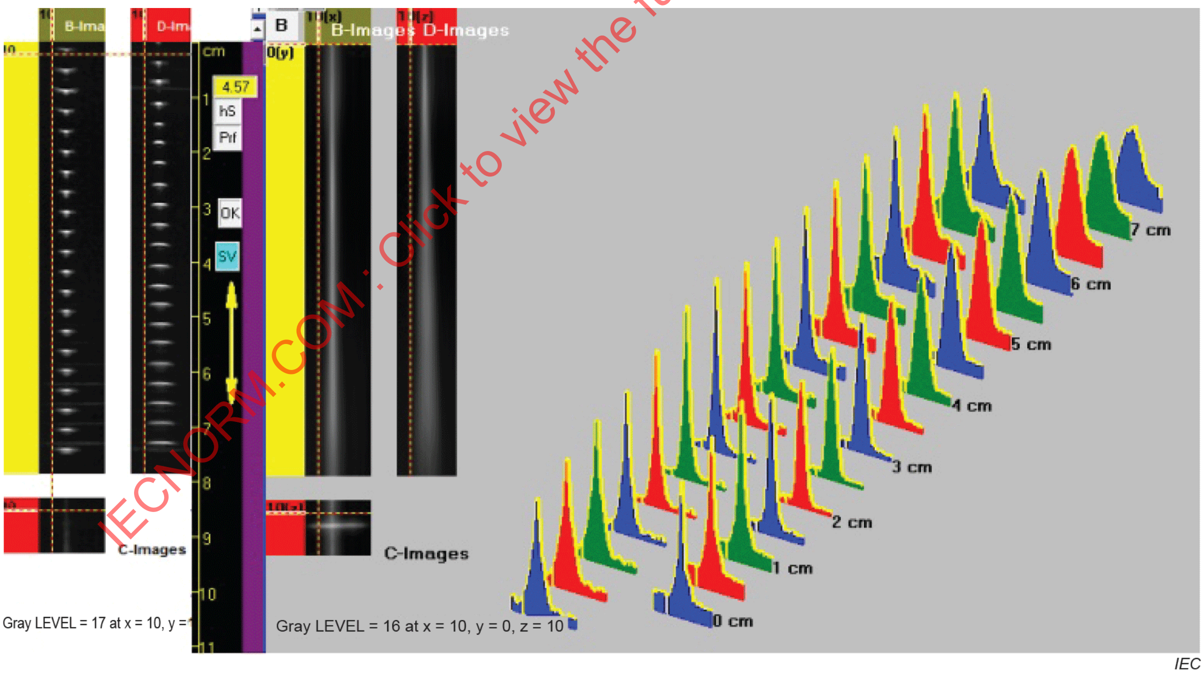


Figure A.15 – (above) Azimuthal and elevational beam profiles obtained from a filament phantom; (below) Constant depth (C-images) from a random-void phantom



Key

Features of calculated beam profiles:

strongly reduced side-lobes;

only azimuthal grating lobes are visible at 6,5-7,5 cm depth

Figure A.16 – Beam profiles calculated for a matrix probe

In most **filament** phantoms for beam profiling over a wide dynamic range, threads are immersed in water. However, low scattering **TMM** and tissue-mimicking liquids have been identified and characterized [16]. In water, the missing attenuation of a **tissue-mimicking material** (**TMM**) fails to broaden the beam profiles as would happen with preferential attenuation of the high frequencies in the transducer **bandwidth** attenuation.