

BS EN 61391-2:2010



BSI Standards Publication

## Ultrasonics — Pulse-echo scanners

Part 2: Measurement of maximum depth of penetration and local dynamic range

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EUROPEAN STANDARD

**EN 61391-2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2010

ICS 17.140.50

English version

**Ultrasonics -  
Pulse-echo scanners -  
Part 2: Measurement of maximum depth of penetration  
and local dynamic range  
(IEC 61391-2:2010)**

Ultrasons -  
Scanners à impulsion et écho -  
Partie 2 : Mesure de la profondeur  
maximale de pénétration et de la plage  
dynamique locale  
(CEI 61391-2:2010)

Ultraschall -  
Impuls-Echo-Scanner -  
Teil 2: Messung der maximalen  
Eindringtiefe und des lokalen  
Dynamikbereichs  
(IEC 61391-2:2010)

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# CENELEC

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

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## Foreword

The text of document 87/400/CDV, future edition 1 of IEC 61391-2, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61391-2 on 2010-04-01.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

- latest date by which the EN has to be implemented  
at national level by publication of an identical  
national standard or by endorsement (dop) 2011-01-01
- latest date by which the national standards conflicting  
with the EN have to be withdrawn (dow) 2013-04-01

Annex ZA has been added by CENELEC.

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## Endorsement notice

The text of the International Standard IEC 61391-2:2010 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

- |                  |      |   |
|------------------|------|---|
| IEC 60601-1:2005 | NOTE | Harmonized as EN 60601-1:2006 (not modified). |
| IEC 61161:1992   | NOTE | Harmonized as EN 61161:1994 (not modified).   |

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61391-1	2006	Ultrasonics - Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of system point spread function response	EN 61391-1	2006
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007

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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 by reflection at tissue boundaries and by scattering within tissues. Various transducer types are employed to operate in a transmit/receive mode to generate/detect the ultrasonic signals. Ultrasonic scanners are widely used in medical practice to produce images of soft-tissue organs throughout the human body.

This standard is being published in two or more parts:

- Part 1 deals with techniques for calibrating spatial measurement systems and measurement of system point spread function response;
- Part 2 deals with measurement of system sensitivity (maximum depth of penetration) and local dynamic range.

This standard describes test procedures for measuring the **maximum depth of penetration** and the **local dynamic range** of these imaging systems. Procedures should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use the standard to prepare their specifications; users should employ the standard to check performance against those specifications. The measurements can be carried out without interfering with the normal working conditions of the machine.

Typical phantoms are described in Annex A. The structures of the phantoms are not specified in detail; instead, suitable types of overall and internal structures for phantoms are described. Similar commercial versions of these test objects are available. The specific structure of a test object selected by the user should be reported with the results obtained when using it.

The performance parameters described herein and the corresponding methods of measurement have been chosen to provide a basis for comparison between similar types of apparatus of different makes but intended for the same kind of diagnostic application. The manufacturer's specifications of **maximum depth of penetration** and **local dynamic range** must allow comparison with the results obtained from the tests described in this standard. It is intended that the sets of results and values obtained from the use of the recommended methods will provide useful criteria for predicting performance with respect to these parameters for equipment operating in the 1 MHz to 15 MHz frequency range. However, availability and some specifications of test objects, such that they are similar to tissue in vivo, are still under study for the frequency range 10 MHz to 15 MHz.

The procedures recommended in this standard are in accordance with IEC 60601-1 [1] and IEC 61391-1.

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 for a specific task 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.

The paradigm used for the framework of this standard is to consider the ultrasound imaging system to be composed architecturally of a front-end (generally consisting of the ultrasound transducer, amplifiers, digitizers and beamformer), a back-end (generally consisting of signal conditioning, image formation, image processing and scan conversion) and a display (generally consisting of a video monitor but also including any other output device). Under ideal conditions it would be possible for users to test performance of these components of the system independently. It is recognized, however, that some systems and lack of some laboratory resources might prevent this full range of measurements. Thus, the specifications and measurement methods described in this standard refer to image data that are provided in

a digitalized format by the ultrasound machine and that can be accessed by users. Some scanners do not provide access to digitized image data. For this group of scanners, tests can be done by utilizing frame grabbers to record images. Data can then be analyzed in a computer in the same manner as for image data provided directly by the scanner.

## ULTRASONICS – PULSE-ECHO SCANNERS –

### Part 2: Measurement of maximum depth of penetration and local dynamic range

#### 1 Scope

This part of IEC 61391 defines terms and specifies methods for measuring the **maximum depth of penetration** and the **local dynamic range** of real-time ultrasound B-MODE scanners. The types of transducers used with these scanners include:

- mechanical probes;
- electronic phased arrays;
- linear arrays;
- curved arrays;
- two-dimensional arrays;
- three-dimensional scanning probes based on a combination of the above types.

All scanners considered are based on pulse-echo techniques. The test methodology is applicable for transducers operating in the 1 MHz to 15 MHz frequency range operating both in fundamental mode and in harmonic modes that extend to 15 MHz. However, testing of harmonic modes above 15 MHz is not covered by this standard.

NOTE Phantom manufacturers are encouraged to extend the frequency range to which phantoms are specified to enable tests of systems operating at fundamental and harmonic frequencies above 15 MHz.

#### 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 61391-1:2006, *Ultrasonics – Pulse-echo scanners – Part 1: Techniques for calibrating spatial measurement systems and measurement of system point spread function response*

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

#### 3 Terms and definitions

For the purposes of this document the following terms and definitions apply:

##### 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

[IEC 61391-1:2006, definition 3.1]

### 3.2

#### **acoustic scan line (scan line)**

one of the component lines which 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

[IEC 61391-1:2006, definition 3.26]

### 3.3 acoustic working frequency

arithmetic mean of the frequencies  $f_1$  and  $f_2$  at which the amplitude of the acoustic pressure spectrum first falls 3dB below the main peak amplitude.

[IEC 61391-1:2006, definition 3.3, modified]

### 3.4

#### **attenuation coefficient**

at a specified frequency, the fractional decrease in plane wave amplitude per unit path length in the medium, specified for one-way propagation

Units:  $\text{m}^{-1}$  (attenuation coefficient is expressed in  $\text{dB m}^{-1}$  by multiplying the fractional decrease by 8,686 dB.)

NOTE 1 When describing the attenuation properties of a material, the variation of attenuation with frequency should be given. This may be done by expressing  $a(f)$ , the attenuation coefficient at frequency  $f$ , as  $a(f) = a_0 f^b$ , where  $f$  is in MHz,  $a_0$  is the attenuation coefficient at 1 MHz and  $b$  is a constant determined by least-squares fitting to experimental data points.

NOTE 2 This parameter specifies the medium's attenuation only; it excludes reflective losses at interfaces enclosing the medium and signal decreases due to diffraction.

NOTE 3 See also **specific attenuation coefficient**.

### 3.5

#### **B-mode**

method of echo-signal display in which the amplitude of the echo signal is represented by modulation of the brightness of the corresponding point on the display

NOTE The location of the point is determined from the transit time of the acoustic pulse and an assumed value for sound speed in tissues; for B-mode imaging, it is also determined from the relative position and orientation of the **acoustic scan line**.

### 3.6

#### **B-scan**

class of data acquisition geometry in which echo information is acquired from points lying in an ultrasonic scan plane containing interrogating ultrasonic beams

[IEC 61391-1:2006, definition 3.9]

### 3.7

#### **backscatter coefficient**

at a specified frequency, the mean acoustic power scattered by a specified object in the  $180^\circ$  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

Units:  $\text{m}^{-1}\text{steradian}^{-1}$

NOTE The frequency dependency should be addressed at places where backscatter coefficient is used, if frequency influences results significantly.

[IEC 61391-1:2006, definition 3.6, modified]

**3.8****backscatter contrast**

ratio between the backscatter coefficients of two objects or regions

[IEC 61391-1:2006, definition 3.7, modified]

**3.9****beam axis**

the longitudinal axis of the pulse-echo response of a given acoustic scan line, a pulse-echo equivalent to the transmitted beam axis of IEC 62127-1

[IEC 61391-1:2006, definition 3.8, modified]

**3.10****digitized image data**

two-dimensional set of pixel values derived from the ultrasound echo signals that form an ultrasound image

**3.11****displayed acoustic dynamic range**

$20 \log_{10}$  of the ratio of the amplitude of the maximum echo that does not saturate the display to that of the minimum echo that can be distinguished in the same or similar location of the display under the scanner test settings

Unit: dB

NOTE On most B-mode scanners echo-signal compression is applied in the receiver, so the **displayed acoustic dynamic range** exceeds the input-signal dynamic range capabilities of the monitor.

**3.12****display threshold (B-mode)**

display luminance just above the luminance when no echo signal is present

**3.13****display saturation (B-mode)**

display luminance at which an increase in echo-signal level or an increase in system sensitivity produces no change in luminance

**3.14****dynamic range**

see **local dynamic range**; see also **displayed dynamic range** and **global dynamic range**

**3.15****field-of-view**

area in the ultrasonic **scan plane** from which ultrasound information is acquired to produce one image frame

NOTE 1 This area can correspond to a two-dimensional or three-dimensional field.

NOTE 2 Definition differs from that of 61391-1 in that it is restricted to the region from which information is acquired.

[IEC 61391-1:2006, definition 3.13 modified]

**3.16****frame rate**

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

[IEC 61391-1:2006, definition 3.14]

NOTE This parameter usually differs from the image display rate on the scanner monitor.

### 3.17

#### **gain**

ratio of the output to the input of a system, generally an amplifying system, usually expressed in decibels.

[IEC 61391-1:2006, definition 3.15]

NOTE The ratio applies for a constant and known acoustical system output.

### 3.18

#### **global dynamic range**

ratio of the maximum to the minimum echo-signal amplitude, even with changes of settings, that a scanner can process without distortion of the output signal

### 3.19

#### **harmonic imaging**

method of imaging in which ultrasound is transmitted at a fundamental frequency and is detected at harmonic frequencies

NOTE Harmonics are generated by the propagation medium or by nonlinear reflectors. The resulting harmonic signal is displayed as an image or part of the image.

### 3.20

#### **local dynamic range**

$20 \log_{10}$  of the ratio, of the minimum echo amplitude that yields the maximum grey level in the digitized image to that of the echo that yields the lowest grey level at the same location in the image and the same settings

Unit: dB

NOTE 1 For an 8-bit image memory, the maximum gray level in the digitized image will be 255.

NOTE 2 Some documents refer to **local dynamic range** as the range of echo signals required to vary the display brightness from barely discernible to maximum brightness at a given location [1]. However, this international standard applies the name **local dynamic range** to the digitized image data rather than data viewed on the image monitor. The name **displayed acoustic dynamic range** is the equivalent to **local dynamic range**, but applied to data viewed on the image monitor.

