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TECHNICAL SPECIFICATION

colour inside

Ultrasonics – Pulse-echo scanners – Simple methods for periodic testing to verify stability of an imaging system's elementary performance

IEC TS 62736:2023-01(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ULTRASONICS – PULSE-ECHO SCANNERS –

Simple methods for periodic testing to verify stability of an imaging system's elementary performance

FOREWORD

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IEC TS 62736 has been prepared by IEC technical committee 87: Ultrasonics. It is a Technical Specification.

This second edition cancels and replaces the first edition published in 2016. This edition constitutes a technical revision.

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

a) expansion of the applicable types of transducers and the frequency range of application;
b) extension of test protocols and image assessments, including for **very-low-echo spheres**;
c) revision of **phantom** designs and their acoustic properties, consistent with the second edition of IEC TS 62791;
d) inclusion of luminance tests for system-image display consistency at scanner and remote monitors;

e) addition of special considerations for 3D-imaging transducers (Annex D) and workbook examples (Annex E).

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

Draft	Report on voting
87/777/DTS	87/791/RVDTS

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 Specification 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 defined in greater detail at www.iec.ch/standardsdev/publications.

Terms **in bold** in the text are defined in Clause 3.

Symbols and formulae are in *Times New Roman italic*.

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- withdrawn,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 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. As ultrasound systems are usually employed under rigorous time restrictions and in diverse environments to help make decisions that are often critical to patients' wellbeing, it is important that the systems perform consistently at the level initially provided and accepted in initial tests, for example, those of IEC TS 62791, IEC 61391-1, 61391-2, and IEC 62563-2. This document provides methods to verify the stability of an imaging system's elementary performance.

This document is deemed necessary because substandard ultrasound-system performance is often accepted or remains undetected in the absence of unequivocal and documented tests. The most common of the failures, in all but the oldest systems nearing retirement, are sub-performance of a transducer-array element or lens or of a cable or electronic channel. There is approximately a 14 % transducer-failure rate and a 10 % system-failure rate per year on first testing [1],[2],[3],[4],[5],[5],[7],[8],[9],[10],[11],[12][1]. Sensitive image uniformity tests for these transducer- and channel-failures are presented here for use daily to monthly (Level 1), annually (Level 2) and biennially (Level 3).

This common occurrence of suboptimal diagnostic examinations has created an urgent need to standardize quality-assurance (**QA**) and performance-evaluation procedures to promote improved efficacy of diagnostic examinations through widespread use of effective **QA** procedures and to dispel myths as to their utility. Proposers believe, however, that existing national and international standards and guides [1],[3],[12],[13],[14] specify or recommend too many tests and inappropriate tests for detecting and discriminating the common flaws in diagnostic ultrasound systems during routine **QA**. These practices include tests, such as spatial resolution, which are low-yield and belong in performance-evaluation procedures, rather than **QA**.

Modern flat-panel display technology is more stable than, and generally far superior to, earlier cathode ray tube (CRT) displays. However, these displays can still exhibit luminance drift, as well as problems such as defective pixels. They still need to be evaluated periodically.

Detection of failures by these recommended pulse-echo tests will probably also detect most failures affecting the operation of other modes, such as colour-flow, harmonic-, elasticity- and compound-imaging. The failures might be more pronounced in these other modes and the fraction of failures in other modes detected by these tests has not been reported.

Image-uniformity **QA** is applicable to transducers operating in the wide 1 MHz to 40 MHz frequency range, as the requirements for phantoms are not stringent for this test. The other tests could be made applicable up to 40 MHz [15],[16] when the depth of penetration measurement is allowed to be relative, rather than absolute, and phantom stability is verified.

NOTE Phantom manufacturers are encouraged to extend the frequency range to which phantoms are specified to enable relative depth-of-penetration tests of systems operating at fundamental and harmonic frequencies above 23 MHz.

System-manufacturing and repair companies, as well as those performing more complete **performance evaluation** for acceptance, replacement, or research might well employ other or additional tests that are not within the scope of this document. More complete tests than those included in the three levels for periodic testing and for assessment at times of particular importance or concern are specified in IEC 61391-1, IEC 61391-2 and IEC TS 62791. These more complete tests are categorized as **performance evaluation**, rather than **quality**

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

assurance or frequent periodic testing. It is possible that good, automated analysis of the high-contrast sphere tests will reduce both the need for optional tests listed here, and for most, more complete **performance evaluation**. Full assessment of distance-measurement accuracy might still be required if automated, 3D distance measurement calibration is not added to the high-contrast sphere tests.

Uniformity tests of transducers not readily amenable to transducer-element testing by the simple image-uniformity procedures specified here (for example, phased-array and 2D-array transducers) are not included in the scope. They are usually evaluated well by careful performance of the high-contrast sphere tests. System manufacturers are encouraged to provide pulsing patterns of the transducer elements to allow testing of individual elements or small-enough groups of elements to enable users to detect significant element failure or to provide access to another implemented and explained element-test programme.

ULTRASONICS – PULSE-ECHO SCANNERS –

Simple methods for periodic testing to verify stability of an imaging system's elementary performance

1 Scope

This document, which is a Technical Specification, specifies requirements and methods for periodic testing of the quality of diagnostic medical ultrasound systems using reflection-mode (pulse-echo) imaging. Image measurement and interpretation workstations are included.

NOTE Usually, "periodic testing" is referred to as "quality control (QC)" or **quality assurance (QA)**.

This document includes minimum sets of such tests intended for frequent users of medical ultrasound systems, for **quality assurance** professionals in their organizations, or those hired from other quality-control and/or service-provider organizations. The procedures are for a wide range of more common diagnostic ultrasound systems, currently operating from 1 MHz to 40 MHz, although available phantoms meet the specifications only from 1 MHz to 23 MHz.

The tests are defined in three levels, with the simplest and most cost-effective performed most frequently:

Level 1 comprises five quick tests/observations to be performed daily to monthly by those normally operating the systems.

Level 2 includes one necessary test for all systems in addition to those of Level 1, two Level 1 tests performed more rigorously, two tests that are for special situations or equipment, and one that is just optional, included because it is highly developed. Level 2 tests are performed annually by those with meaningful **quality assurance** training.

Level 3 extends the two special situations tests to all systems, adds one optional test and includes a periodic review of the QA programme.

Frequent distance-measurement accuracy tests are recommended in this document only for certain classes of position encoding that are not now known to be highly stable and without bias. **QA** in all dimensions is recommended in this document as the first test for such systems.

The test methodology is applicable for transducers operating in the 1 MHz to 23 MHz frequency range. The types of transducers used with these scanners include

a) electronic phased arrays,

b) linear arrays,

c) convex arrays,

d) mechanical transducers,

e) two-dimensional arrays operated in a 2D imaging mode,

f) transducers operating in 3D imaging mode for a limited number of sets of reconstructed 2D images, and

g) three-dimensional scanning transducers based on a combination of the above types.

All tests on scanners considered here evaluate basic pulse-echo techniques and might detect most failures in other modes. Dedicated Doppler systems, or other systems for detection of blood motion, are excluded from this scope as specialized equipment is required to test them. Such test equipment can be specific to the intended application of the Doppler system.

This document includes definition of terms and specifies methods for measuring the **maximum relative depth of penetration** of real-time ultrasound B-MODE scanners, though this penetration measure is listed as less frequently applied.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60050-802, *International Electrotechnical Vocabulary – Part 802: Ultrasonics* (available at <http://www.electropedia.org>)

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-802 and the following apply.

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

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

3.1
quality assurance
QA
regularly performed procedures to ensure consistent performance

Note 1 to entry: Quality control is a part of quality assurance. Another term used is quality maintenance.

3.2
performance evaluation
set of tests performed to assess specific absolute performance of the object tested

Note 1 to entry: Typical times for ultrasound system **performance evaluation** are at pre-purchase evaluation, new and repaired system acceptance testing, according to IEC 61391-1 and IEC 61391-2 and [1],[17],[18],[19],[20],[21],[22], and at times of performance difficulties and end-of-useful-life evaluations. Level 3 **QA** tests include many of those recommended for such **performance evaluation**.

3.3
phantom
device designed to mimic some aspects of the human body for the purposes of testing or training

3.4
addressable patch
smallest addressable group of transducer elements

3.5
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 grey-scale display the **pixel value** is converted to a luminance by some, usually monotonic, function. The set of integer values representing the grey 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.

[SOURCE: IEC TS 62791:2022, 3.6]

3.6
mean pixel value
MPV
mean of **pixel values** detected over a designated area or volume in an image or 3D stack of images

Note 1 to entry: For **low-echo spheres** here, *MPV* is defined for an area *A* or volume in a **phantom** image or stack of images, where *A* is somewhat smaller than the area of a circle of diameter *D*. The phrase "somewhat smaller than" is introduced as partial compensation for the partial volume effect, primarily in the elevational dimension.

Note 2 to entry: The partial volume effect is a term common in computed tomographic, magnetic resonance and ultrasound imaging. This process refers to the effect of the finite imaging resolution, particularly the slice thickness. The signal (ie, **pixel values**) at points near the object boundaries will include contribution from that object and contributions from the material around it. For example, if the object is a sphere with a diameter close to the thickness of the slice, then you cannot define a good measurement region in the image of the sphere in which the signal does not include components from material lying outside the sphere.

3.7
maximum depth of penetration
maximum range in a **phantom**, with properties meeting the specifications of IEC 61391-2, at which the **mean pixel value** corresponding to signals from the weakly reflecting, background scatterers are 1,4 times the **mean pixel value** corresponding to images displaying only electronic noise at that same depth

Note 1 to entry: The **maximum depth of penetration** is expressed in metres (m) and conventionally in centimetres (cm).

3.8
maximum relative depth of penetration
maximum range in a **phantom**, at which the **mean pixel value** corresponding to images displaying echoes from weakly reflecting and background scatterers are 1,4 times the **mean pixel value** corresponding to images displaying only electronic noise at that same depth

Note 1 to entry: The specified properties of the phantom are somewhat relaxed from those specified in IEC 61391-2, as modified in IEC/TS 62791:2022, 3.2.

Note 2 to entry: The adjective "relative" is used because the **phantom** specifications defined in this document are so loose that measurements of the "maximum range" with different **phantoms** cannot be compared. The measurements are only for tests of stability, i.e. comparisons between measurements on the same **phantom** over time.

Note 3 to entry: For available **phantoms** and specifications, see [16],[17], and for a potential alternative measure of depth of penetration, see [15].

Note 4 to entry: The **maximum relative depth of penetration** is, by international standards, expressed in metres (m) and conventionally in centimetres (cm).

3.9
median absolute deviation
MAD
median of the absolute value of the deviations from the median of a data set

Note 1 to entry: The *MAD* is similar to the standard deviation but, as the median of linear deviations rather than squared deviations, it is more resilient to outliers [18].

3.10
specific attenuation coefficient
attenuation coefficient at a specified frequency divided by the frequency

Note 1 to entry: The **specific attenuation coefficient** is usually expressed in decibels per centimetre per megahertz (dB $cm^{-1}MHz^{-1}$); extrapolation to other frequencies makes the explicit assumption of linear dependence of the attenuation coefficient on frequency.

[SOURCE: IEC 61391-2:2010, 3.33, modified by rephrasing "at a specified frequency, the slope of attenuation coefficient plotted against frequency", which assumes a broadband measurement.]

3.11
equivalent sensitivity
sensitivity that is statistically the same or has smaller variance and bias

3.12
backscatter coefficient
intrinsic backscatter coefficient
η
intrinsic property of a material at some frequency, equal to the differential scattering cross-section per unit volume for a scattering angle of 180°

[SOURCE: IEC TS 62791:2022, 3.2, modified – the note has been deleted.]

3.13
low-echo sphere
hypoechoic sphere
spherical inclusion in a **phantom** with a **backscatter coefficient** lower than the **backscatter coefficient** of the surrounding tissue-mimicking material

[SOURCE: IEC TS 62791:2022, 3.3]

3.14
very-low-echo sphere
high-contrast, low-echo sphere
sphere with −40 dB, or greater, contrast with its background material

3.15
low-echo sphere diameter
D
diameter of the low-echo spherical inclusions in a **phantom**

Note 1 to entry: It is generally assumed that all **low-echo sphere**s in a particular **phantom** have the same diameter D. The diameter tolerance is ±1 %.