NOTE 3 This quantity is influenced by the grey scale (dynamic) transfer function associated with the echo display.

### 3.21

#### **maximum depth of penetration**

maximum distance in a tissue-mimicking phantom of specified properties for which the ratio of the digitized B-mode image data from background scatterers to the digitized B-mode image data displaying only electronic noise equals 1,4

Unit: m

NOTE The phantom and noise-only images are obtained using identical system settings.

### 3.22

#### **operating condition**

any one of the possible particular control settings for a discrete or a combined operating mode

### 3.23

#### **operating mode (discrete)**

mode of operation of **medical diagnostic ultrasonic equipment** in which the purpose of the excitation of the ultrasonic transducer or ultrasonic transducer element group is to utilize only one diagnostic methodology

NOTE Examples of **discrete operating modes** are A-mode (A), M-mode (M), static B-mode (sB), real-time B-mode (B), continuous wave Doppler (cwD), pulsed Doppler (D), static flow-mapping (sD) and real-time flow-mapping Doppler (rD) generally using only one type of acoustic pulse at a given depth.

[IEC 62127-1:2007, definition 3.39.2]

### 3.24

#### **operating mode (combined)**

mode of operation of a system that combines more than one **discrete operating mode**

[IEC 62127-1:2007, definition 3.39.1]

### 3.25

#### **perfect planar (or specular) reflector**

an interface that has a reflection coefficient of 1,0 and whose dimensions are large compared to the local width of the ultrasound beam

NOTE 1 The pressure-amplitude reflection coefficient of a water-to-air interface is 0,9994 (derived from  $Z_w = 1480\ 000\ \text{kgm}^{-2}\text{s}^{-1}$  and  $Z_a = 413\ \text{kgm}^{-2}\text{s}^{-1}$ )

NOTE 2 In practical measurements a variety of targets may be used. These can all be referred to the perfect planar reflector by calculation or by careful comparison.

### 3.26

#### **phantom**

a volume of material behaving in essentially the same manner as tissue of the same dimensions, with respect to absorption and scattering of the ultrasound radiation in question, used for dosimetry or for the evaluation of sonographic images in diagnostic sonography (see **tissue mimicking phantom**)

[IEC 60050-881:1983, 881-12-54 modified]

### 3.27

#### **pulse-echo technique**

method of interrogating a region by insonifying it with pulsed sound beams and detecting and displaying echo signals arising from scatterers or reflectors

### 3.28

#### **reflection coefficient (sound pressure)**

ratio of the reflected pressure amplitude to the incident pressure amplitude for plane waves incident perpendicularly on a smooth interface separating two media

### 3.29

#### **scan line**

see **acoustic scan line**

### 3.30

#### **scan plane**

acquired image plane containing the acoustic scan lines

### 3.31

#### **scan volume**

volume from which echo data are acquired and that contribute to a 3D- image

### 3.32

#### **sensitivity**

minimum reflection coefficient in water of a plane reflector, oriented and positioned for maximum response, which produces a **display threshold**

NOTE For the purpose of this standard, the maximum depth of penetration for visualizing background echoes in a phantom is used as an indication of sensitivity.

**3.33****specific attenuation coefficient**

at a specified frequency, the slope of attenuation coefficient plotted against frequency

Units: dB m<sup>-1</sup>MHz<sup>-1</sup>

**3.34****speckle pattern**

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

[3.30 of IEC 61391-1:2006]

**3.35****statistically independent images**

images acquired from planes or directions such that the normalized cross-correlation of the underlying speckle pattern over a fixed region of interest, prior to any speckle reduction smoothing, is less than 0,2

NOTE Statistically independent images are obtained from a phantom containing randomly distributed scatterers by translating the scanning plane, steering the beam, etc., such that the underlying speckle pattern changes sufficiently to reduce the correlation. Images whose speckle target cross-correlation is  $\sim 0,2$  or lower are sufficiently de-correlated to implement measurements in this standard.

**3.36****test object**

device containing one or more groups of object configurations embedded in a tissue-mimicking material or another medium (see also **phantom**, **tissue-mimicking phantom**)

[IEC 61391-1:2006, definition 3.33]

**3.37****tissue-mimicking material**

material in which the propagation velocity (speed of sound), reflection, scattering, and attenuation properties are similar to those of soft tissue for ultrasound in the frequency range 1 MHz to 15 MHz

[IEC 61391-1:2006, definition 3.36, modified]

**3.38****tissue-mimicking phantom**

object comprising **tissue-mimicking material**

**4 General requirement**

The manufacturer's specification shall allow comparison with the results obtained from the tests described in this standard.

**5 Environmental conditions**

All measurements shall be performed within the following ambient conditions:

- temperature, 23°C ± 3°C;
- relative humidity, 45 % to 75 %;
- atmospheric pressure, 86 kPa to 106 kPa.

Properties of ultrasound phantoms, such as speed of sound and attenuation coefficient, are known to vary with temperature. Consult the specifications published by the phantom manufacturer to determine whether the expected acoustic properties are maintained under the

above environmental conditions. If not, the environmental conditions over which expected and reproducible results can be obtained from the phantom or test object shall be adopted for tests.

## 6 Equipment and data required

### 6.1 General

The test procedures described in this document shall be carried out using tissue-mimicking phantoms and electronic test equipment, together with digitized image data acquired from the ultrasound scanner.

### 6.2 Phantoms

#### 6.2.1 Phantoms required

An ultrasound phantom is required for performance of measurements complying with this standard. A phantom that contains a large, uniform region is required for determining the maximum depth of penetration. The uniform region shall extend over at least one third of the width of the imaged field when the depth setting is either at 20 cm or at its maximum value, if this is less than 20 cm. The acoustical properties of this phantom are specified in 6.2.2.

Test apparatus for measuring local dynamic range as called for in this standard is outlined in 6.2. However, users may also estimate the **local dynamic range**. Properties of phantoms that can be used for these estimates are outlined in 6.2.3.

#### 6.2.2 Phantom for maximum depth of penetration

The **maximum depth of penetration** expresses the maximum range at which echoes from weakly reflecting scatterers in a phantom having defined properties can be detected at a specified level above noise [5-12]<sup>1)</sup>. A phantom for measuring the maximum depth of penetration is shown in Figure A.1 in Annex A. The essential components of this phantom include a block of tissue-mimicking material with background scatterers that give rise to echo signals. The tissue-mimicking material shall have the following properties:

Speed of sound:	$(1\,540 \pm 15) \text{ m s}^{-1}$ at 3 MHz
Density:	$(1,00) \pm 0,03 \text{ g cm}^{-3}$
Specific attenuation coefficient	$(0,7 \pm 0,05) \text{ dB cm}^{-1}\text{MHz}^{-1}$ in the 1 MHz to 15 MHz frequency range
Backscatter coefficient:	$(3 \times 10^{-4} \text{ cm}^{-1}\text{sr}^{-1}) \pm 3 \text{ dB}$ at 3 MHz; with a “frequency to the $n$ ” ( $f^n$ ) dependence, where $2 < n < 4$ from 1 MHz to 15 MHz. The value of the backscatter coefficient of the phantom shall be reported as a function of frequency, together with the results obtained with the phantom.
Dimensions:	The phantom shall provide a uniformly scattering and attenuating field that extends to a depth of at least 20 cm for testing penetration depth at low frequencies (less than 5 MHz). The lateral and elevational dimensions shall be such that there is at least a 6 cm wide by 6 cm thick region of uniform tissue-mimicking material at distances corresponding to the maximum depth of penetration for the scanner and transducer under study. Larger cross-sections may be required to provide a uniform region when testing 3-D scanning systems.

<sup>1)</sup> Figures in square brackets refer to the Bibliography.

Suitable phantoms for this test can be constructed using, for example, water-based gels having microscopic inhomogeneities that are uniformly distributed throughout to produce the desired attenuation level [13-18]. Such phantoms also require solid particles, such as 40-micrometer diameter glass beads to provide backscattered signals at a controlled amplitude [18,19]. A number of manufacturers<sup>2)</sup> can produce tissue-mimicking materials and phantoms that follow these specifications.

### 6.2.3 Phantoms to estimate local dynamic range

An estimate of the local dynamic range can be obtained easily in the clinic by scanning phantoms that contain spherical, cylindrical or truncated cylindrical objects, whose backscatter coefficients vary by known amounts relative to the background material [20]. Backscatter variations of up to 24 dB (15 dB greater than the background, 9 dB less than the background) are available in some commercially available phantoms<sup>3)</sup>.

### 6.3 Test equipment for measuring local dynamic range

The most convenient method for measuring **local dynamic range** is to use signal injection, whereby acoustic pulses having precisely controlled amplitudes are applied to the imaging system transducer directly [21-24]. Figure 1 presents a typical setup. The measurement requires a signal generator<sup>4)</sup> that produces sine-wave voltage signals at a frequency that is within the bandwidth of the transducer-imaging system under test. A planar, single-element transducer, whose centre frequency also is within the bandwidth of the system transducer, serves as a coupling device between the signal generator and the system transducer. The diameter of the coupling transducer should be smaller than 1/3 the aperture of the system transducer. A test should be performed to determine the dependence of the acoustic output of the coupling transducer with driving voltage. This can be done using methods described in IEC 61161:1992 [4]. The coupling transducer is driven with a sinusoidal voltage signal by the signal generator. The acoustic output of the coupling transducer should be proportional to the driving voltage to within 2,0 dB for acoustic signal level variations equal to the local dynamic range of the ultrasound system under test.

An external electrical attenuator<sup>5)</sup> is placed between the signal generator and the coupling transducer. Alternatively, some signal generators have suitable built-in attenuators. The attenuator should have a range of at least 100 dB over the 1 MHz to 15 MHz range.

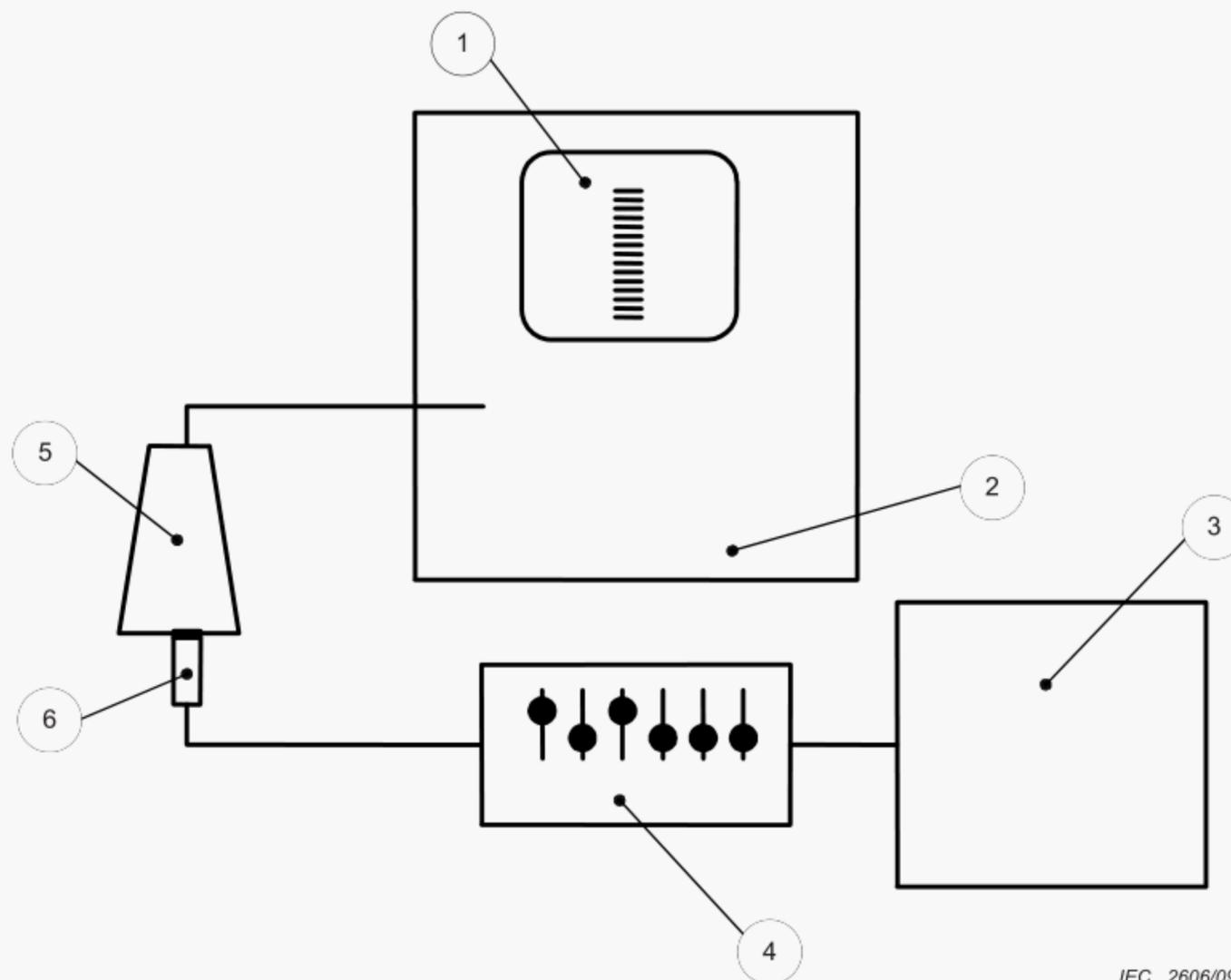
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2) These include, for example, ATS Labs; Bridgeport, CT, USA ([www.atslabs.com](http://www.atslabs.com)); CIRS, Norfolk, VA, USA ([www.cirsinc.com](http://www.cirsinc.com)); and Gammex/RMI, Middleton, WI, USA ([www.gammex.com](http://www.gammex.com)). This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these companies.

3) An example of a suitable phantom is the Model 439 general purpose phantom, ATS Labs, Bridgeport, CT, USA ([www.atslabs.com](http://www.atslabs.com)). This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.

4) For example, the Model 33220A Function Generator, Agilent Technologies, Santa Clara, CA, USA. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.

5) For example, the Model 839, Kay Elemetrics Corp, Pine Brook, NJ, USA. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.



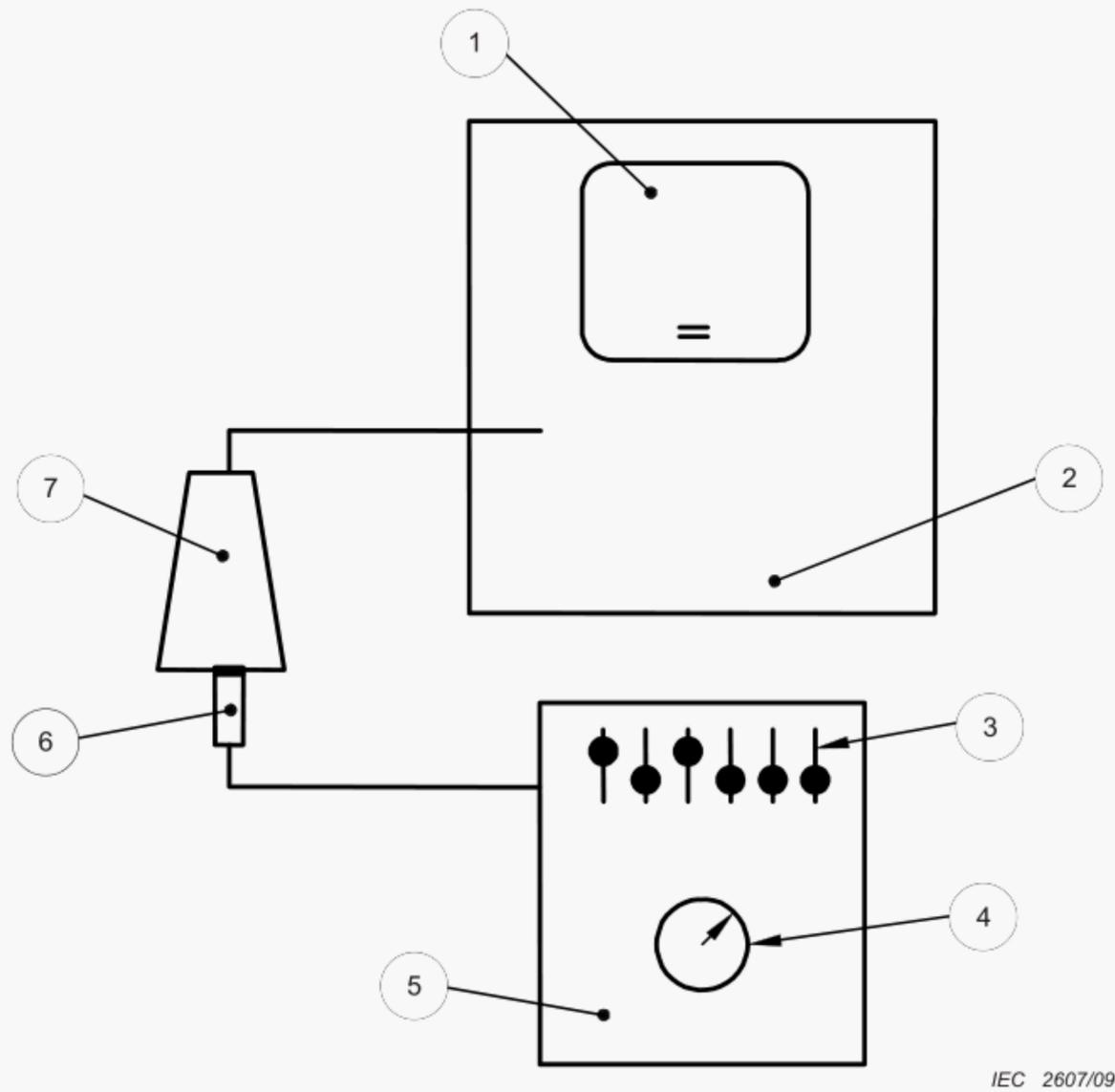
IEC 2606/09

**Key:**

- 1 Displayed B - mode signal
- 2 Ultrasound system
- 3 Signal generator
- 4 Attenuator
- 5 System transducer
- 6 Coupling transducer

**Figure 1 – Arrangement for measuring local dynamic range using an acoustic-signal injection technique**

An equivalent alternative arrangement uses a custom designed burst generator [21] for this measurement (Figure 2). With such units, in response to each transmit pulse from the imaging system transducer, the coupling transducer produces an electrical-voltage signal that triggers the burst generator. Following a user-defined time delay, which typically is between  $10\ \mu\text{s}$  and  $100\ \mu\text{s}$  depending on the field of view of the scanner, the generator produces one or more electrical pulses. These are applied to the coupling transducer, which then transmits a series of acoustic pulses into the system transducer. After signal- and image-processing by the ultrasound system, these pulses are presented as apparent echoes in the image memory and on the B-mode image display. The location of the apparent echo signals on the image depends on the time delay set in the burst generator and on the area on the system transducer aperture that is in contact with the coupling transducer. The generator must provide signal level variations that extend over a range that is greater than the **local dynamic** range of the system under test.



IEC 2607/09

**Key:**

- 1 Displayed B - mode signal
- 2 Ultrasound system
- 3 Attenuator
- 4 Burst delay
- 5 Triggered burst generator
- 6 Coupling transducer
- 7 System transducer

**Figure 2 – Arrangement for measuring local dynamic range using an acoustically-coupled burst generator**

A third possible arrangement applies signal injection directly to the ultrasound system. With this arrangement, conditioned signals of known amplitude, frequency, and duration are fed into the system amplifiers, bypassing the transducer. With such arrangements, precisely controlled changes in simulated echo-signal amplitude can be introduced, and the system response to these changes can be quantified. Direct injection has been used extensively on systems employing single-element transducers [22-24]. Devices that apply signal injection for imaging systems employing transducer arrays are becoming commercially available as well, and these are noted in 7.2.3 below.

#### 6.4 Digitized image data

Test criteria described in this document are applied to digitized image data derived from the ultrasound scanner being evaluated. In all cases, image-pixel brightness (gray) levels for all spatial locations in the image must be available. Image data typically are in a matrix consisting of at least  $300 \times 300$  pixels and at least 8 bits (255 levels) of gray-scale resolution.

Scanners for which this standard applies may be grouped according to the source of the digitized image data. The first group includes systems for which digitized image data are directly available from the scanner or over an image network. Sources of digitized image data from this group include the following:

Direct DICOM [25]-images from the scanner. Image data in a DICOM format are available on most scanners. Software capable of transferring and opening DICOM formatted images is available.

Digital image files available from the scanner itself. This method is used by most scanner manufacturers for in-house quality-control testing and image-processing development. Capabilities often exist to extend the method for use by clinical personnel using, for example, file-transfer-protocol (ftp) resources. Alternatively, many scanners provide image files on removable media, such as USB-thumb drives, magneto-optical disks, zip disks, or CD-ROM, and these are appropriate sources of digital images data as well.

Image-archiving systems. Many imaging centers use commercially available Picture Archiving and Communication Systems (PACS) for viewing and storing ultrasound-image data. Manufacturers of PACS systems usually provide means to acquire images in an uncompressed format, such as a 'tiff' (Tagged Image File Format) or a DICOM (Digital Imaging and Communications in Medicine [25])-format, to workstations that have access rights to the image data.

A second group of scanners includes those simpler devices that do not provide digitized image data but provide standard video signals, image data that can be captured into a computer and then analyzed. For these scanners, a video-frame grabber may be used to acquire digitized image data. The video signal grabbing has to be provided under exactly specified conditions to avoid or minimize signal distortions. Specific care and attention has to be taken for the following parameters:

The input dynamic range of the video-frame grabber has to be adjusted according to the maximum signal amplitude of the video output.