3.16
lesion signal-to-noise ratio
$LSNR$
ratio of the **mean pixel value** over a region of a detected target in an image, minus the **mean pixel value** over a specified region of the background echo signals, to the standard deviation of the **mean pixel values** contributing to the background

Note 1 to entry: This term might also be referred to as the lesion contrast-to-noise ratio.

[SOURCE: IEC TS 62791:2022, 3.11, modified – the note has been replaced with a new note.]

3.17
lesion signal-to-noise ratio for the *n*th low-echo sphere
$LSNR_n$
numerical value quantifying the **detectability** of the nth macroscopically uniform, **low-echo sphere** surrounded by a macroscopically uniform, background material and existing in the volume of a **phantom** for which image data has been obtained

[SOURCE: IEC TS 62791:2022, 3.12, modified – the notes have been deleted.]

3.18
$LSNR_m$
mean lesion signal-to-noise ratio
conceptual version of this common term (mean signal-to-noise ratio) for detected **low-echo spheres,** whose centres lie within an unspecified volume segment

[SOURCE: IEC TS 62791:2022, 3.13]

3.19
$LSNR_{m\boldsymbol{d}}$
mean lesion signal-to-noise ratio for depth interval $\boldsymbol{d}$
mean lesion signal-to-noise ratio for detected **low-echo spheres** whose centres lie within the volume segment corresponding to **depth interval label** d

Note 1 to entry: **Low-echo spheres** with centres located less than a distance $D/2$ from a lateral image boundary are excluded.

[SOURCE: IEC TS 62791:2022, 3.14, modified – the term “mean LSNR” has been removed and note 2 has been deleted.]

3.20
reference value of mean lesion signal-to-noise ratio
$LSNR_{md,ref}$
reference values of $\underline{LSNR}_{md}$ provided by the manufacturer for a given transducer model and settings, or values acquired in acceptance testing or the first or first-N periodic tests on a given transducer and settings

3.21
useable range
$Я_u$
range or ranges over which the negative of $\underline{LSNR}_m$ is ≥ 1,41

Note 1 to entry: **Useable range** is more fully defined as the **useable range** for imaging **low-echo spheres** of a specified size. It is usually expressed in centimetres [cm].

3.21.1
$Я_1$
minimum depth at which the negative of $\underline{LSNR}_m$ is ≥ 1,41

3.21.2
$Я_2$
first maximum depth at which the negative of $\underline{LSNR}_m$ is ≥ 1,41

3.22
mean useable contrast over the useable range
$|LSNR_{mя}|$
mean $|LSNR_m|$ over the **useable range** or combined **useable ranges** of a transducer under given settings

[SOURCE: IEC TS 62791, 3.9 and 3.14 modified]

3.23
clarity index
C_l
figure-of-merit for overall performance of a transducer in imaging specified **low-echo spheres** in the employed mode and system, equal to the log absolute value of the **mean lesion signal-to-noise ratio** averaged over the **useable range** times the **useable range**

Note 1 to entry: Symbolically C_l represents $\log|LSNR_{mя}| \times Я_u$, where these symbols are defined in 3.21 and 3.22.

3.24
depth interval
interval between boundaries of contiguous, or overlapping, depth segments into which an image area is subdivided for computation of $LSNR_{m_d}$ values as a function of depth

Note 1 to entry: A rectangular scan area will be subdivided into discrete or overlapping horizontal bands; a sector scan area will be subdivided into annular ring segments, the angular limits being determined by the sector angle. Rectilinear projection of these discrete or overlapping area segments in the elevational direction will create volume segments analogous to slabs and partial cylindrical shells respectively.

[SOURCE: IEC TS 62791:2022, 3.9, modified – in the definition, “or overlapping” has been added, and in the note the reference to the figure and “with thickness equal to the depth interval extent Δ” have been deleted.]

3.25
depth interval label
d
integer for identifying **depth intervals** in an image

Note 1 to entry: d = 1, 2, …, d_{max} where 1 is at the least depth and d_{max} is at the greatest depth.

[SOURCE: IEC TS 62791:2022, 3.9.1]

3.26
detectability
numerical value quantifying the probability that a human observer will detect an object in an image having background speckle

[SOURCE: IEC TS 62791:2022, 3.10]

3.27
signal-to-noise ratio
SNR
ratio of signal plus noise at a given depth in the image to noise obtained with a clean transducer in air at the same depth

Note 1 to entry: The **signal-to-noise ratio** here is defined specifically in this document for the application of the **maximum depth of penetration** measurement. The noise here refers to electronic noise only.

Note 2 to entry: SNR is defined in 61391-2:2010, 7.1.3, in Formula (2).

Note 3 to entry: A more general definition of SNR is given in IEV 702-08-61.

3.28
time gain compensation
TGC
amplification of the signal with time after the transmit pulse to approximately correct for attenuation by the tissues transited and reduce overly strong signals from tissue boundaries close to the transducer

4 Symbols and abbreviated terms

4.1 Symbols

The non-display **QA** parameters defined in this document are listed in Table 1 and sourced from IEC TS 62791 with some modifications.

Table 1 – Overview to the symbols and definitions of the QA terms, other than those for the display

Symbol	Term or definition	Corresponding Term
A	square area in an **image plane** selected for calculation of MPV	3.6
D	**low-echo sphere diameter**	3.15
d	integer for identifying **depth intervals**	3.25
d_{min}	integral number of the **depth interval** chosen as the minimum depth for applying the data analysis	3.25
d_{max}	greatest integral number of the **depth intervals** allowed by the chosen maximum *possible* depth for data analysis	3.25
$LSNR$	le**sion signal-to-noise ratio**	3.16
$LSNR_n$	**lesion signal-to-noise ratio for the nth low-echo sphere**	3.17
$LSNR_{\text{m}}$	conceptual **mean lesion signal-to-noise ratio**	3.18
$LSNR_{\text{m}d}$	**mean lesion signal-to-noise ratio for depth interval** d	3.19
$LSNR_{\text{m}d,\text{ref}}$	**reference value of mean lesion signal-to-noise ratio**	3.20
$\lvert LSNR_{\text{m}Я}\rvert$	**mean useable contrast over the useable range**	3.22
MPV	**mean pixel value**	3.6
$Я_{\text{u}}$	**useable range**	3.21
$Я_1$	minimum depth of the **useable range**	3.21.1
$Я_2$	first maximum depth of the **useable range**	3.21.2
SNR	**signal-to-noise ratio**	3.27
η	**backscatter coefficient**	3.12

The **QA** parameters related to displays explained in this document are listed in Table 2 and sourced from IEC 62563-1 and 62563-2.

Table 2 – Overview of the symbols and definitions of the display QA terms

Symbol	Mathematical definition	Definition and explanation All in 11.3.3
L_{amb}		Luminance generated by the ambient light on the surface of an image display device when the image display device is off.
L_{min}		Minimum luminance generated by an image display device at digital driving level (DDL) = 0 measured at the centre of the screen. It includes veiling glare specific to the test pattern used for measurement. It is measured with no ambient light.
L_{max}		Maximum luminance generated by an image display device at digital driving level (DDL) = max measured at the centre of the screen. It includes veiling glare specific to the test pattern used for measurement. It is measured with no ambient light.
L'_{min}	$L_{min} + L_{amb}$	Luminance that is perceived by the human eye at the centre of the screen at digital driving level (DDL) = 0.
L'_{max}	$L_{max} + L_{amb}$	Luminance that is perceived by the human eye at the centre of the screen at digital driving level (DDL) = max.
R_d		Diffuse reflection coefficient (provided by manufacturer with a specific measurement method, ideally following the methods defined in [21]).
r'	L'_{max} / L'_{min}	Luminance ratio of an image display device.
Δ_L	$\Delta_L = 2 \times \frac{L_{high} - L_{low}}{L_{high} + L_{low}}$	Maximum luminance deviation, a measure of display uniformity, with L_{high} and L_{low} being the highest and lowest luminance, respectively [22].
a	L_{amb} / L'_{min}	Safety factor (IEC 62563-1)
(u', v'')		CIE chromaticity coordinates for white point [23].
$\Delta(u', v')$		Colour distance between two sets of measured chromaticity coordinates in the $u' - v'$ space corresponding to CIE15:2018 [23]

4.2 Abbreviated terms

The meanings of abbreviated terms used in this document are given in Table 3:

Table 3 – Abbreviated terms

Abbreviation	Meaning
CCD	charge-coupled device
CD–ROM	compact disc–read-only memory
CRT	cathode ray tube
DDL	digital drive level
DICOM	Digital Imaging and Communications in Medicine (DICOM®) Standard
ftp	file-transfer-protocol
JND	just-noticeable difference (Annex E)
GSDF	greyscale standard display function (Annex E)
IQ	imaginary quadrant
LCD	liquid crystal display
LUT	look-up table
PACS	picture archiving and communications system
QA	quality assurance
RF	radio frequency
ROC	radius-of-curvature
ROI	region of interest
SOS	speed of sound
TIFF or tiff	tagged-image file format

5 General recommendation

The manufacturer's specifications should allow comparison with the results obtained from the tests defined in this document.

For compliance with this document, manufacturers should provide a description of how to recover pre-sets (nearly complete set of settings controllable for image acquisition and display), since such settings are affected by software updates. They should provide a capability to rapidly recover such settings or most equivalent settings available.

Other expectations of system manufacturers are explained in 8.3.

6 Environmental conditions

All measurements should be performed within the following ranges of ambient conditions:

– temperature: 23 °C ± 16 °C for uniformity tests; 23 °C ± 3 °C for other measurements;
– relative humidity: 10 % to 95 %, except 40 % to 75 % for relative depth of penetration;
– atmospheric pressure: 86 kPa to 106 kPa, except 66 kPa to 106 kPa for relative depth of penetration.

A wide temperature range is specified for uniformity tests because these tests are not significantly dependent on speed of sound.

These conditions may be relaxed to the extent **phantom** manufacturer's specifications specifically so allow for standard use.

Properties of ultrasound **phantoms**, such as speed of sound, **backscatter coefficient** and attenuation coefficient, are known to vary with temperature. The specifications published by the **phantom** and ultrasound-system manufacturer should be consulted 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 should be adopted for tests.

7 Quality assurance levels

7.1 General

Three levels of ultrasound **QA** are based on the time required for performance and the interval between tests. These levels are similar to those recommended by the European Federation of Societies in Ultrasound in Medicine and Biology [1]. Recommended schedules for performing these three levels of tests are provided in Table 4, along with some examples of flexibility to provide a reasonable cost-to-benefit ratio for performing the tests. Some professional judgement should be employed in the scheduling.

Table 4 – Outline of tests by level

Test	Evaluation	Action, if deviation found	Intervals
Level 1	-	Store results & confirm with:	-
Inspection for damage to transducer face or housing and cable	Visual inspection of the transducer assembly for cracks that allow the ingress of conductive fluid and for other damage, particularly to the lens	Level 2 tests or maintenance[a]	Daily
Image uniformity for well used transducers	Visual with clean transducer face held in air or system's transducer self-check	Level 2 tests or maintenance	At least weekly
Monitor function	Visual	Level 3 tests, adjustments or maintenance	Monthly
Hard copy (if available)	Visual	Adjustments or maintenance	Monthly
Mechanical Inspection	Visual inspection for all mechanical components and power cord, especially stable wheel mounts and clean air filters	Level 2 tests or maintenance	Monthly
Level 2			
Repeat Level 1 tests	On all transducers, include image uniformity with **phantom**[a]. See Clause 9	Adjustment or maintenance	Annually[b]
High-contrast, low-echo sphere visualization	Evaluate ranges of visualization of randomly placed spheres. See 10.3	Adjustment or maintenance	Annually[b]
Distance and other spatial size measurements	See 10.5 and IEC 61391-1:2006, 7.4	Adjustment or maintenance	Annually except as noted
Maximum relative depth of penetration (optional)	See 11.2	Adjustment or maintenance	When sensitivity loss is suspected[c]
Spatial resolution (optional; redundant with **high contrast, low-echo sphere** visualization)	IEC TS 62791 or, in lateral, axial and elevational directions, IEC TR 61390:2022, 3.16, 6.3.3.	Adjustment or maintenance	Optional

Test	Evaluation	Action, if deviation found	Intervals
Level 3[d]			
Repeat Level 2 tests			Every 2 years
Image displays, system and interpretation	Measure the grey scale transfer curve. See 11.1	Adjustment or maintenance	Once
Maximum relative depth of penetration (optional)	See 11.2; preferably absolute as in IEC 61391-2:2010, 7.1	Adjustment or maintenance	Every 2 years
System-image display	See 11.3	Adjustment or maintenance	Every 2 years
Distance/other spatial measurements	All systems in all measurement directions, See 11.4 and IEC 61391-1:2006, 7.4.	Adjustment or maintenance	Every 2 years
Performance in clinical use and evaluation of **QA** programme	Survey chief user and interpreter and assess the **QA** programme. See 11.5	Repeat needed Level 3 tests, adjustments or maintenance	Every 2 years
Contrast-detail **detectability** (optional)	IEC TR 61390:2022, 6.3.4 Not described further in this document	Adjustment or maintenance	When extensive assessment is desired

[a] It is reasonable to limit these Level 2 tests to frequently used transducers, if internal transducer self-checks are implemented [43].