The digitizing amplitude resolution (given by the pixel byte size) must be better than that of the gray-scale resolution of the video-output signal. A minimum of 8 bits or 256 gray levels is required.

Conversion-function linearity has to be assured.

The spatial resolution (given by the pixel size) of the digital picture must be better than the original video line density of the image.

The video-capture frame rate of the video-frame grabber must be high enough to allow acquisition of data to keep up with input data rates, if the imaged field is moved. Keep in mind the difference between scanning frame rate and output video frame rate.

A cable matched for input/output impedance has to be used to avoid reflections in the line.

Alternatively, some post-processing software on ultrasound scanners enables the user to determine the pixel values within a selected region of interest (ROI). For some tests, such as determining **local dynamic range**, this tool is convenient for monitoring the image pixel value.

The digitized image data must be representative of those on the display monitor of the scanner. Thus, image data derived from the scanner shall not undergo any post-processing modifications before being subjected to analysis as described in this standard.

## 7 Measurement methods

Measurement results will depend on the system transducer, frequency, and the operating conditions and mode. These shall be specified for system characterizations performed in accordance with this standard and with IEC 61391-1. Maximum depth of penetration should be measured at each frequency.

### 7.1 System sensitivity: maximum depth of penetration

#### 7.1.1 Scanning system settings

To determine the **maximum depth of penetration**, the system-sensitivity controls shall be adjusted to provide echo signals from as deep as possible into the phantom. This adjustment generally requires the following:

- a) the transmit energy (labelled, for example, “output;” “power,” etc.) should be at its highest setting;
- b) the transmit focal distance is positioned at or as closely as possible to the apparent maximum depth of penetration;
- c) the system overall gain is set at high enough levels that electronic noise is displayed on the image monitor.

Signal processing settings, such as logarithmic compression and other pre-processing functions, as well as image display settings, such as post-processing, shall be in typical positions that are used clinically. If a preset is used, the intended clinical application for the preset as well as the above control setting values shall be recorded.

#### 7.1.2 Image acquisition

The **maximum depth of penetration** is determined from the image pixel signal-to-noise ratio vs. depth. An image of the penetration phantom is acquired, taken with the scanner optimized for maximum penetration (Figure 3A). This usually results in the background echo signals from the phantom fading into the displayed electronic noise. An image also shall be acquired with the transducer not coupled to the phantom, while using the same output, gain and processing settings. The latter image will be used to compute the depth-dependent electronic noise level for the transducer, receiver, and scanner signal-processing settings. Care must be taken to assure that transducer mechanical loading when the probe is coupled to the phantom does not result in different noise levels than when the probe is in air. If this occurs, the transducer can be coupled to a dummy load, such as a block of attenuating rubber that has similar acoustical impedance as the phantom but is not echogenic at depths corresponding to the **maximum depth of penetration** in the phantom. This will result in an “electronic noise only” image, as shown in Figure 3 B.



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A) Image of a uniform section in a tissue-mimicking phantom; B) Image displaying electronic noise only, obtained with the operating controls set the same as for A but with the transducer decoupled from the phantom.

**Figure 3 – Image of the penetration phantom**

### 7.1.3 Analysis

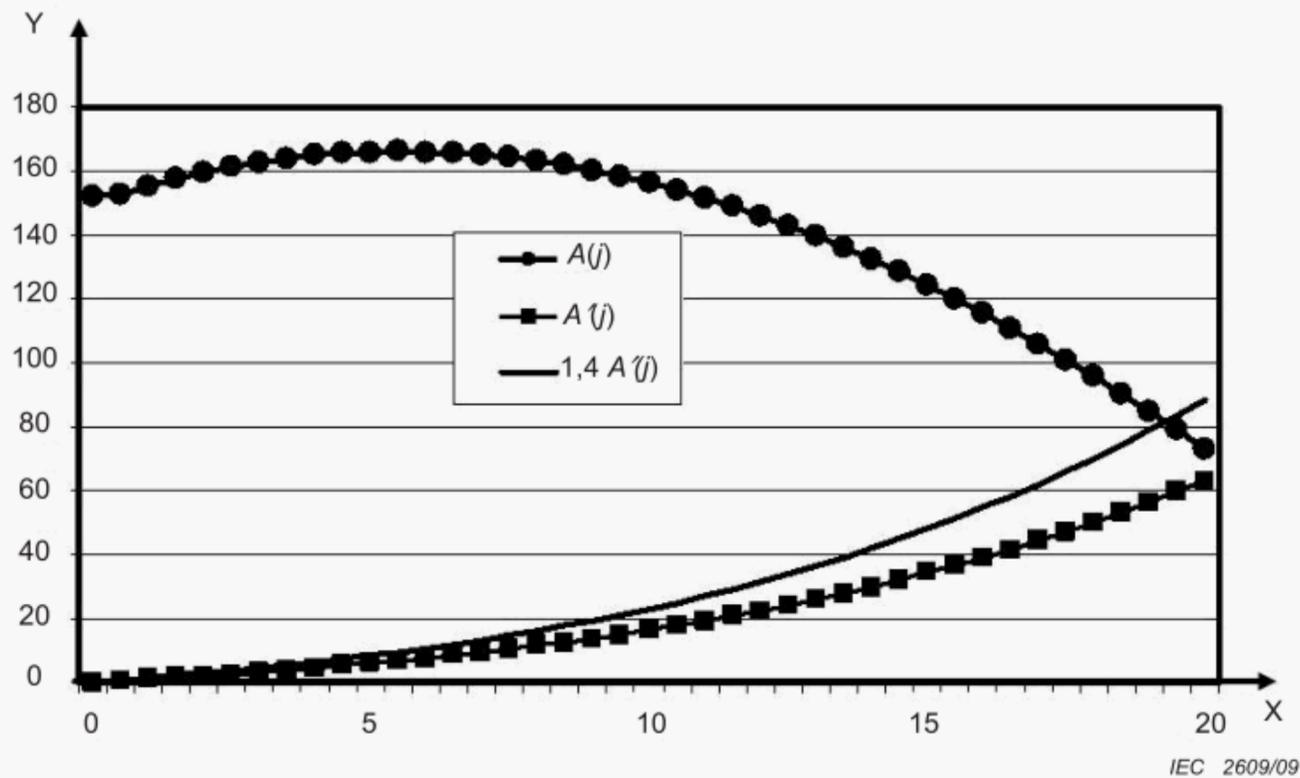
The digitized image data for a rectangular region-of-interest (ROI) extending from the near field to the bottom of the image form a matrix,  $a(i,j)$ , where  $i$  refers to the column (horizontal position) and  $j$  to the row (vertical position) in this matrix. The mean pixel value (gray level) vs. depth,  $A(j)$  is then computed by averaging pixel values corresponding to a constant depth from the transducer. With sector transducers such as phased arrays and curvilinear arrays, it may be necessary to apply a more complex ROI when computing the  $A(j)$  values, unless the width of the ROI is narrow, such as less than 1/10 of the sector width at the maximum depth. A mean value of  $A(j)$  shall be obtained by averaging data from 3 or more independent images, obtained by repositioning the transducer to different locations. Similarly,  $A'(j)$ , the mean pixel brightness (gray) level vs. depth shall be determined for the image containing noise only.

Typical plots of  $A(j)$  and  $A'(j)$  vs. depth are illustrated in Figure 4. Here we see the  $A(j)$  values gradually merging towards the  $A'(j)$  as depth increases. Let  $s(j)$  be the depth-dependent echo-signal level, that is, the average echo signal vs. depth in the image in the absence of any electronic noise. Assuming the signal and noise are not correlated, and that the B-mode image is a display of echo-signal level, it may be shown that the average signal vs. depth for the image of the phantom is

$$A(j) = \sqrt{s(j)^2 + A'(j)^2} \quad (1)$$

Thus, the signal-to-noise ratio for depth,  $j$ ,  $SNR(j)$  is:

$$SNR(j) = \sqrt{\frac{A(j)^2}{A'(j)^2} - 1} \quad (2)$$

**Key:**

Y Mean image pixel (data) value

X Depth into phantom (cm)

The solid line is  $1,4 A'(j)$ , and it equals  $A(j)$  at a depth of 19 cm, defining the maximum depth of penetration.

**Figure 4 – Mean digitized image data value vs. depth for the phantom image data ( $A(j)$ ) and for the noise image data ( $A'(j)$ )**

The depth at which the signal-to-noise ratio decreases to 1 shall be taken as the **maximum depth of penetration**. This corresponds to the ratio  $A(j)/A'(j) = 1,4$ . Also for cases in which  $s(j)$  is not proportional to the echo-signal level, the value  $A(j)/A'(j) = 1,4$  shall be used as a practical definition of the **maximum depth of penetration**.

This measurement of penetration into an attenuating phantom may be used to compare imaging performance of similar systems, evaluate effects of system upgrades, and in some cases help identify faulty transducers when the fault results in subtle loss of sensitivity. Thus, measuring the **maximum depth of penetration** can be useful during acceptance tests, during routine performance tests, and when evaluating hardware and software upgrades. However, sometimes added penetration is accompanied by decrease in lateral resolution because of preferential attenuation of higher frequency components of pulsed-ultrasound beams in tissue and/or if low pass filters are used in the receiver of the ultrasound instrument. Thus, the **maximum depth of penetration** reveals only one aspect of image performance because it provides no information on spatial- and contrast-resolution at the depths considered. Thus, depth of penetration should be considered as a simple but valuable tool, estimating a “best case” of imaging, where only electronic noise limits ability to visualize a target.

Some imaging systems, particularly those operating at lower frequencies, provide penetration that exceeds the available path lengths in most phantoms. When this is the case, one can only determine that the **maximum depth of penetration** exceeds the maximum path length, or the dimensions of the phantom.

## 7.2 Local dynamic range

### 7.2.1 Scanning system settings

The **local dynamic range** is the echo-amplitude variation causing the image brightness to vary from a digital image value of 1 to the display maximum, i.e., 255 for 8-bit image-amplitude resolution, when reflectors at a fixed location on the image are considered for a fixed setting of the system. The **local dynamic range** varies with operator control settings, such as “log-compress” and “pre-processing”. The measurement method enables specification of this parameter for fixed settings of these controls. Settings that are typical for one or more commonly used clinical applications shall be chosen. The chosen settings shall be recorded.

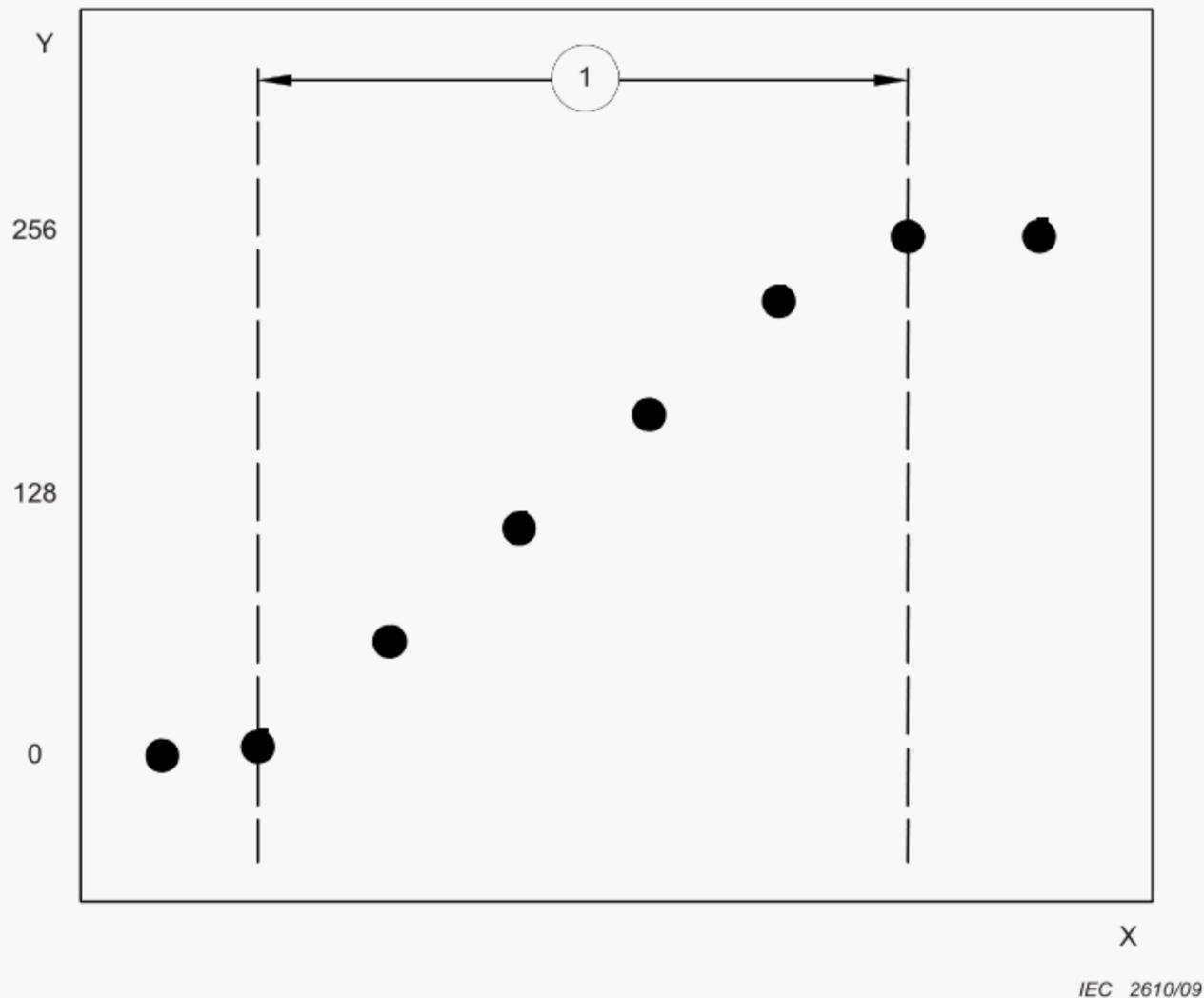
### 7.2.2 Measurement method

Simulated echo signals of varying and precisely controlled amplitudes shall be introduced into the system transducer using a coupling transducer as shown in Figure 1 or Figure 2. The frequency of the simulated signals should be within 10 % of the nominal frequency setting of the system, or within 10 % of the **acoustic working frequency** [4] of the device for the system settings at which the **local dynamic range** is measured. Using the method shown in Figure 1, signals are produced at the input of the ultrasound system as the generator continuously produces a low amplitude sine wave signal applied to the coupling transducer. This results in a patch of simulated echo signals on the display, the patch varying in brightness with depth because of TGC settings, transducer-sensitivity variations, and transducer-focus settings.

A region of interest (ROI) is selected in the middle of the displayed echo region, beyond the location of the display of the transducer ringdown, and the attenuator is adjusted to its highest calibrated setting. The ultrasound system gain is then adjusted until the signals within the ROI reach display threshold, or no echoes can be detected at the monitor. An image is recorded and stored for analysis. The signal attenuator is then reduced, nominally by 5 dB, another image is recorded, and so on. This process is continued until the brightness of the display or other indicators shows that the digitized image data have reached their maximum value over several attenuator steps, as indicated by display saturation on the monitor.

Analysis shall consist of determining the maximum digitized-image data value for pixels within the ROI of each image vs. the attenuator setting. This is done by applying an image-analysis program that can provide the peak value, mean value, and standard deviation of digitized-image data within the ROI. The program may be applied to the image data either offline or through system analysis tools directly on the scanner, if such tools are available. A plot is then generated of the digitized-image data value vs. the relative amplitude of the signal applied to the coupling transducer, as established by the attenuator setting. (See Figure 5.) The **local dynamic range** is then given by the signal level resulting in variation from the minimum- to the maximum-level image

The setup shown in Figure 2 may also be used. Here the generator is triggered by the signal from the coupling transducer, resulting in a signal burst that is synchronized with the transmit pulse applied to the system transducer. The data acquisition, storage, and analysis follow the same procedure as that outlined in the previous paragraph. Some burst-generator models [21] provide an exponentially decaying signal following the preset time delay. For simple ultrasound systems, if the rate of exponential decay is known, the depth range over which apparent echo signals change from the maximum to the minimum level in memory, along with the exponential decay rate, can be used to determine the **local dynamic range** [24]. However, most modern ultrasound systems apply an internally set TGC, which usually cannot be disabled by users. Furthermore, dynamic-aperture and dynamic-receive focusing functions may introduce other depth-dependent signal variations. Thus with most ultrasound systems, these depth-dependent factors cannot be disabled or accounted for and the method outlined in the previous paragraph must be used.

**Key:**

1 Local dynamic range

Y Image data value

X Relative amplitude of pulse (dB) (attenuator setting)

The local dynamic range is given by the signal amplitude variation resulting in a change in the image data value from minimum to maximum.

**Figure 5 – Digitized-image data vs. attenuator setting during local dynamic range measurements using acoustic signal injection**

### 7.2.3 Type II testing for measuring local dynamic range

Rather than using a coupling transducer, as shown in Figures 1 and 2, some imaging systems, particularly those employing single-element transducers, allow the user to apply signals from burst generators directly to the system input [22,23]. Depending on the capabilities of the generator, this approach can be used for testing many system functions, including **local dynamic range**. Direct application of signals to array-transducer systems also is possible using specialty devices<sup>6)</sup> designed to couple signals directly to the array transducer port. Connectors must be available that are specific to the system under test<sup>7)</sup>. In either case, the signals from the generator are applied to the system preamplifiers. By varying the signal in known steps, the response at the image memory can be measured, as in Figure 5. The **local dynamic range** is determined using the signal variation that corresponds to a transition in digitized image data values from minimum to maximum.

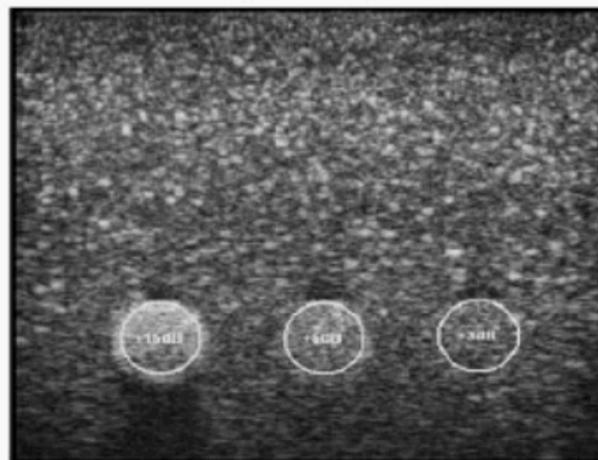
<sup>6)</sup> For example, First Alert, Sonora Medical Systems, Longmont, Colorado, USA.

<sup>7)</sup> Consult with scanner manufacturer before coupling third party test devices to transducer ports.

#### 7.2.4 Estimating local dynamic range using backscatter contrast

Many quality-assurance phantoms used by clinical personnel contain targets (“inclusions”) that have backscatter contrast and are viewed on B-mode images at various brightness levels. Typical values for backscatter contrast between inclusions and background are  $-6$  dB,  $-3$  dB,  $+3$  dB, and  $+6$  dB. Thijssen et al (2007) have described methods for estimating the **local dynamic range** from the digitized-image data of such phantom inclusions [20,26].

To estimate **local dynamic range**, post-processing maps on the imaging system are adjusted for a linear setting (on a logarithmic scale). The phantom is imaged and digitized-image data are retained, as in Figure 6. Several (e.g., five) such statistically independent images are obtained.

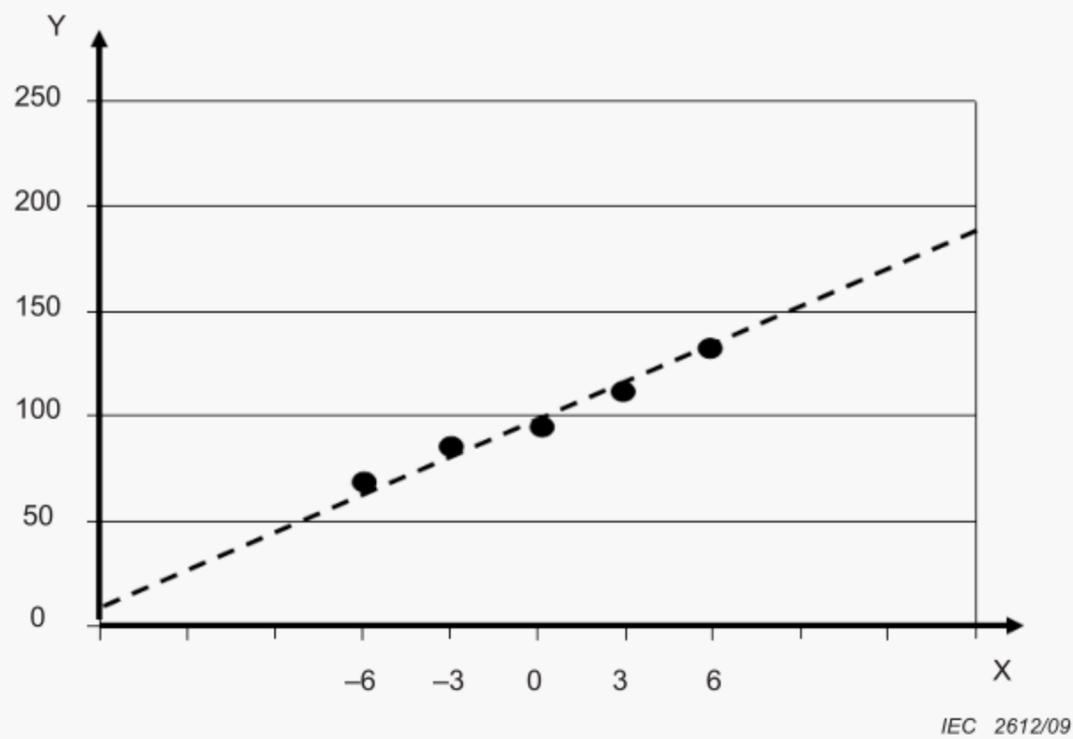


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The inclusions have nominal backscatter contrast levels of  $+15$  dB,  $+6$  dB and  $+3$  dB.