[b] Systems used in breast cancer screening and other critical, high-use applications should receive Level 2 tests every six months.

[c] Currently required as annually (up to 14 months) by ACR [20] and conditionally by EU ÖNORM S5240-22 [22].

[d] In large medical systems with many inexpensive ultrasound units, Level 3 and even Level 2 tests on all scanners might be hard to justify. In these situations, rapid replacement followed by repair or recycling in response to concerns from Level 1 tests might be appropriate, with Level 3 tests of perhaps 10 or 20 of the units every other year. In small, possibly isolated, practices, Level 1 tests should be performed and every effort made to obtain Level 2 and Level 3 **quality assurance** and correction of malfunctions.

7.2 Level 1 tests

Level 1 tests are short-duration (approximately 5 min) checks, to be performed daily to monthly by the ultrasound system users. They are performed visually, requiring no **phantoms** or other special equipment, only record keeping. Only limited training and practice are required. Alternative methods of proven and at least **equivalent sensitivity**, as well as interpretability to end users, may be employed. See Table 4. The image uniformity tests will detect substantial transducer-element and cable- and electronic-channel degradation. Monitor function tests will detect noticeable change in display luminance, uniformity and resolution.

While both Level 1 and Level 2 tests are simple, it might be helpful to have a **quality assurance** professional, such as a medical physicist or hospital engineer involved, to ensure initiation of the tests and adequate record maintenance.

7.3 Level 2 tests

Level 2 tests are performed annually by users or **QA** professionals. They are simply Level 1 tests plus the high-contrast sphere test, a more sensitive version of the image-uniformity test, and any other tests indicated for special conditions, such as mechanically scanned transducers. The more sensitive, image-uniformity test is performed with a **phantom** and digital or visual averaging of a cine loop. See Clause 10. Alternative methods of proven and at least **equivalent sensitivity** and interpretability to end-users may be employed.

The **very-low-echo sphere** visualization will reveal the cumulative effects of main and other lobes and clutter of the beam, showing over what distances from the transducer and with what clarity, a high-contrast, **very-low-echo sphere** of the tested diameter can be visualized. This test relates to sensitivity as well as overall resolution. **Maximum relative depth of penetration** is a measure of overall system sensitivity.

7.4 Level 3 tests

Level 3 tests are performed by **QA** professionals every two years. They are designed to detect or verify defects that are less frequent than those detected by the image-uniformity test and they require more specialized, stable **phantoms**. These tests include as a minimum: Level 1 and Level 2 tests, plus measurement of **maximum relative depth of penetration,** and quantitative tests of displays used during scanning and during remote interpretation. Distance-measurement variance and bias tests are required initially on some systems and regularly on others. See Table 4 and Clause 11. The **maximum relative depth of penetration** and optional measures are recommended to be absolute, as in **performance evaluations**, to allow comparison with results from other sites. This test is not required when **low-echo sphere** tests are performed. These measures should be self-consistent to detect changes in the ultrasound systems tested over many years. Acceptance tests and other full-**performance evaluations** are part of complete **quality assurance** but are treated separately because they are covered by other standards already referenced. Several Level 3 procedures are specified by reference.

8 Equipment and data required

8.1 Phantoms and software

8.1.1 General

The test procedures described in this document should be carried out using tissue-mimicking **phantoms** and electronic test equipment, together with digital-image data acquired from the ultrasound scanner and appropriate software for image evaluation.

With appropriate attention, a **phantom** is likely to maintain its manufacturer-specified properties and tolerances thereof for at least four years provided the user follows the recommended maintenance and is scanning the phantom modestly, less than 250 h per year. Tolerances on some specifications are given in 8.1.2 and 8.1.3. The **phantom's** manufacturer should provide at least a four-year warranty. For water-based tissue-mimicking materials this durability can be attained by the warranty requiring periodic monitoring of the **phantom's** weight as specified by the manufacturer. When the weight has decreased by a specified amount, the **phantom** can be returned to the manufacturer for transfusion with sufficient aqueous solution to return the **phantom** to its weight (and presumably ultrasonic properties) at the time of manufacture. When a **phantom** is starting to desiccate – as water-based **phantoms** do – or otherwise decay, transition of existing **QA** data to that with a new **phantom** is possible, if the two **phantoms** have consistent acoustic properties. If such a transition is undertaken, note clearly the time of the change.

8.1.2 Phantoms for Level 2 and Level 3 quality assurance

See 8.1.3 and 8.1.4 for additional specifications and Annex A for example geometries of a **phantom** for both image-uniformity and **maximum relative depth of penetration** testing (Figure A.1) and a more compact and less expensive **phantom** for image-uniformity testing only (Figure A.2). Figure A.3 shows a **phantom** for assessing all three parameters, namely

– uniformity,
– **maximum relative depth of penetration**, and
– distance-measurement variance and bias.

Suitable **phantoms** for these tests can be constructed using, for example, water-based gels, open-pore sponges or urethane rubbers, having microscopic inhomogeneities that are uniformly

distributed throughout, to produce the desired attenuation level [15],[17],[24],[25],[26],[27], [28],[29],[30]. **Phantoms** without other backscatter generators require particles, such as 40 µm-diameter glass beads to provide backscattered signals at a controlled amplitude [28],[31].

8.1.3 Additional phantom specifications for Level 2 quality assurance

8.1.3.1 General

These specifications should be met in the 1 MHz to 23 MHz frequency range, except as noted. These specifications include the components of **high-contrast,** (**very-low-echo**) **sphere phantoms**. Several manufacturers[2] can produce tissue-mimicking materials and **phantoms** that comply with the following specifications. More stringent requirements are listed in 8.1.4 for Level 3 tests, other than image uniformity for which lax specifications are adequate.

8.1.3.2 Phantoms specifically for image uniformity and spatial tests, and optional Level 2 tests

Image uniformity, spatial size, resolution, and **maximum relative depth of penetration** tests also may be performed with **phantoms**, or sections thereof, having background material meeting the tighter specifications in 8.1.3.3. See the discussion in 8.1.4 for cautions about using **phantoms** with the loose specifications of 8.1.3.2 for spatial size and optional Level 2 tests.

Speed of sound: (1 500 ± 100) m s^{-1} at 3 MHz for image uniformity testing only.

Speed of sound for distance measurement shall meet specifications for Level 3 tests in 8.1.4.

Mass density: (0,95 to 1,15) g mL^{-1}

Specific attenuation coefficient: (0,3 to 0,9) dB $cm^{-1}MHz^{-1}$, choosing the higher end for a compact image-uniformity **phantom**. The high value minimizes reverberation artifacts.

Backscatter coefficient: $(3^{+27}_{-2,7} \times 10^{-4}$ $cm^{-1}sr^{-1})$ at 3 MHz and frequency (f) dependence of (f^q), where $3 \leq q \leq 4$ from 1 MHz to 23 MHz.

Scanning surface: The scanning surface should allow acoustic contact of the entire, active area of the transducer with the **phantom**.

Dimensions: For image uniformity tests, the **phantom** should provide a uniformly scattering and attenuating field that extends to a depth of at least 6 cm.

8.1.3.3 Phantoms with high-contrast, very-low-echo spheres

8.1.3.3.1 General

Speed of sound of both materials: (1 540 ± 10) m s^{-1}. For **phantoms** designed for specific applications to body parts with speed of sound clearly different than 1 540 m s^{-1}, materials with that speed of sound may be used. In that case, the **phantoms** shall be labelled clearly as intended for that application with a label stating "nonstandard speed of sound of (insert the intended speed) ± 10 m s^{-1}".

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2 These include, for example, CIRS/Mirion Technologies, Norfolk, VA, USA (www.cirsinc.com); Gammex/RM/SunNuclearI//Mirion Technologies, Middleton, WI, USA (www.gammex.com), True Phantom Solutions, Windsor, ON, CA (www.truephantom.com) and Kyoto Kagaku Co., Ltd, Kyoto, Japan www.kyotokagaku.com(http://www.kyotokagaku.com).). This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products. These and lower-contrast, sphere **phantoms** are defined in IEC TS 62791.

Mass density: (0,95 to 1,15) g mL^{-1}. For the **high-contrast** (**very-low-echo**) **spheres** themselves, −40 dB sphere mass density should be within 0,02 g mL^{-1} of that of the background material.

Specific attenuation coefficient: (0,50 ± 0,04) dB $cm^{-1}MHz^{-1}$ at 3 MHz and the value for the high-contrast sphere material should be within 0,04 dB $cm^{-1}MHz^{-1}$ of the background value. Deviations from these values in the 1 MHz to 23 MHz frequency range should be specified by the manufacturer.

Backscatter coefficient For the background material: $5^{+15}_{0} \times 10^{-4}$ $cm^{-1}sr^{-1}$ at 3 MHz and frequency dependence of f^q, where $3 \leq q \leq 4$, and for the high-contrast sphere material, no higher (less negative) than −40 dB relative to the background material.

Long-term stability: With appropriate attention, a **phantom** is likely to maintain its original values of **backscatter coefficient** within ±5 dB, attenuation coefficient/frequency within ±8 %, propagation speed ±1 % and mass density ±2 % for at least four years unless under heavy use, i.e. more than 250 h per year.

8.1.3.3.2 Phantoms for use with adequate sensitivity in the frequency range 1 MHz to 23 MHz

The **phantom** should allow imaging to a depth of at least 18 cm and provide for display of the entire B-scan image frame. High-contrast spheres should be available for **detectability** assessment over the entire image frame and the diameter of these spheres should be specified by the manufacturer within ±8%. The mean number of spheres per unit volume should be at least one per millilitre, but the volume fraction consisting of spheres should not exceed 15 %. Scanning windows should provide for contact of the entire emitting surface of the transducer (active area of a transducer), while allowing elevational translation of the transducer over a sufficient distance that the most likely number of spheres traversed by the scan plane at or near the focal distance(s) is 75 or more in a 5 mm **depth interval**.

Sphere diameter: A diameter of 4 mm ± 0,2 mm is recommended for adequate **QA** in the 1 MHz to 23 MHz range.

With some of the highest resolution ultrasound scanners, a **very-low-echo sphere diameter** between 3 mm and 4 mm might be found to be appropriate. For more complete **performance evaluation** above 7 MHz, smaller spheres are recommended in 8.1.3.3.3.

8.1.3.3.3 Phantoms for use with higher sensitivity in the frequency range 7 MHz to 23 MHz

For higher sensitivity to resolution changes with transducers in the frequency range 7 MHz to 23 MHz, specialized **phantoms** with smaller, (2,2 ± 0,2) mm sphere diameters are recommended with imaging to a depth of at least 8 cm. High-contrast spheres should be available for **detectability** assessment over the entire image frame and the diameter of these spheres should be specified by the manufacturer within ±8 %. The mean number of spheres per unit volume should be at least eight per millilitre, but the volume fraction consisting of such spheres should not exceed 15 %. Scanning windows should provide for contact of the entire emitting surface of the transducer while allowing elevational translation of the transducer over a sufficient distance that the most likely number of spheres traversed by the scan plane at or near the focal distance(s) is 110 or more in a 2 mm **depth interval**.

8.1.3.3.4 Total internal-reflection surfaces

Total internal reflection surfaces may be used to conserve the size of **phantoms** and the numbers of **low-echo spheres** needed for fabrication. It has been shown that for **phantoms** with high-contrast spheres having diameters of 3 mm to 4 mm, two parallel, plate-glass surfaces causing total internal reflection are acceptable in the **phantom**, as shown in

IEC TS 62791:2022, Figure A.1 and Figure A.2. For **phantoms** with high-contrast spheres having diameters of 2 mm, two parallel, planar, alumina or plate-glass surfaces causing total internal reflection are acceptable, as shown in IEC TS 62791:2022, Figure D.1; a surface roughness of the alumina of 6 µm or less is sufficient.

8.1.3.3.5 Spatially random distribution of very-low-echo spheres

To minimize manufacturing costs, the spheres are spatially randomly distributed. To verify random distribution throughout a **phantom,** the measured distribution in various regions should be approximated by the Poisson probability distribution function (IEC TS 62791:2022, 6.2.4)

$$P(u) = \frac{e^{-v} v^{u}}{u!} \tag{1}$$

where

v is the mean number of high-contrast sphere centres per millilitre.

For example, if v = 1 and $P(u)$ is the probability of there being u high-contrast sphere centres in an arbitrarily chosen 1 mL volume, the standard deviation (σ) is $\sigma = v^{1/2} = 1$.

8.1.4 Additional phantom specifications for Level 3 quality assurance and optional Level 2 tests

Maximum relative depth of penetration is used here, rather than **maximum depth of penetration**, as defined in the referenced standard, IEC 61391-2, because the more expensive and perhaps less robust test objects that are required for the absolute measurements specified in IEC 61391-2 are not absolutely required for **quality assurance**. However, absolute measures are recommended, using **phantoms** specified in IEC 61391-2 to allow comparison of a user's current system performance with published values and those values obtained in that user's own system with other **phantoms**. The tissue-mimicking material should have the following properties. These are similar to those specified in IEC 61391-2 except that a **phantom's** acoustic-property requirements, though not its stability requirements, are relaxed here for facilities using the same phantom for a long period of quality-control testing, or a series of **phantoms** having consistent properties.

For all but the uniformity and **very-low-echo sphere phantom** tests, more rigorous **phantom** material specifications for Level 3 **QA** over the 1 MHz to 23 MHz frequency range are as follows:

Speed of sound (SOS): (1 540 ± 10) m s^{-1}, to avoid substantial complications.

When filaments are included with appropriate spacing to simulate 1 540 m s^{-1} SOS for each of the scan geometries available on an ultrasound system, then (1 500 ± 80) m s^{-1} at 3 MHz is tolerable. This extreme flexibility is allowed for **quality assurance** only, assuming appropriate notifications of the expected or possible errors in focusing and on- and off-axis distance measurements are on the **phantom**. Users should be instructed to use a filament group with curvature close to that of the transducer, as can be seen easily on the image.

NOTE If the speed of sound in the phantom is not as assumed by the ultrasound system, the focus will be displaced and degraded. These are minor effects in the consistency checks of quality assurance. However, speed of sound is of great concern in checking for distance-measurement error, unless that has been tested carefully in Level 3 performance tests and consistency has been tracked carefully in quality assurance tests. This flexibility is provided because of the convenience and longevity of urethane rubber phantoms with SOS equal to 1 450 m s^{-1}, typically. However, for the majority of ultrasound systems, i.e. those that assume SOS equal to 1 540 m s^{-1}, different groups of filaments are required, carefully spaced for their depth in the phantom to give unbiased distance measurements for phased arrays and linear arrays. Filament placement on an angular arc specifically matched to the curvature and placement of curved, linear arrays or to the placement of phased arrays is necessary. With any deviation of machine-assumed SOS from the phantom SOS, deviation of the assumed angle or location of view of the filaments or in assumed curvature of the linear array will cause errors in lateral distance measurements[3]. In other words, it is impossible for a single set of filaments to provide correct lateral distance measurements for different linear-array curvatures or for both curved arrays and linear arrays. These lateral/azimuthal and axial distance measurement problems are not encountered for the increasing number of ultrasound systems that have an adjustment for speed of sound that can be set to that of the phantom, when the filaments or other targets are placed at their expected

distances. It is best to have the lateral distance filaments on arcs with radii of curvature that match those of the arrays for which the filament patterns are designed.

Mass density:	(0,95 to 1,15) g mL^{-1} stable to within ± 0,02 g mL^{-1}.
Specific attenuation coefficient:	(0,50 ± 0,04) dB $cm^{-1}MHz^{-1}$ dB $cm^{-1}MHz^{-1}$ at 3 MHz. Deviations from this value in the 1 MHz to 23 MHz frequency range should be specified by the manufacturer.
Backscatter coefficient:	For **phantoms** not including the randomly-distributed, **very-low-echo spheres:** ($3^{+27}_{-2,7}$ x 10^{-4} $cm^{-1}sr^{-1}$) (±10 dB) at 3 MHz. Background material for phantoms including the **randomly-distributed, very-low-echo spheres:** 5^{+15}_{0} × 10^{-4} $cm^{-1}sr^{-1}$ at 3 MHz. In both cases the frequency dependence from 1 MHz to 23 should be f^q, where $1 \leq q \leq 4$. The value of the **backscatter coefficient** of the **phantom** should be reported as a function of frequency, together with the results obtained with the **phantom**.
Scanning surface:	The scanning surface should allow acoustic contact of the entire, active area of the transducer with the **phantom**. A well to contain a thin layer of degassed water or saline to ease acoustic coupling is convenient.
Dimensions:	The useable **phantom** depth should be at least 22 cm for testing **maximum relative depth of penetration** at low frequencies (2,5 MHz to 5 MHz) and deeper for lower frequencies. The lateral and elevational dimensions should 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 relative depth of penetration** for the scanner and transducer under study. Larger cross-sections might be required to provide a uniform region when testing 3D scanning systems.
Target position error:	Filament or other spatial measurement targets should be located and stable in each test object to within 0,1 mm of the specified location. See IEC 61391-1.

8.2 Image data

8.2.1 Digital-image data

Level 3 test criteria described in this document, particularly **maximum relative depth of penetration**, are best applied to digital-image data derived from the ultrasound scanner being evaluated. This requires knowledge of image-pixel brightness (grey) levels for all spatial locations in the image. Digitized image data typically are in a matrix consisting of at least 640 × 480 pixels and at 8 bits (256 levels) of grey-scale resolution. Availability of and downloading of image data with the maximum resolution computed in the system is recommended. For more detailed **performance evaluation**, particularly for premium- and mid-level machines, RF or IQ (real and imaginary) signal data are desired by many users. These data are not required for procedures in this document. As described in Annex B, free software is offered commercially, which is purported to simplify acquisition of these data, their recording, storage and immediate and long-term analysis.

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

a) Direct DICOM® – images from the scanner [32].

   Image data in a DICOM-format are available on most scanners. Software capable of transferring and opening DICOM-formatted images is available at no cost [http://rsbweb.nih.gov/ij/].[3]

b) Other digital-image files available from the scanner itself; lossless preferred, if available.

   This method is used by most scanner manufacturers for in-house quality-control testing and image-processing development. Many file types are acceptable for **QA** work as long as adequate resolution is maintained. 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-image data as well. Full-screen capture is available on many systems, sometimes by storing a single image rather than a cine loop.

The second group of scanners includes those simpler devices that do not provide digitized image data directly but provide standard video signals, i.e. image data that can be captured into a computer and then analysed. For these, increasingly rare, scanners, a video-frame grabber may be used to acquire digital-image data. The video-signal grabbing should be provided under stable conditions to minimize signal distortions. The following provisions apply:

– The input dynamic range of the video-frame grabber should be adjusted to accommodate the maximum signal amplitude of the video output.
– The digitizing amplitude resolution (given by the pixel-byte size) shall be better than that of the grey-scale resolution of the video-output signal. A minimum of eight bits or 256 grey levels is necessary.
– Conversion-function linearity should be assured.
– The display spatial resolution (given by the pixel size) of the digital picture shall be at least as good as the original video line density of the image.
– The video-capture frame rate of the video-frame grabber shall 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 should be used to avoid reflections in the line.
– Image test patterns are required for scanner display testing [33]. In worst-case situations the ultrasound system's display screen can be photographed with a digitizing CCD camera, under low light conditions and with repeatable photographic settings and field of view, but this is more difficult to control quantitatively.

8.2.2 Image-archiving systems

Many imaging centres 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 minimally compressed "tiff" (tagged image file format) or an uncompressed format, such as a raw or a DICOM-format [32] to work stations that have access rights to the image data.

Clips are sometimes only sent from the US scanner in compressed format. Those clips can be sent with lossless compression, if possible. Or, as long as the compression ratio (compressed size divided by original size) is kept constant over time for lossy compression, useful **QA** measurements can be made from compressed clips. As usual, all system settings affecting the measures such as gain, output, focal zones, are kept constant. All such settings should be maintained consistently through all **QA** testing between the same and similar systems through use of **QA** pre-sets.

[3] DICOM® is the registered trademark of the National Electrical Manufacturers Association for its Standards publications relating to digital communications of medical information. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.

In worst-case situations the ultrasound system's display screen can be photographed under low-light conditions and with repeatable photographic settings and field of view, with a digitizing CCD camera, but this is more difficult to control quantitatively.

8.3 Expectations of system suppliers

With some arrays, such as phased arrays and most 2D-arrays, clinical imaging systems never form transmit- or receive-beam apertures of a very small number ($1 \leq N \leq 10$) of sequential elements, as is necessary for sensitive, image-based detection of reduced element (channel) performance. Thus, the loss of one or a few elements will never show up in a uniform **phantom** as a substantial loss of signal in N of the scan lines. Thus, beam formation and scanning with small numbers of elements is usually done in near-field focal zones of linear and curved-linear arrays. Availability of this test sequence should be described clearly and prominently (for example, in the index and table of contents) in the operator's manual or in a well-publicized supplement thereto. The sequence should allow testing of each transducer element or the small numbers of elements selected for transmit and receive apertures. Ideally, if five adjacent elements are combined in the lateral direction for transmit and receive, the next aperture should drop one element on one end and add another on the other end of the aperture, and so on. The number of elements in each transmit aperture and each receive aperture of this sequence and their sequencing should be specified in the documentation. For 2D-arrays and other arrays where beam formation and scanning with a small number of elements is not done clinically, at least for short depths, a test sequence should be provided to allow the simple **QA** tests of all **addressable patches** or small groups of **addressable patches** of transducer elements and channels, as provided in this document.

Small grouping of addressable patches may be reported to enable some disguise of proprietary transducer addressing methods. A better alternative is a list of necessary statistics on patch responses that should be agreed upon by user groups and the system supplier and reported. This should include locations of outliers, without necessarily giving a total number or size of patches.

Manufacturer-provided or third party-provided electrical tests (Annex C) for which there are strong data showing a good correlation with these **QA** measures and which provide a mapping and summary of element performance may be employed by the user. However, the phantom-based **QA** tests for uniformity described in this document should be performed at least twice a year to verify that the provided tests are adequately sensitive.

Manufacturers should provide system-display test patterns necessary for the display testing described in 10.3 and within the time frames specified there. These patterns should be easily accessible and employable by the end user. The capability for calibrating the system display to the DICOM grey-scale standard display function should also be provided [32]. Optimal display calibration is appropriate and important for the ultrasound-scanner display since, in practice, this display is used for diagnostic interpretation.

9 Level 1 test methods

See 7.2 for additional information on those tests which should be performed and results recorded daily, weekly, or monthly. Inspect all equipment, including scanner, monitor, transducers and scan console, to make sure all mechanical components are fully intact and all mechanical systems are functional. Pay particular attention to power cables, wheels supporting the system, air filters and transducers. Check the transducer face for lens damage and delamination, the casing for cracks as a potential shock hazard and the cable insulation and grommets for wear. Adjust settings to the most reproducible positions consistent with obtaining the necessary images.

The image-uniformity test is a visual assessment looking for vertical stripes or other abnormal banding in the images, similar to those described in detail in the Level 2 test. Clear the transducer face of any gel or other materials and hold it in the air for the test. Adjust settings as in the Level 2 tests, except increase the gain, if possible, such that electronic noise can be barely seen. Most element/channel defects of serious, immediate clinical significance will be detected visually. If the gain cannot be increased enough to show electronic noise in usual settings, it might be possible to do so in engineering/service settings. If a transducer self-check is available in the ultrasound system that electronically checks the performance of individual elements or small clusters thereof, verify that the transducers have passed the test.

For monitor function, display the test patterns described in 10.3. Ascertain that the uniformity and resolution of the image appears consistent with previous tests. There should be no more than two defective pixels. The ambient light should not make it difficult to see details on the screen.

In the hard copy and stored images, verify that the images presented to interpreting and referring physicians show essentially the same features as on the ultrasound system display and, that the ultrasound system display shows what is seen on the interpretation copy.

These results/observations should be recorded in a checklist in a **QA** record book in paper or digital form and deviations should be acted upon in a timely manner.