**Figure 6 – Image of phantom with inclusions (circles)**

The analysis consists of tracing regions of interest (ROI) over the imaged inclusion (Figure 6) and computing the mean pixel value for each inclusion. To avoid effects of shadowing caused by possibly greater attenuation within the inclusions, it is recommended that the mean pixel value be computed only from the top half of the imaged inclusion. The ensemble-average mean pixel level for each inclusion is then plotted vs. the target backscatter contrast (Figure 7).

**Key:**

Y Image gray level

X Nominal echo level (dB)

The dashed line is a linear regression of these data, which can be used to estimate the local dynamic range (adapted from Thijssen, 2007).

**Figure 7 – Ensemble-average mean pixel value vs. backscatter contrast of inclusions**

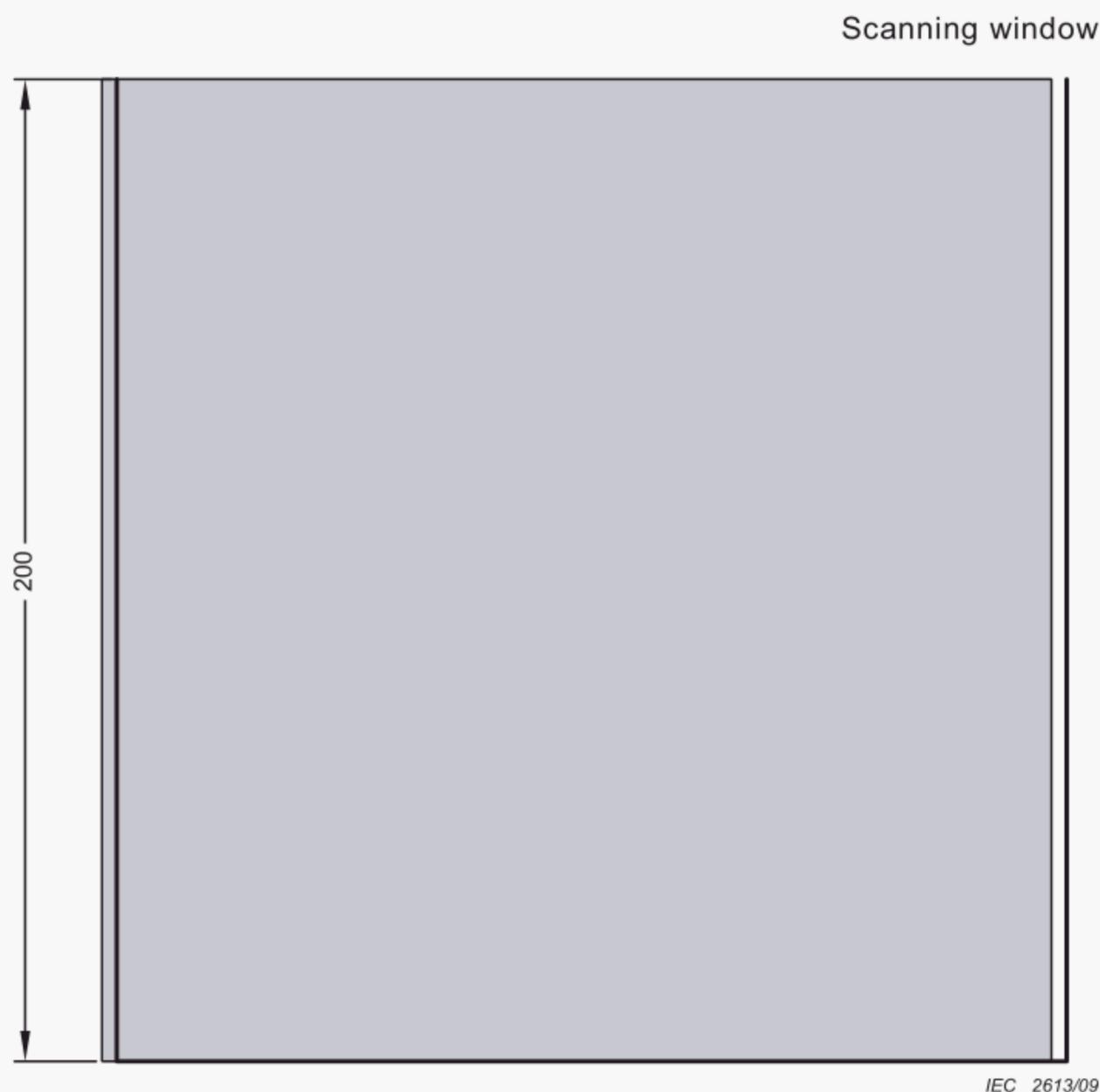
A linear regression of the form  $y = mx + b$  is done, where  $y$  is the ensemble-average mean pixel value for an inclusion,  $x$  is the relative backscatter contrast of the inclusion in dB, and  $m$  and  $b$  are fitting constants. From this line, the range of the backscatter-contrast variation that (theoretically) results in  $y$ -values that range from 1 to the maximum digitized-image data value (ie, 255) is determined, and this provides an estimate of the **local dynamic range**.

## Annex A (informative)

### Phantom for Determining Maximum Depth of Penetration

#### A.1 Phantom for determining maximum depth of penetration

A phantom for measuring the maximum depth of penetration is shown in Figure A.1. It consists of a block of tissue-mimicking material. The specific attenuation coefficient of the phantom shall be  $(0,7 \pm 0,05) \text{ dB}\cdot\text{cm}^{-1}\cdot\text{MHz}^{-1}$  in the 1 MHz to 15 MHz frequency range to provide effective testing of the penetration capabilities of the system.



The vertical dimensions are given in mm.

**Figure A.1 – Phantom for maximum depth of penetration tests**

Two levels of specific attenuation coefficients are commonly available in commercial phantoms,  $0,5 \text{ dB cm}^{-1}\text{MHz}^{-1}$  and  $0,7 \text{ dB cm}^{-1}\text{MHz}^{-1}$  [15,16]. The latter more effectively represents the clinical case of a difficult-to-penetrate patient, when the maximum **depth-of-penetration** results are most appropriate. Average attenuation coefficients of  $2,54 \text{ dB}\cdot\text{cm}^{-1}$  at 3 MHz ( $0,84 \text{ dB cm}^{-1}\text{MHz}^{-1}$  for the specific attenuation coefficient at this frequency) have been reported in liver of patients with fatty infiltrated livers [27] and a specific attenuation coefficient of  $0,83 \text{ dB cm}^{-1}\text{MHz}^{-1}$  in an animal model of diseased liver [28]. Hence,  $0,7 \text{ dB cm}^{-1}\text{MHz}^{-1}$  is a [minimum] requirement for the specific attenuation coefficient of a phantom for measuring penetration capabilities, and is the required attenuation in the phantom for the purposes of this standard.

For effective testing of machines intended for abdominal imaging, the size of the phantom should be such that it provides at least a path of 20 cm to the deepest targets. The speed of sound at 3 MHz must be  $(1\,540 \pm 15) \text{ m s}^{-1}$ . The backscatter coefficient (at 3 MHz) must be  $(3 \times 10^{-4} \pm 3 \text{ dB}) \text{ cm}^{-1} \text{ sr}^{-1}$ , with a “frequency to the n” ( $f^n$ ) dependence, where  $2 < n < 4$  from 1 MHz to 15 MHz. Wear et al., [29] have shown that laboratories versed in backscatter-coefficient measurements can achieve this level of accuracy, particularly when applying suitable reference objects, such as calibrated reference phantoms [30]. Although the frequency dependence of backscatter coefficients for many tissues in the human body that are imaged with ultrasound does not behave in this fashion [27], the above requirement is selected because it is not known whether phantom materials are available that match complex tissue behaviour more closely. Practical materials contain scattering targets with a simpler frequency dependence [15,16], and this is acceptable for the purposes of this standard. Specification of the backscatter coefficient at 3 MHz rather than 1 MHz results in only a small and acceptable variation in echo levels obtained at different depths for materials with slightly different frequency dependencies as long as the attenuation coefficient meets the specification in this standard.

These specifications must apply over the temperature range given in Clause 5 above.

## **Annex B** (informative)

### **Local dynamic range using acoustical test objects**

#### **B.1 General**

This annex describes two alternative test objects and associated measurement techniques for measuring local dynamic range. Both test objects incorporate a series of reflectors that provide echo signals with different amplitudes. Both specularly reflecting interfaces [32] and interfaces whose dimensions are on the order of the ultrasound wavelength [33] have been described. Although test objects incorporating these devices are not commercially available, with careful assembly and calibration these devices can provide results equivalent to those obtained with the signal-injection methods described in subclause 7.2 of this standard. Both types of test objects require that:

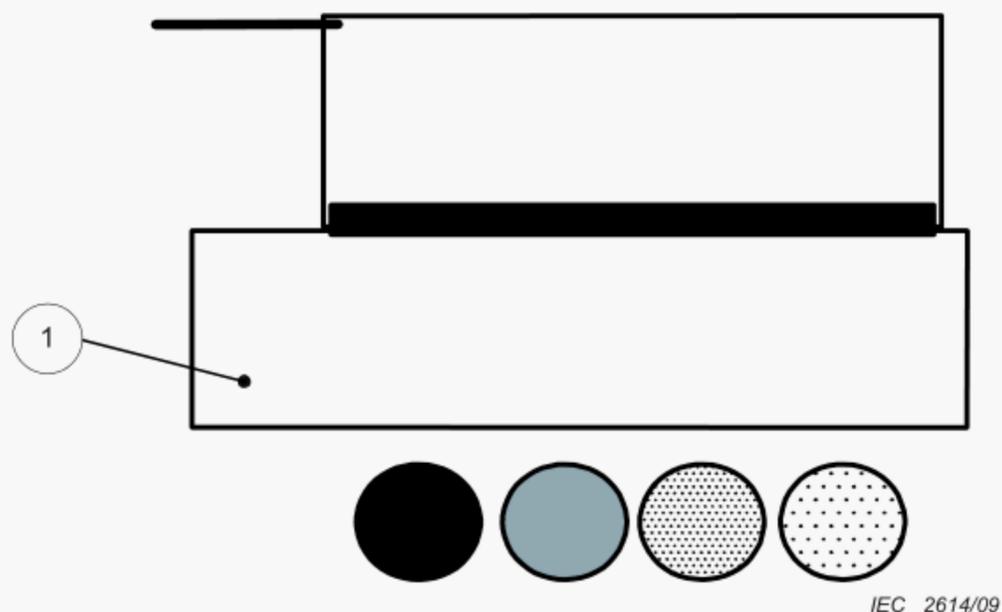
- a) the reflecting surface be smooth within 1/20th of a wavelength of the highest ultrasound frequency being evaluated;
- b) that the thickness (length of the target) be longer than one-half of the pulse duration of the tested ultrasound pulse times the speed of sound in that material and in the surrounding medium;
- c) that the surface shape be rigorously as specified (i.e., flat); and
- d) that the dimensions be as specified.