10 Level 2 measurement methods

10.1 Mechanical inspection

As in Level 1, inspect all equipment, including scanner, monitor, transducers and scan table, to make sure all mechanical components are fully intact and all mechanical systems are functional. Pay particular attention to power cables, wheels supporting the system, air filters and transducers. Check the transducer face for lens damage and delamination, the casing for cracks as a potential shock hazard and the cable insulation and grommets for wear.

10.2 Image uniformity for transducer element and channel integrity

10.2.1 General

The image-uniformity test is primarily a test of ineffective transducer elements or their signal channels, including cables and connections [34]. Measurement results of all Level 2 tests will depend on the system transducer, frequency and the operating conditions and mode [31]. These shall be specified and employed regularly for consistent **QA** measurements that can be repeated for detection of change over time, as well as detection of unacceptable image uniformity.

10.2.2 Apparatus scanning procedures and system settings

Level 2 tests are designed for use in pulse-echo imaging mode but might be adapted to Doppler and other modes, when desired or needed for possible increased sensitivity. Utilize a **phantom** meeting the appropriate set of specifications in 8.1 or Table 4. Place the transducer in a liquid-filled well or employ a coupling gel or lotion. All arrays, including convex arrays should contact the **phantom** over the entire emitting surface. When this is not possible for a large convex array, the tests may be performed with more difficulty using multiple views that together cover the entire emitting surface. For tests other than elevational-distance measurements, a 3D/4D-mode capable transducer, comprising a 2D-array or a mechanically scanning, linear array can be operated in 2D-mode with the convex array or linear array fixed in position. Thus, it can be assessed as a linear or convex array. Specific settings for other tests, such as **maximum relative depth of penetration**, are provided in 11.2.2.

Scanning procedures and system settings are as follows:

– Set the imaging to the shortest focal zone possible, with no spatial compounding.

– Set the displayed dynamic range to a relatively low value; approximately 50 dB is recommended to maximize the image contrast, making artifacts more conspicuous.

– Set image depth to the smallest value that still shows the entire transducer face. This can result in smaller transmit and receive apertures and smaller image pixel size.

– Overlapping of annotations on the image shall be avoided.

– Set output power at the maximum, if possible without saturating image pixels and increase gain to maximize signal level near zero depth, while avoiding saturation near the maximum **pixel values**.

– Disable the speckle reduction and any artifact-removal (particularly shadow-removal) settings, if possible.

– Except as otherwise noted, settings, such as frequency, should be in typical positions that are used clinically, preferably at the pre-set (default) settings presented by the system for the most common application and body habitus for that system and the transducer under test. All of the values for these settings should be recorded.

– The grey-scale characteristic curve setting shall be reproducible. It is possible but usually not essential, to measure the characteristic curve as detailed in IEC 62563-1. The grey-scale characteristic display curve should be set to the one that has the most purely logarithmic compression, a straight line in image-**pixel value** as a function of logarithmic, received signal level. If these settings are not available, the characteristic curve of the most important clinical application for that transducer should be chosen. In either case a 50 dB displayed dynamic range is preferred.

– Obtain help, if necessary, on finding these and other settings affecting **QA** results and record them, so that they can be reset if another operator has changed them.

– **Time gain compensation (TGC**) should be set to the most useful and then reproducible settings possible. "Most useful" is for uniform brightness with depth. Often "most reproducible" is flat **TGC** at either extreme of maximum, minimum or middle gain.

– Phased- and 2D-array tests are performed with a modified paper clip test in M-mode [34] or with special imaging sequences from the system manufacturer as specified in 8.3. With those arrays, employ the system test sequence provided by the system supplier, following any special directions provided.

– All settings should be recorded and stored in **QA** uniformity- and penetration-test, pre-set files to make reproducible tests practical with the more complex settings. Many of the settings are recorded when only a single image, as opposed to a cine loop, is stored.

– Signal processing settings, such as logarithmic compression, speckle reduction, and other pre-processing functions, as well as image-display settings, such as post-processing, should be in typical positions that are used clinically, as mentioned above, and recorded.

10.2.3 Image acquisition

Some practice is required to obtain test data consistently. The image acquisition procedure is as follows.

– Spread coupling gel smoothly over the scan path.

– Press the transducer lightly to create a thin layer of gel under the transducer with a supply of gel in front of the transducer in the direction to be scanned. Slightly less pressure in the direction of scanning will help the transducer ride over a consistent, thin layer of gel.

– Then move the transducer slowly in a direction normal to the scan plane, from one end of the **phantom** or well to the other. Additional independent images can be obtained by tilting the transducer about its contact line with the **phantom**. Perform the sweep or sweep and tilt at a speed that allows, during the sweep, acquisition of almost a full cine loop of images or preferably 50 or more images individually or by frame grabber. Coupling and scanning recommendations for electronically scanned 2D- and mechanically self-scanning (termed 3D- or 4D-) arrays are provided in Annex D.

– Record the images to a location where they can be processed or retrieved for processing.
– Clean the scan path, repeat gel distribution and repeat this acquisition for a consistency check.
– Repeat until consistency is obtained (IEC 61391-2).
– When cine loop capabilities are not available, record images as rapidly as possible as the transducer is scanned slowly over the **phantom**.

10.2.4 Analysis

For high sensitivity and quantification, compute the median-averaged image value $a_{i,j}$ over all images, k = 1 to N, in the sweep, or sweep and tilt, for each pixel at coordinate i,j. The resulting, highly averaged image is likely to reveal drops in image brightness in the pixels below compromised transducer elements or channels. To quantify the image brightness non-uniformity, compute the median **pixel value** in depth over at least 10 % of the image depth, for example, from 2 mm to 20 mm in each column in the image, while avoiding noisy sections of the image. For linear arrays that means simply averaging the image-**pixel values** in each column at depths over that range, from 3 mm to 10 mm. The hashed lines in Figure 1 (right) are added to show this region of axial averaging, over a smaller range of 2 mm to 8 mm. This collection of median values as a function of pixel number along the transducer surface forms the lateral profile of Figure 1 (left). This processing is performed using any one of many available software applications for this type of task. The task can be performed fairly easily in general-purpose software or uniformity-specific software[4]. Automated analysis could be performed on images from enough different clinical cases produced by a given transducer to assess non-uniformity in images from the transducer [35].

Several narrow losses, or a multi-element loss greater than 6 dB, are considered defects. A criterion other than 6 dB and based on statistics of the profile is given below. Three defective elements well separated from each other are the greatest number of defective elements usually allowed. With a 50 dB dynamic range and reasonably logarithmic compression, a loss greater than or equal to 6 dB would be displayed as a dip greater than or equal to one-tenth of the full grey-level range, or 26 on the 256-level scale shown in Figure 1. Some experience will be required in learning to interpret these data. Performance of transducers with unacceptable defects by this criterion should be compared with results of tests by the service provider or other measurements, such as complete transducer-face imaging [36], or a complete electrical test of the elements. Other specifics of measurement with available specialized software, including production of profiles with convex linear arrays, are given in Annex B.

4 Examples are Matlab, and NIH imageJ with special plug-ins. See examples from available shared or commercial software in Annex B. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products.

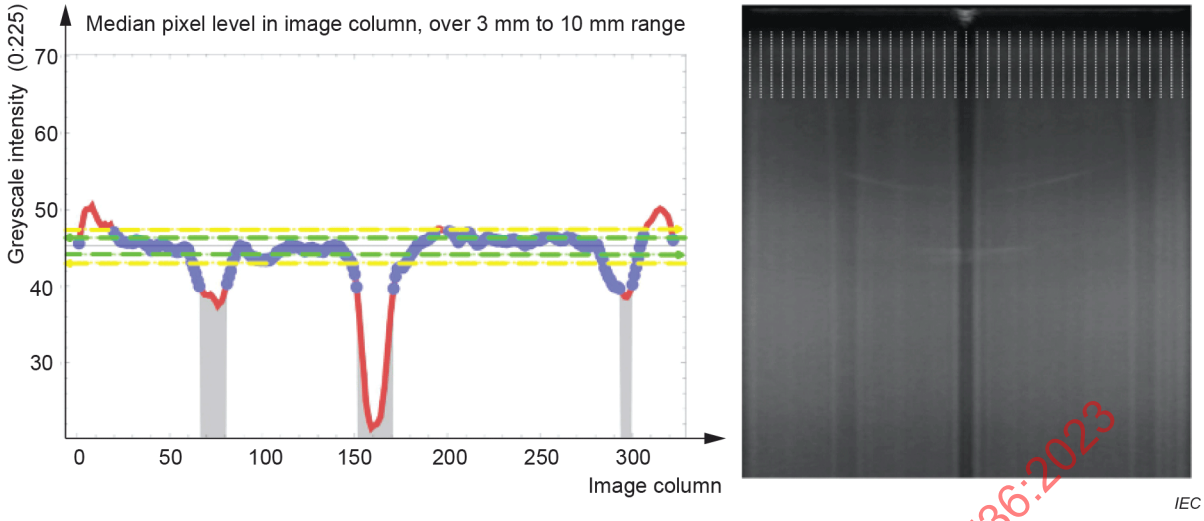


Figure 1 – Median-averaged image (right) and its lateral profile (left)

On the right side of Figure 1 is a median-averaged image derived from a large stack of images of a uniform, stirred liquid **phantom**; white vertical lines at the top (3 mm to 10 mm depth) show the range over which the signal of each scan line was median-averaged to make the profile on the left. A 0,53 mm diameter fish line filament was placed across a central element to simulate two defective transducer elements. This filament casts the main shadow seen in the image and the profile. This effect of a shadowing material is usually larger than that of the covered elements being disconnected. Two lesser shadows are seen that are due probably to less sensitive or lost single elements. On the left side of Figure 1, the set of blue points overlaid on the red line constitutes the central three fourths (75 %) of the profile data. The dotted green (yellow) lines mark one (two) **median absolute deviations** above and below the profile median. The grey "shadows" merely extend (simplistically) below sections of the data that reside in the bottom eighth (12,5 %) of the profile set.

Results of this analysis should be recorded in a database including at minimum, the signal change and half-width thereof and location on the array. Such recording should be done for all areas of scan-line signal change in the image, where the change exceeds recommended limits for the tested type of transducer and system. Also, conclusions from the tests should be included. When such recommended limits are unavailable, are not fully satisfactory or when practicable in other cases, the database should include the median-averaged image and brightness profile, both as in, or similar to, Figure 1, and a means of plotting the results of signal-change amplitude, dip width, or the product of amplitude and dip width, as a function of time in a control chart [37]. The control chart can help define deviations exceeding certain confidence limits, or two or three standard deviations, from the mean or median of the previously recorded values. These limits are typical thresholds for declaring a clear degradation and usually obtaining corrective action. See Clause B.2.

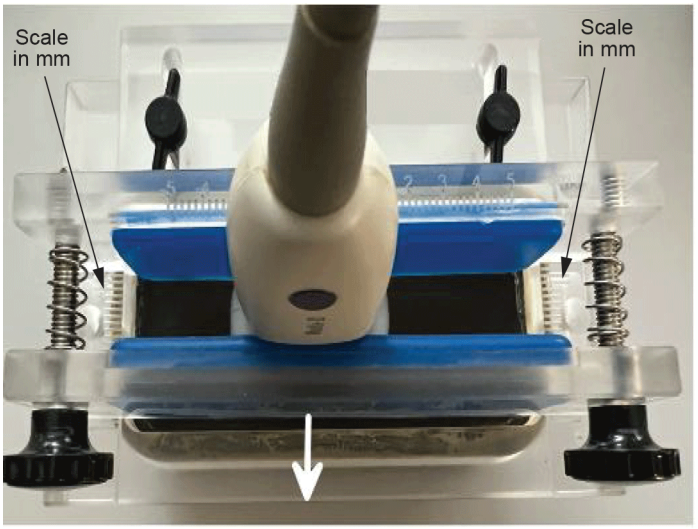
10.3 Randomly distributed high-contrast sphere visualization

10.3.1 Methodology

The basic unit for data acquisition for transducer types a) through e) of Clause 1 is a digitized grey-scale image including the entire selected field of view. Typically, at least eight bits (256 levels) of distinct grey levels are realized. For transducer types f) and g) of Clause 1, see Annex D.

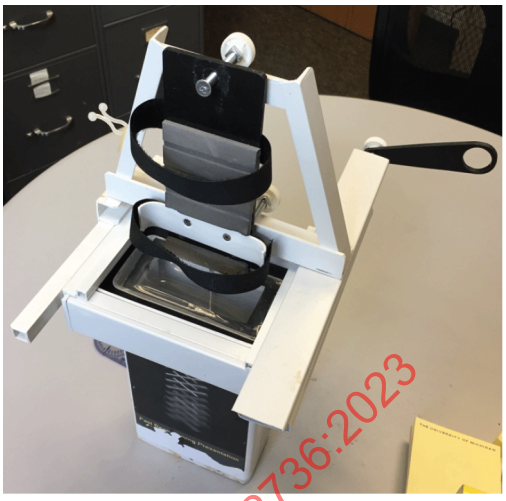
The measurement protocol involves acquiring images while the transducer under test is translated in the elevational direction over a section of the specified **phantom**. For those performing only visual or 2D analysis, free-hand scanning can be utilized. When 3D analysis is to be performed, or reanalysis is anticipated in the future, then spatially correct 3D scanning is required. For those systems in which the beam axes corresponding to the image frame lie in a plane (defining the "scan plane"), the transducer should be held in contact with a section of the scanning window (with adequate coupling gel) by an apparatus which also allows translation in the elevational direction, thereby allowing acquisition of image frames with scan planes parallel to one another (Figure 2 and IEC TS 62558:2011, Figure A.7). The apparatus shall either allow movement at a constant rate or in steps at a defined increment per image frame. The scan rate or step size should be known for automated analysis but can be deduced by adequate image analysis. The maximum translational increment between acquired frames should be less than or equal to one fourth of the sphere diameter.

NOTE It is customary that software and hardware will be made available that simplify acquisition, recording and long-term storage of these data.



IEC

a) Simple transducer holder allowing manual, parallel motion, in the direction of the short white arrow, in equal, chosen increments



IEC

b) Example of a manual quantitative slider providing displacement of 1 mm/turn with transducer holder and tilt adjustment [38]

IEC

c) Use of a carpenter's square and ruler to enable parallel motion in equal, chosen increments

Figure 2 – Examples of portable apparatus for moving the transducer: a) and c) in equal, chosen increments or b) at a known rate

Recording, analysis, storage of results, comparison with past results (similar to that illustrated in Figure B.2), and long-term storage of these data sets and results should be performed by semi-automated software, such as that explained in IEC TS 62791. Such software is likely to make ultrasound **QA** much more reproducible, precise, rapid and efficient.

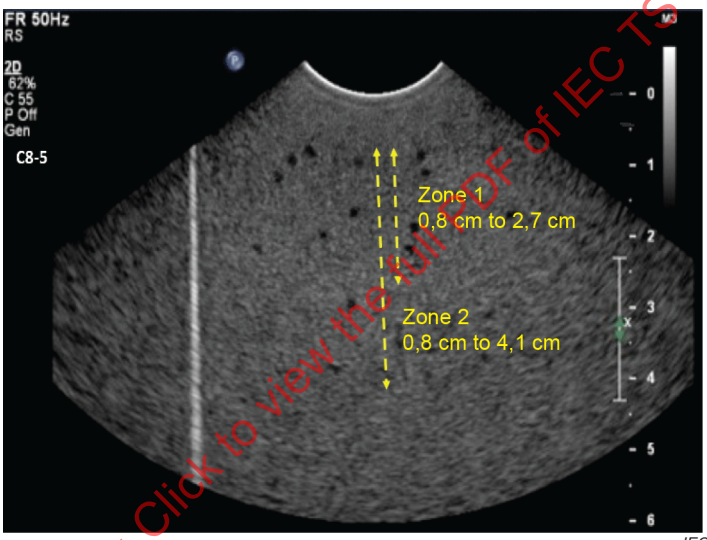
10.3.2 Procedure

10.3.2.1 General

Employ standard pre-sets for a common application for the transducer under test. Ideally, the application chosen for pre-sets will be one in which small, spherical lesions are to be detected. It might then be modified for the **phantom** used and stored as the **QA** pre-set for this test. These and other similar tests of resolution and contrast are very sensitive to system settings such as gain, **TGC**, focal zones and dynamic range and some post-processing. Adjust the **TGC** at the most reproducible position that allows uniform brightness of the echoes over the imaging depth. Adjust the gain to where signal or noise can just barely be seen in the darkest spheres. Then decrease the gain by 6 dB (50 %). Save those settings as a **QA** pre-set for that transducer model on that scanner model. Sweep the transducer in its elevational direction along the length of the **phantom** for a linear array that will fit in the narrow direction of the scan window. For convex and sectored arrays, it is best to scan across the narrow width of the window.

NOTE It might prove simpler to translate the **phantom**.

10.3.2.2 Automated analysis



[SOURCE: IEC 62791: 2022, Figure C.8.]

Figure 3 – Example of visual estimation of the two defined depth zones in which spheres can be detected with two degrees of fidelity and clarity

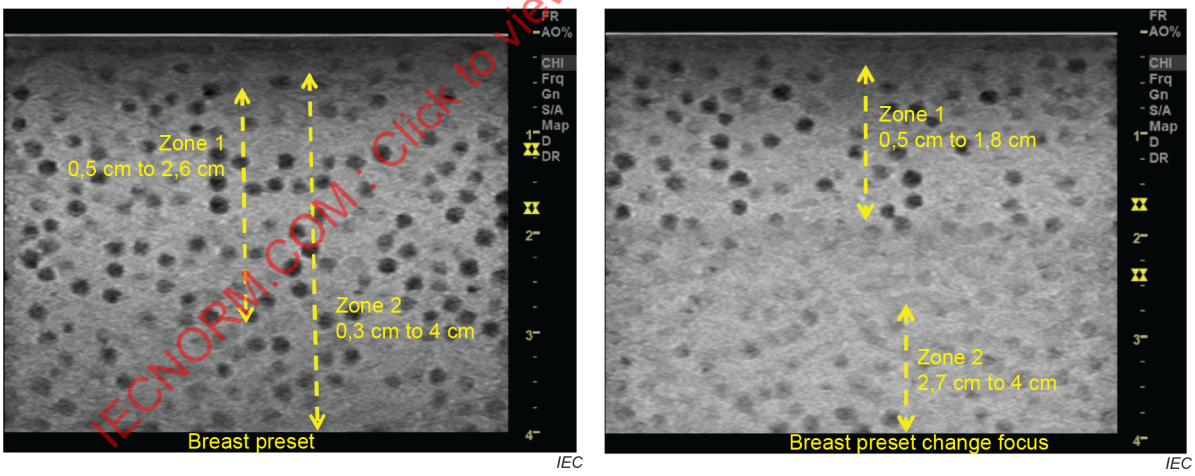
If automated analysis software is employed, the $LSNR_n$ for the nth sphere with its centre lying in the volume segment determined in each **depth interval**, d, spanning the entire depth range available, as in IEC TS 62791 [15] and [39], should be computed, preferably in overlapping **depth intervals**. The mean of the $LSNR_n$'s for all spheres with centres in a given **depth interval** should be computed to obtain its $LSNR_{md}$. Select a set of reference values, $LSNR_{md,ref}$, for each **depth interval**. These values might be provided by the manufacturer, acquired in acceptance testing or acquired in the first periodic tests. Means of the values for the first few periodic tests might also be used as reference values when there is substantial variability in the individual values of candidates for $LSNR_{md,ref}$. In **QA** measurements over time, plot a control chart, as in Figure B.2, for each depth range, creating a 3D chart with ($LSNR_{md,ref} - LSNR_{md}$) on the ordinate, test date on the abscissa and **depth interval**, d, on the z-axis. Report anomalies when these numbers exceed the statistically determined control limits at any point. Control charts might alternatively be plotted separately on each of the four numbers, or the single aggregate number, C_1, described below.

Automatically detect the range over which the negative of $LSNR_{md}$ is ≥ 1,41, between the bounds $Я_1$ and $Я_2$. If this **useable range** is in multiple segments, quote those ranges $Я_1$ to $Я_2$, $Я_3$ to $Я_4$, … $Я_n$ to $Я_m$. Compute the mean absolute value of $|LSNR_{md}|$-values over the **useable range** or combined set of **useable ranges**. This mean absolute value is the **mean useable contrast over the useable range**, $|LSNR_{mЯ}|$, for the single range, $Я_1$ to $Я_2$, or the set of ranges: $Я_1$ to $Я_2$, $Я_3$ to $Я_4$, … $Я_m$ to $Я_n$ with total length $Я_1$ to $Я_p$. Also compute log $|LSNR_{mя}|$. The product log $|LSNR_{mя}| \times Я_u$ is the transducer/imaging-device/imaging-mode, small-lesion **clarity index,** C_l, which is a single number that can be used as a figure-of-merit to quote as an overall performance metric of the transducer in imaging small objects with the imaging device in the employed mode. This procedure usually results in just four meaningful numbers, $Я_1$, $Я_2$, $|LSNR_{mя}|$, and the **clarity index,** C_l. Occasionally $Я_2$ will be replaced by $Я_p$. These four numbers, or more if the **useable range** is split into multiple ranges, should be reported by manufacturers in transducer/imaging-device/imaging-mode specifications.

10.3.2.3 Visual analysis

If automated-analysis software is not employed, visual interpretation is performed on a cine loop of the imaged sweep, or other captured 3D image stacks. The images should be displayed at a rate at which the viewer is most comfortable making the following estimates of Zone 1 and Zone 2. Zone 1 and Zone 2 are, respectively, the depth ranges over which: 1) the spheres are clearly visible, 2) are reasonably well delineated, but with very limited contrast. That rate should be repeated in the future. Examples are given in Figure 3 and Figure 4.

Figure 4b) illustrates an error in the ultrasound system software. The large failure in focusing in the 1,8 cm to 2,7 cm range in Figure 4b) occurred inappropriately with a minor shift in the focal zone placement from that in Figure 4a). While **quality assurance** consists mainly of revealing changes over time at fixed settings, it is worth validating on **phantoms** any poor system function, whenever image quality is unexpectedly poor in clinical use at any settings.



a) b)

Figure 4 – Additional examples of visual estimation of the depth Zone 1 and Zone 2, each of which represents a certain degree of fidelity and clarity (IEC 62791)

Any clearly discernible and reproducible reduction in Zone 1 lengths, or in Zone 2 lengths that are not due to increases in Zone 1 lengths, are considered an important change in the image quality. These changes might be due to some other improvement in the image as perceived by the service person or producers of software upgrades. However, if the measured change is not due to deterioration of the **phantom** or measurement with incorrect coupling, the correction of such changes should be pursued vigorously. These are considered the best overall measures of ultrasound transducer and system performance.

10.3.3 Data recording

Good record keeping is essential to performance of good **quality assurance**. A control chart as described and illustrated in Annex B is a very effective way of tracking variation of a measure within its own statistical variation to show what is significant. A database of some sort is required to record and store these data for analysis. Annex E includes examples of simple workbook databases for recording the data over time and performing simple analyses.

10.4 Image displays; system and interpretation; maximum relative depth of penetration; spatial resolution

Maximum relative depth of penetration measurement is to be performed at Level 2 when sensitivity loss is suspected. See 10.2. In general, the absolute, rather than the relative measurements, are preferred, as in IEC 61391-2:2010 7.1.

Spatial resolution measurements are optional as they are highly redundant with **very-low-echo sphere** visualization for detecting changes in system performance. The two-dimensional, axial and lateral, spatial measurements have rarely detected system-performance defects or changes not seen by the required tests. Automated, three-dimensional, axial, lateral and elevational measurements are becoming available. These beam profiles are likely to have the precision to provide, in three curves, only slightly different performance information on a transducer and system as a does a single, **very-low-echo sphere** curve. See IEC TS 62791 or, in lateral, axial and elevational directions, IEC TR 61390:2022, 6.3.3.2 to 6.3.3.4, for good procedures.

10.5 Distance and other spatial measurements

Only under the following conditions are these measurements required in Level 2 tests:

– when distance measurement instability or inaccuracy is suspected;

– when measuring elevational displacement in mechanically swept linear, curved-linear and phased arrays;

– in many interventional guidance systems;

– when measuring lateral displacement beyond the real-time field of view;

– in mechanically swept single-element, annular-element, 2D-array- and similar scan-heads.

Those systems are more subject to subtle errors than systems with displayed distances relying only on modern digital clocks and spacing of elements in a rigid array. Particularly when distance measurements are critical, as in obstetrics, distance measurement accuracy in mechanically scanned directions should be measured at least annually. The accuracy of measurements on these less-stable systems should be tested as well as the uniformity of the distance scale. The first **QA** tests on a system should include a full set of distance measurements, if acceptance or other **performance evaluations** have not been performed, and documentation of all distance measurements has not been verified.