These criteria are rather extensive and the user is referred to the references for complete specifics.

#### **B.2 Acoustical test object containing specular reflectors**

##### **B.2.1 Conceptual diagram of test object**

The test object consists of a set of specular reflecting targets, with known relative reflection coefficients. A diagram of a possible arrangement is presented in Figure B.1. The transducer is fixed above the targets using an apparatus that provide for controllable and measurable lateral and elevational movements of the transducer as well as tilting of the scan plane in the elevational direction. The transducer is oriented to image the top surface of specular reflectors whose reflection coefficients, R1, R2, R3, and R4 differ.

**Key:**

1 Attenuating block

**Figure B.1 – Possible arrangement of reflectors for determining local dynamic range**

The test objects R1 to R4, are a set of specularly reflecting targets, with known relative reflection coefficients. For example, stainless steel, acrylic, polyethylene and 'Sylgard', a silicone rubber, could make up such a set [32,34]. The targets may be placed in water or in a tissue-mimicking material. The magnitude of an echo from a specular reflector can be very sensitive to the alignment of the reflector relative to the ultrasound beam. Therefore, care must be taken to assure consistent alignment for all reflectors.

Another material that could be used to provide weakly reflecting interfaces with known reflection coefficients is polyhydroxyethylmetacrylate (pHEMA) [35]. This material is sometimes used to form soft, corneal contact lenses for humans and is available commercially from Ciba/Geigy<sup>8)</sup> and other manufacturers of contact lenses. Once cast and shaped, the material absorbs water, the amount depending on the chemical composition. Three varieties are available, W38, W88 and W72; in water their reflection coefficients relative to a **perfect planar reflector** are :  $(-15,8 \pm 0,2)$  dB,  $(-23,3 \pm 1,0)$  dB and  $(-33,1 \pm 1,0)$  dB, respectively [35].

An acoustics lab equipped with a single-element transducer, a pulser-receiver, and an oscilloscope can verify the reflection coefficients of such reflectors.

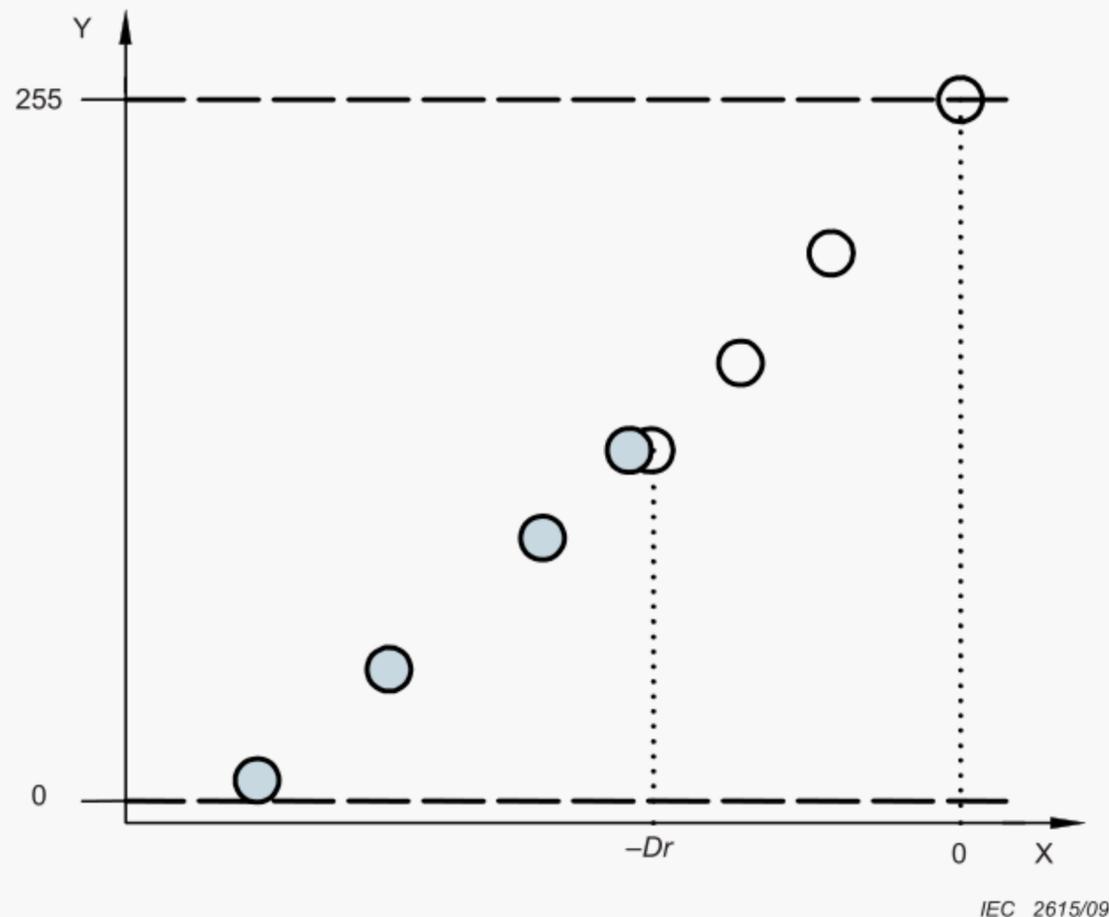
An acoustic attenuator is needed to reduce the amplitude of the echo signals from the targets. The attenuator may be of **tissue-mimicking material** or another absorber, such as rubber. Sufficient acoustic attenuation is necessary to reduce the echo signal from the strongest reflector, so that it does not saturate the display at midrange gain-settings on the scanner. A block of **tissue-mimicking material** with attenuation coefficients of  $0,7 \text{ dB cm}^{-1}$  at 1 MHz and path length of 4 cm will provide a signal reduction of 22,4 dB at 4 MHz, and this would be suitable. Alternatively, the reflectors can be incorporated directly into a **tissue-mimicking phantom** with **tissue-mimicking material** in the path between the transducer and the reflectors.

**B.2.2 Determining local dynamic range using specular reflectors**

Using a fixture to position the transducer, image the phantom shown in Figure B.1. Tilt the scanning plane so that the maximum echo signal possible is received. Then use the overall gain control to adjust the instrument's sensitivity until you are sure the echo signal from the

<sup>8)</sup> This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this company.

strongest reflector is at display saturation. For an 8-bit pixel display system, this procedure would result in at least one pixel value in the echo complex from the reflector being at the level “255.” Using the same sensitivity settings, image weaker reflectors in the phantom. The dynamic range is found from the reflection coefficient (relative to that of the strongest interface) of the weakest reflector that can be imaged.



**Key:**

Y Displayed intensity

X Reflection of coefficient RE strongest (dB)

Reflection coefficients are with respect to the strongest reflector. Open circles: highest gain; closed circles, gain lowered such that echo signal level from strongest reflector is at same displayed intensity as the intensity for the weakest reflector scanned at the highest gain.

**Figure B.2 – Displayed intensity (or image pixel value) vs. reflector reflection coefficient**

In almost all cases, the range of reflection coefficients available from the set of specular reflectors will result in an echo-amplitude range that is less than the **local dynamic range** of the ultrasound machine. Call the range of echo amplitudes  $Dr$ . The following procedure can be carried out to extend the measurement range beyond  $Dr$ .

Proceed as described above, imaging the strongest interface with the sensitivity adjusted to just produce display saturation or the maximum digitized-image data value available. Then image the weaker reflectors and note the maximum image data value from each of the resulting echo signals. Use this procedure to generate a plot of digitized-image data values vs. reflector reflection coefficients, as in Figure B.2 (open circles).

Suppose the test fixture employs 4 reflectors. The maximum image pixel value for the weakest reflector at this gain setting, designated “gain 1,” is  $s_1(R_4)$ , where the reflection coefficient of this reflector is  $-R_4$  dB with respect to that of the strongest reflector. With the transducer positioned once again to image the strongest reflector, reduce the receiver gain in the system until the image value from this reflector is at  $s_1(R_4)$ . Call the gain value “gain 2.” Then continue the process as before, finding the pixel values,  $s_2(R_i)$  from each of the weaker reflectors for this new sensitivity setting, 2, where the subscript  $i$  refers to a specific reflector

and “2” is gain setting 2. Use these new values to extend the curve representing digitized-image data value vs. reflection coefficient, as in Figure B.2 (closed circles).

If the echo from the weakest reflector in the set is still above display threshold for sensitivity setting 2, repeat the steps in the previous paragraph. That is, while imaging the strongest reflector, reduce the gain of the instrument until the echo from it is at a level  $s_2(R_4)$ . Then proceed as before to extend the pixel value vs. reflection coefficient curve using the new sensitivity setting, 3.

The **local dynamic range** is found from the **reflection coefficient** (relative to that of the strongest interface and at the original gain setting) of the weakest reflector,  $R_{\text{weakest}}$  that can be imaged. That is,

$$\text{Dynamic range} = R_{\text{weakest}} + Dr(n-1) \quad (\text{B.1})$$

where  $n$  is the number of different gain settings needed to span the **local dynamic range** of the scanner for the signal-processing settings tested and  $Dr$  is the range of reflection coefficients in the test object.

The reflection coefficients of many weakly reflecting interfaces are temperature-dependent. Therefore, unless correction factors are available, caution should be exercised to maintain the same reflector temperature as that used during calibration of the interfaces [32].

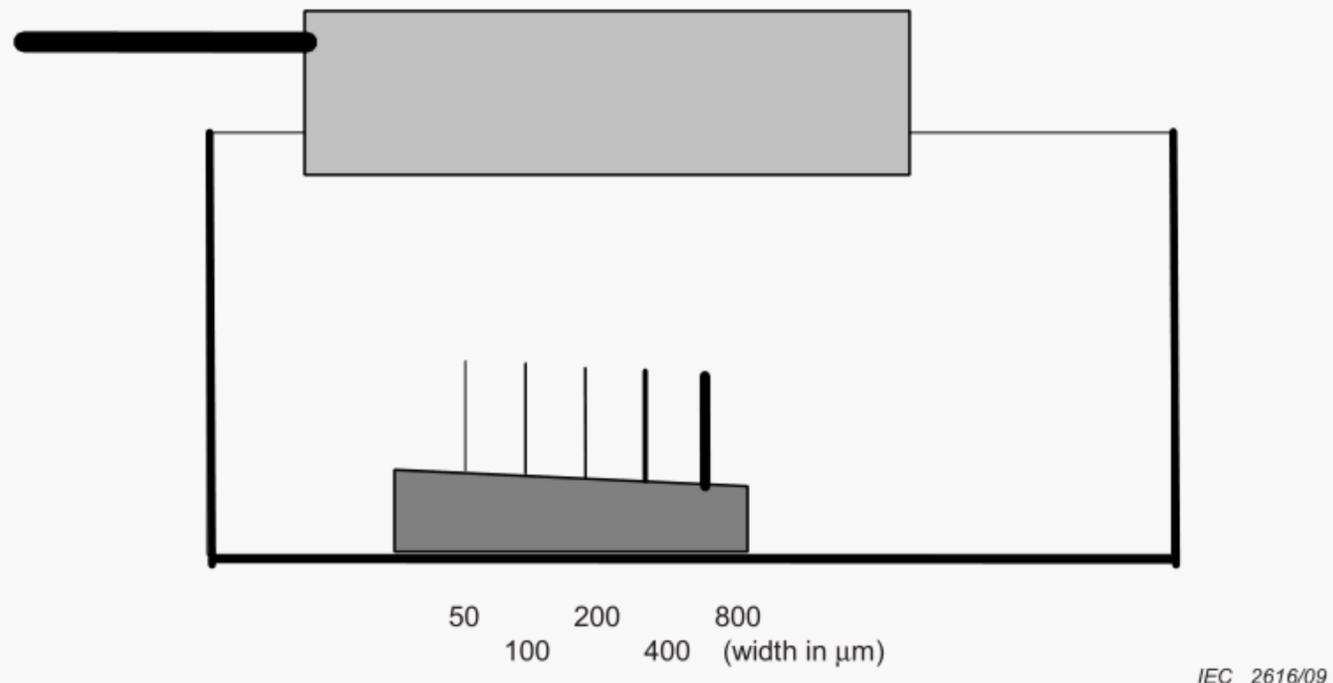
### B.3 Acoustical test object incorporating flat-ended, stainless-steel wires

#### B.3.1 Test object design

Another alternative test object for **local dynamic range** tests has flat-ended stainless-steel wires immersed in degassed water (Figure B.3). The backscatter cross-section of the wire is proportional to the fourth power of its diameter, so by providing a group of wires each having a different diameter, echo signals with known amplitude variations can be generated. Backscattering cross sections for different sized wires are shown in Figure B.4 (adapted from [33]).

Their advantage over large specular reflectors is that by incorporating different diameter wires, a greater range of echo amplitudes is available for **local dynamic range** measurements [33, 336]. For the 1 MHz to 15 MHz frequency range, stainless-steel wire diameters of 50  $\mu\text{m}$  to 1 600  $\mu\text{m}$  (50  $\mu\text{m}$ , 75  $\mu\text{m}$ , 100  $\mu\text{m}$ , 150  $\mu\text{m}$ , 200  $\mu\text{m}$ , 300  $\mu\text{m}$ , 400  $\mu\text{m}$ , 600  $\mu\text{m}$ , 800  $\mu\text{m}$ , 1 200  $\mu\text{m}$ , and 1 600  $\mu\text{m}$ ) should be provided. The targets consist of straight steel cylinders (wires) with a length of 15 mm mounted in such a fashion that their axes are oriented in the direction of the incoming ultrasound beam.

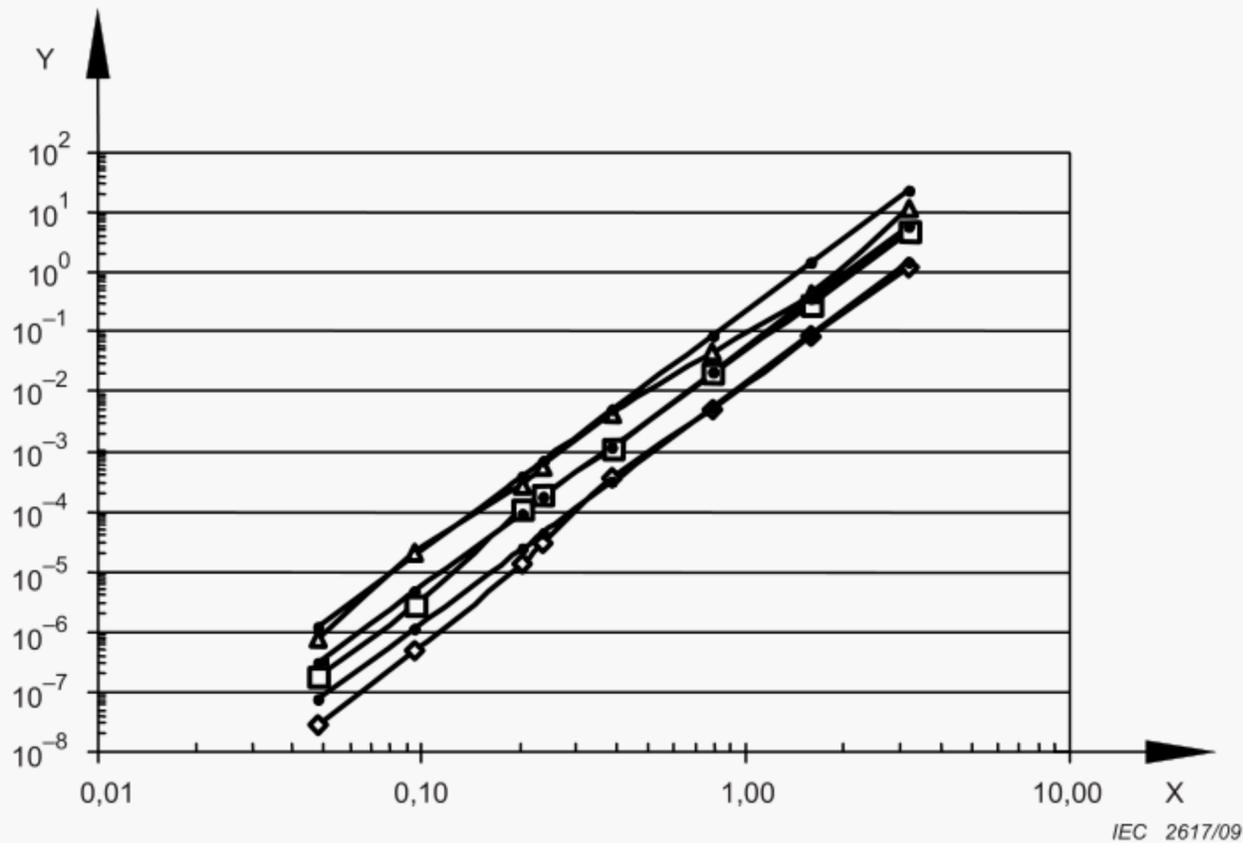
The targets are immersed in degassed water and supported in a way that echo signals from their ends can be displayed by the ultrasound imaging system without interference from supporting structures. The distance between targets should be chosen such that the echoes from a strong target do not interfere with the echoes from a weaker target. To take advantage of the axial resolution of a scanner, the weaker target should be placed slightly closer (by a distance of approximately the pulse duration multiplied by the speed of sound) to the transducer. For very accurate measurements the distance from the transducer to the target should be the same for each target to avoid errors due, for example, to variations in depth dependent gain, or “TGC”. For the arrangement in Figure B.3, this requires the user to produce a separate image for each target, where the distance between the transducer and test object is varied so that the target of interest is always at the same depth.



The ends of wires 50 μm, 100 μm, 200 μm, 400 μm and 800 μm in diameter are imaged as shown.

**Figure B.3 – Flat ended wire test object for determining local dynamic range**

Figure B.4 presents backscatter cross-sections for wires ranging in diameter from 50 μm to 3 800 μm. The echo signal strength spanned is 76 dB. To be useful in the 10 MHz range, a maximum wire diameter of 1 mm should be used. **Local dynamic range** measurements for ultrasound machines operating at lower frequencies can incorporate wire diameters as large as 3,2 mm [33].

**Key:**

$Y \sigma$  [CM<sup>2</sup>sr<sup>-1</sup>]

X diameter [mm]

The straight lines are from theory, showing a  $D^4$  proportionality. The deviations from theory at large diameters are ascribed to inaccurate orientations of the targets. The deviations at small diameters indicate a breakdown of simple theory.

**Figure B.4 – The experimentally observed backscattering cross section of flat-ended stainless-steel wires as a function of diameter for three frequencies:  $\triangle$  9.6 MHz;  $\square$  4.8 MHz;  $\diamond$  2.4 MHz [33]**

### B.3.2 Determining local dynamic range using flat-ended wire targets

With the flat-ended stainless-steel wires, the ultrasound scanning plane is carefully aligned so that the ultrasound beam for which echoes are detected from any given target is parallel to the target's axis. For linear-array transducers, this alignment can be achieved by careful positioning of the scan plane, then maximizing the echo signal by translating and tilting the scan plane. For sector transducers, for which beams emerge at many angles, use can be made of the fact that the central beam of the sector usually emerges perpendicular to the surface of the transducer. Thus, imaging the target with this region of the scanned field will enable the calibration curve in Figure B.4 to be used. This may be done most advantageously by attaching the ultrasound transducer to an x-y translation system that also allows the scan plane to be tilted, then proceeding to generate image data from each of the reflectors after translating the transducer and orienting it with the reflector of interest.

For the small targets, alignment is less critical than for large targets. Lubbers and Graaff [33] give the following relation between frequency  $f$  (in MHz), diameter of the target  $D$  (in mm), required accuracy of the orientation  $\theta$  (in degrees) and the desired accuracy of the back scatter cross section  $\zeta$  (in dB)

$$f D \theta / \sqrt{\zeta} < 13$$

The method for varying the receiver gain to extend the measurement beyond the echo signal amplitude range presented by the reflectors themselves and the subsequent analysis techniques are identical to that described in B.1.1 of this annex for specular targets.

The advantage of this approach over use of specular reflectors as in Clause B.1 is that it readily provides a large target echo signal dynamic range, where echo levels exceeding 80 dB have been reported [33]. One disadvantage may be artefacts (edges, shoulders, rosette artefacts) corresponding to the effective beam-width. This may contribute to a spread in echo-signal values depending on observation direction.

**NOTE** For transducers with a large numeric aperture, a spread in values of the observation direction occurs. This aspect still needs theoretical analysis and experimental verification.

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