Specific instructions are provided in 10.4 and in IEC 61391-1:2006, 7.4.

11 Level 3 measurement methods

11.1 General

These tests should be performed and results recorded at least every other year, using **phantoms** defined in 8.1. They should also be performed upon acceptance testing and when problems such as system sensitivity and display-system performance are suspected and clear problems are not documented by the image-uniformity tests. As in 10.2.4, the results of tests should be plotted in control charts to aid selection of significant deviations from the mean or median of the measurements. See Clause B.2.

Measurements of the grey scale characteristic curve or at least the local dynamic range, according to IEC 61391-2, is recommended upon acceptance testing at least for one of the scanners of a given model. Furthermore, the user is reminded to repeat all the Level 2 tests of Clause 10.

11.2 Maximum relative depth of penetration

11.2.1 Assessment

The **maximum depth of penetration** is currently the best imaging method for simple tests of ultrasound system sensitivity. Similarly, after that, the **maximum relative depth of penetration** is currently the next best imaging method for assessing changes in system sensitivity. Because the measurement is relative, the properties can be defined relatively loosely, as in 11.2.2. However, for comparisons with others, it might be helpful to use the more tightly defined values specified in IEC 61391-2:2010, 6.2.2 and 7.1. Visual measurements of depth of penetration might be too inconsistent to document modest changes in system sensitivity; procedures have been developed to quantify this measure. Since the image uniformity and **very-low-echo sphere** measurements are also related to system sensitivity and measure more frequent and diverse problems with the transducer and system, performance of these tests makes the **maximum depth of penetration** or relative penetration an optional measurement in Level 2.

11.2.2 Scanning system settings

The following is adapted with minor changes from IEC 61391-2:2010, 6.2.2 and 7.1. **Maximum relative depth of penetration** should be measured at the pre-set (default) frequency presented by the system for the most common application for that system and transducer and for any other transducer, whose sensitivity is suspect and is not already slated for repair after image-uniformity tests. To determine the **maximum relative depth of penetration**, the system-sensitivity controls should 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 near its maximum, i.e. as close as possible to the apparent **maximum relative depth of penetration**.

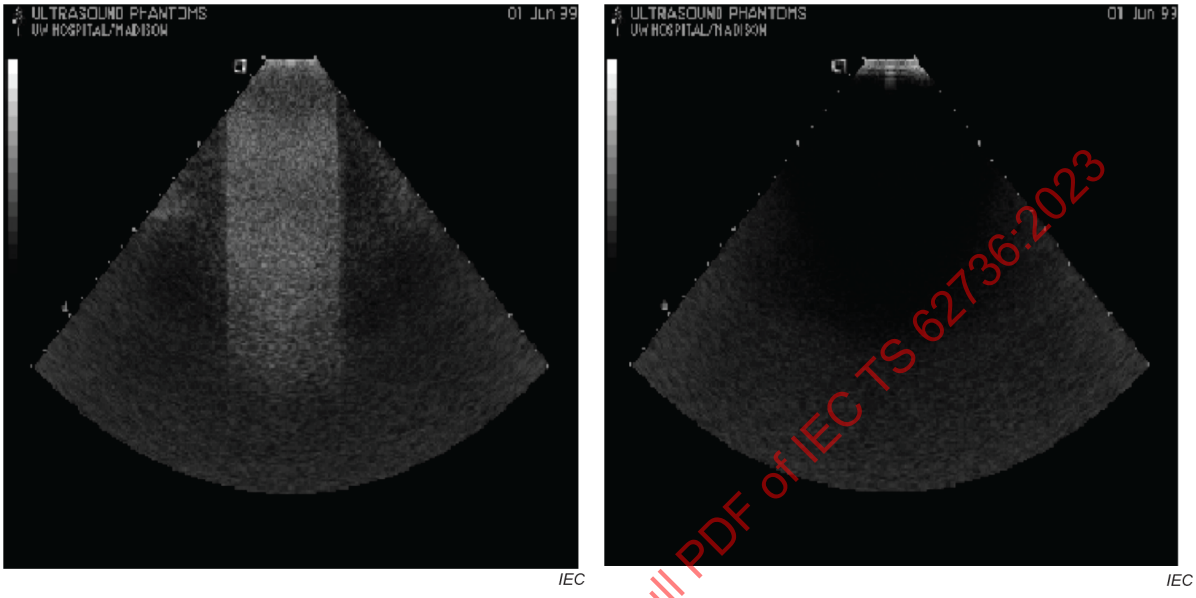
c) The system overall gain and **TGC** are set at high enough levels that electronic noise is displayed on the image monitor or until some pixels approach maximum brightness in the region where relative depth of penetration is measured. In the latter case, displayed dynamic range should be set to its largest setting. In either case, care should be taken to verify that image pixels are not saturated or that a real signal is not displayed as zero, i.e. pegged high or low.

Signal processing settings, such as logarithmic compression and other pre-processing functions, as well as image display settings, such as post-processing, should be in typical positions that are used clinically, preferably at the pre-set (default) frequency presented by the system for the most common application for that system and transducer and for the most difficult body habitus. If a pre-set is used, the intended clinical application for the pre-set as well as the above control setting values should be recorded.

These tests are performed in the most common mode employed, for example harmonic or fundamental. The latter is best in most cases unless the **phantom** is not deep enough to provide a measurement. If clutter from multiple scattering in the **phantom** appears to extend the measurement to unrealistic depths, consider choosing a different standard set of controls or consider the possibility that scattering in the **phantom** is too strong.

11.2.3 Image acquisition

The **maximum relative depth of penetration** is determined from the image-pixel **signal-to-noise ratio** versus depth. A cine loop of images is acquired while sweeping normal to the image plane across the relative depth of penetration **phantom**. For this acquisition, the scanner is optimized for maximum performance (Figure 5a). This optimization usually results in the background echo-signals from the **phantom** fading into the displayed electronic noise.



a) Image of a uniform section in a tissue-mimicking phantom; phantom is bright rectangle

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

[SOURCE: IEC 61391-2:2010, Figure 3.]

Figure 5 – Maximum relative depth of penetration – image acquisition

A cine loop of images also should be acquired with the transducer not coupled to the **phantom**, while using the same output, gain and processing settings. The latter image set will be used to compute the depth-dependent electronic noise level for the chosen transducer, receiver, and scanner signal-processing settings. This will result in an "electronic noise only" image, as shown in Figure 5b). It has been conjectured that transducer mechanical loading, when the transducer is coupled to the **phantom**, can result in different noise levels than when the transducer is in air. Be aware that this might occur. With wobbler transducers having a fluid path to the window of the transducer housing, where reverberations in the fluid path might be bad, and with new systems and styles of transducers, compare noise levels with the transducer in air and with the transducer coupled to a dummy load, such as a block of attenuating rubber that has similar acoustical impedance to the **phantom** but is not echogenic at depths encompassing the **maximum relative depth of penetration** in the **phantom**. If the noise level is lower with the anechoic block, use those measurements with that and similar transducers.

11.2.4 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 refers to the row (vertical position) in this matrix. Acquire a full cine loop of independent images, while slowly scanning the transducer normal to the image plane across the length of the **phantom** with each image labelled k. Then each voxel in a 3D-matrix is labelled $a(i,j,k)$. A mean value of $A(i,j)$ should be obtained by averaging data from all the images. The **mean pixel value** (grey level) versus 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 curved-linear arrays, it might 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 one-tenth of the sector width at the maximum depth. Similarly, $A'(j)$, the **mean pixel value** (mean numerical grey level in the ROI) versus depth should be determined for the image containing noise only.

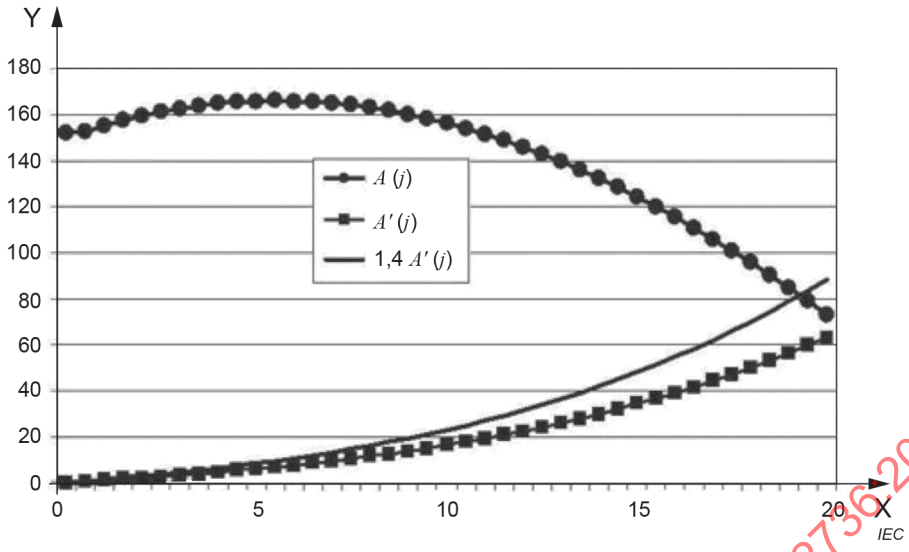
Typical plots of $A(j)$ and $A'(j)$ versus depth are illustrated in Figure 6. The $A(j)$ values are seen gradually merging towards the $A'(j)$ as depth increases. Let $s(j)$ be the depth-dependent echo-signal level, that is, the average echo-signal versus depth in the image in the absence of any electronic noise. Assuming the signal and noise are not correlated, and that the B-mode image is a display of the echo-signal level, it can be shown that the average signal versus depth for the image of the **phantom** is

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

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

$$SNR(j) = \sqrt{\frac{A(j)^2}{A'(j)^2} - 1} \tag{3}$$

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



Key

X depth into **phantom** (cm)

Y mean image **pixel** (data) **value**

Figure 6 – Mean digitized image-data value versus 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 should be taken as the **maximum relative depth of penetration,** or the **maximum depth of penetration,** if using a calibrated **phantom.** This corresponds to the ratio $A(j)/A'(j)$ = 1,4, i.e. where 1,4 $A'(j)$ crosses the $A(j)$ curve. Also, for cases in which $s(j)$ is not proportional to the echo-signal level, the value $A(j)/A'(j)$ = 1,4 should be used as a practical definition of the **maximum relative depth of penetration**.

Results of this immediate analysis of **maximum relative depth of penetration** should be recorded in a database [37] as referenced at the end of 10.2.4.

11.2.5 Commentary

Unlike the **performance evaluation** standard IEC 61391-2:2010, 7.1.3, this measurement of relative depth of penetration into an attenuating **phantom** cannot be used to compare imaging performance of similar systems, unless the tests are performed on the same **phantom** or with a **phantom** meeting the more rigorous specifications in IEC 61391-2. If the same **phantom** is employed, the **maximum relative depth of penetration** can be used to evaluate effects of system upgrades, and in some cases help identify faulty transducers when the fault results in subtle loss of sensitivity. Measuring the **maximum relative depth of penetration** can be useful during acceptance tests only when comparing with pre-purchase tests performed with the same **phantom**. Sometimes, added performance in depth of penetration is accompanied by decrease in lateral resolution because of preferential attenuation of higher frequency components of pulsed-ultrasound beams in tissue and, if low-pass filters are used, in the receiver of the ultrasound instrument. Thus, the **maximum relative 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, **relative depth of penetration** should be considered as a simple but valuable tool for estimating a "best case" of imaging, where only loss of signal or electronic noise limits the ability to visualize a large target.

Some imaging systems, particularly those operating at lower frequencies, provide depth of imaging performance that exceeds the available path lengths in most **phantoms**. When this is the case, one can only determine that the **maximum relative depth of penetration** exceeds the maximum path length available in the **phantom** and record and track the **signal-to-noise ratio** (SNR) at some specific region of interest (ROI) in the image field over time.

11.3 System-image display

11.3.1 General

Consistent presentation of ultrasound images is important as the images are transferred over picture archiving and communications systems (PACS) and displayed at various locations. This need for consistency in presentation is not unique to ultrasound image displays but applies to most medical imaging devices. As health systems grow larger and the number of remote imaging centres increases, it is imperative to ensure that images viewed on network-connected monitors are consistent with the images displayed on the scanner monitor and viewed by the sonographer when adjusting system controls. A standard called the greyscale standard display function (GSDF) has been widely adopted for grey-scale medical-image viewing, and it has addressed the need for consistent image presentation [32]. The GSDF is a mathematically defined mapping of an input "just-noticeable difference" (JND) index to luminance values on image displays based on the Barten model [32], which holds that equal changes in digital values result in equal changes in perceived brightness. The GSDF compliance can be achieved by transforming digital image values into digital driving levels (DDLs) accepted by a display device to produce luminance values that are related to input digital image values by the GSDF [32].

For the majority of medical imaging modalities, including digital radiography, CT, MRI, and nuclear medicine, the GSDF is followed for the image-review workstation display. However, in diagnostic ultrasound imaging, there is a wide variation in the current state of practice pertinent to the **performance evaluation** of the ultrasound display monitors, particularly in the area of consistent presentation between the scanner display and the PACS display. This inconsistency might stem from the following issues.

a) IEC 62563-2 categorizes medical display devices into three categories: I, II, and III. One of the main characteristics to determine which category an image display belongs to is the GSDF compliance. Only category III is designated for those image display devices that have luminance response functions other than GSDF. Ultrasound scanner displays should be categorized in accordance with IEC 62563-2 indicating II or III. Category III scanner displays can cause a great uncertainty in ultrasound image presentation along the imaging chain from scanner displays to other displays, including multi-functional reading-room workstation displays that follow the GSDF. If a scanner display is designed to be stand-alone or to be networked with only the displays of its own kind, the users should be made aware.

b) Some ultrasound vendors employ a strategy of applying image processing to the scanner-display look-up table (LUT) instead of to the images in the presentation-value (P-value) space. In such situations, the image enhancement achieved by processing on the scanner display is not transferrable down the presentation stream to the PACS display.

c) There is a lack of guidance specific to the ultrasound image modality. While there are standards for medical imaging displays, the guidance for various imaging modalities is generally provided with blanket criteria not ideal for the unique visual tasks and evolution of preference in diagnostic ultrasound-imaging procedures. Ultrasound images typically do not have the dynamic range of radiography from which the blanket criteria evolved. Also, the ambient light varies widely in ultrasound scanning rooms, leading to the necessity to specify the viewing conditions.

d) Test patterns of standardized display testing are not universally available on ultrasound scanners, limiting the visual evaluation of the ultrasound display performance to verify the consistency in presentation. Many users are obliged to rely on the ultrasound vendors to set up the display monitors with no **quality assurance** testing tools.

The evaluation methods described in IEC 62563-1 and [21] are for medical-image display systems in general. All test patterns referred to are specified in detail in the American Association of Physicists in Medicine's (AAPM's) TG-18 report [21] or its updated versions in the TG-270 report [33] and their equivalents in IEC 62563-1 and [40], and these patterns are available as digital images. Routine ultrasound system display assessments and recommended frequency of tests are described throughout 11.3 and summarized in Table 5. The assessments should be performed more frequently than specified here, if so recommended by the ultrasound (US)-system and interpretation-station manufacturers.

11.3.2 Level 1 tests of the US system and interpretation-station display

The display should be cleaned prior to testing.

The mechanical integrity of the display should be assessed via careful inspection for problems such as screen surface scratches, cracks, pen marks, and mechanical stability of the display support.

Visual assessment of overall display performance should be done with the TG18-QA pattern (see Figure 7) [21]. The 5 % contrast patches starting at 0 % and at 95 % of maximum luminance should be used to evaluate quickly the luminance contrast-response in the minimum and maximum-ends of the grey levels. The visibility of 5 % and 95 % should be clear. Along the 16 grey levels of luminance patches from the darkest to the brightest, each patch contains four small corner patches that differ by ±4 **pixel values** from the patch background, +4 in the upper left and lower right corners, −4 in the lower left and upper right corners. Using these patches, the user is able to evaluate the visibility of a subtle contrast level at 16 grey levels of background. Performed under the clinically used viewing conditions, this provides a visual assessment of the luminance contrast-response over the entire luminance range of the display. Alternatively, a simplified visual assessment is to verify the legibility of the characters "QUALITY ASSURANCE" with progressively decreasing contrast in the three patches of the minimum, median, and maximum grey levels. According to DIN 6868-157 [40], all the characters should be legible in the median and maximum grey-level patches, and at least "QUALITY ASSURANCE" in the minimum grey-level patch for displays in an examination room with immediate establishment of a diagnosis. Also, the user should visually assess the line-pair bar patterns at the centre and the corners, as well as verify the continuity of the smooth grey-scale ramps at the sides. In addition, make sure there are no artifacts, such as cross talk, video signal artifacts, burnt-in artifacts.

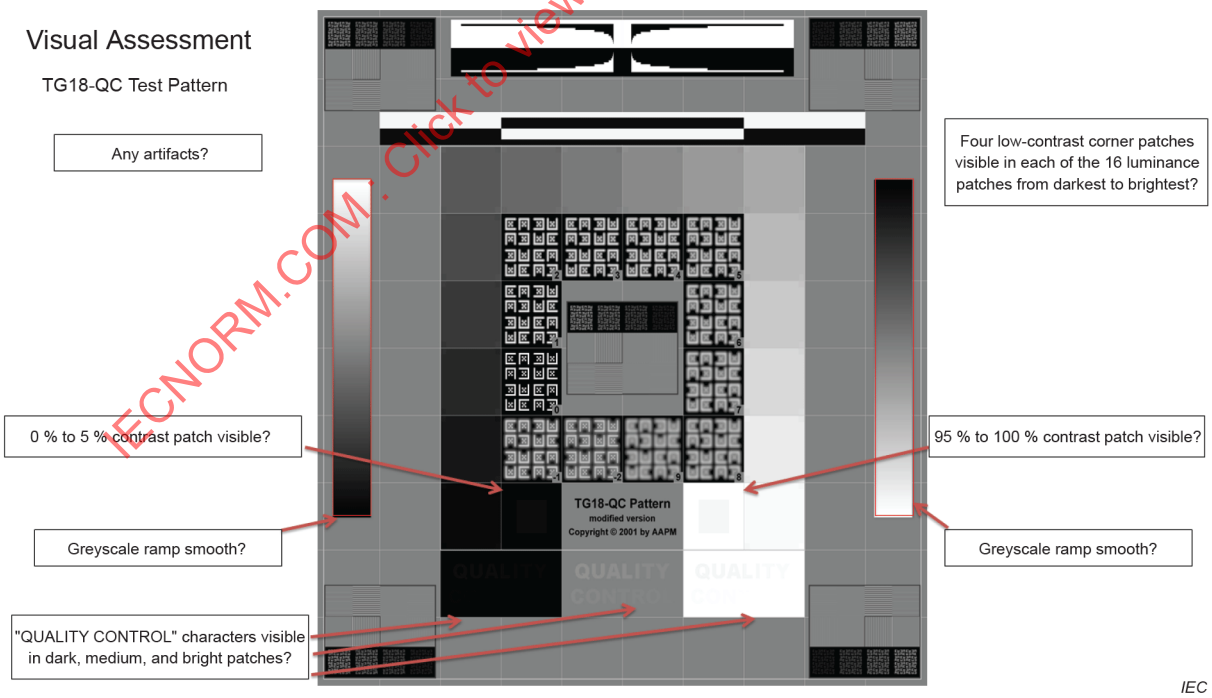


Figure 7 – TG18-QA test pattern for visual evaluation testing [21],[33]

11.3.3 Level 2 and Level 3 display tests

11.3.3.1 Ambient luminance

Ambient luminance (L_{amb}) refers to the luminance generated from the reflection off the surface of the display of sources of visible light, other than the display itself. The ambient luminance is superimposed on the user's view of the clinical image, reducing the image contrast and interfering with the visibility of the displayed image. Due to the mobile nature of ultrasound imaging systems, it is crucial to monitor the ambient luminance and its effect on the perceived luminance response of the display. The ambient luminance can be measured directly. However, it is not easy to do. Alternatively, the ambient illuminance can be measured and multiplied by the diffuse reflection coefficient (R_d) of the display screen to calculate the ambient luminance value, with the assumption that no specular reflection occurs in a well-controlled viewing environment. It is important to understand the different reflection properties of various displays. Typical values of R_d range from 0,002 $cdm^{-2}lux^{-1}$ to 0,010 $cdm^{-2}lux^{-1}$, though higher values are possible with glossy displays or protective panels [33].

The appropriateness of the ambient luminance level is determined by the safety factor a, the ratio of the ambient luminance (L_{amb}) versus L'_{min}, which is the sum of the minimum luminance (L_{min}) and the ambient luminance (L_{amb}). It is recommended that the safety factor a be less than 0,6 for category I displays as specified in IEC 62563-2. It is also noted that if the room illumination conditions are stable and the ambient contribution to the display luminance is considered in the luminance response calibration, then the safety factor a is not mandatory. Some ultrasound systems have display configurations for totally dark, semi-dark, and light viewing conditions. To accommodate the different ambient light levels, the minimum luminance of the display is increased for higher ambient light levels and the luminance response function is adjusted accordingly. It is important that the ultrasound system display is calibrated according to the assumed ambient light of the ultrasound imaging environment. In situations where the ambient light is not controllable, for example performing a portable ultrasound exam in a bright room, the user should be aware of the potential for degraded contrast at the lower end of the grey levels and can use the Level 1 visual assessment testing method described earlier to assess the reduction in the visibility of the low-contrast subjects in the darker region of the TG18-QA pattern.

11.3.3.2 Luminance response function

a) TG18-LN8-01 b) TG18-LN8-09 c) TG18-LN8-18

Figure 8 – Examples of TG18-LN luminance patterns for luminance measurements [21]

The quantitative evaluation tests involve measurements of the luminance values at various image grey levels. A set of 18 test patterns (TG18-LN-01 to TG18-LN-18) was designed for this purpose. Each pattern consists of a central test region embedded in a uniform background with central **pixel values** of 0, 15, 30, …, and 255 (see Figure 8). The patterns cover equal increments of **pixel value** over the entire range of **pixel values**. The luminance (L) at the centre

of the pattern is measured. The combined luminance for each step (L') is the sum of the measured luminance (L) and the ambient luminance (L_{amb}). These combined luminance values at various image grey levels are used to generate the luminance response function. It covers the range from the minimum luminance, L'_{min}, to the maximum luminance, L'_{max}, and the steps in between. Based upon the measured luminance response function, the contrast-response function is calculated and compared to the one calculated from the GSDF to check for GSDF compliance.

The AAPM-TG270 Report extends the luminance response measurement from the 18-point test in TG18 to a 256-point, full grey-scale evaluation [33]. This method is only necessary during equipment purchase evaluations and when troubleshooting, if further investigation is needed. Automated testing software for this kind of measurement is desirable.

11.3.3.3 Minimum and maximum luminance

The minimum luminance, L_{min}, is the luminance when the minimum **pixel value** is displayed. Based upon the manufacturer's configuration, this value can vary widely from near zero to above 1,0 cd/m^2. Given the recommendation of the safety factor $a = L_{amb}/L'_{min} \leq 0{,}6$ in IEC 62563-2, total darkness for L_{min} is not desirable. When L_{min} is too low, the effects of ambient luminance can obscure the contrast presented in the darkest regions of the image.

The maximum luminance, L_{max}, is the luminance when the maximum **pixel value** is displayed. Typically, the ultrasound scanner display has lower L_{max} than the reading room workstation displays. This condition is important to verify during acceptance testing. The stability of the maximum luminance should be verified during Level 2 and Level 3 tests.

The ratio of the maximum combined luminance ($L'_{max} = L_{max} + L_{amb}$) to the minimum combined luminance ($L'_{min} = L_{min} + L_{amb}$) is defined as the luminance ratio (r'). r' shall be greater than 100 for both category II and category III displays (IEC 62563-2). The stability of the luminance ratio should be verified during Level 2 and Level 3 tests. The r' can be monitored for a quick check of the presentation consistency from one display to another.

11.3.3.4 Contrast response

An observer's perception of image brightness and contrast is determined in part by the change in luminance for each grey level change, i.e. the slope of the measured luminance response function. The difference in luminance per grey level change is called the contrast response. Based upon the luminance response function, the contrast response function is calculated, which is then compared with the expected contrast response for a DICOM-GSDF display with ±20 % variation limits for category II displays (IEC 62563-2). It is an essential metric for presentation consistency.

11.3.3.5 Display luminance uniformity

Luminance uniformity can be inspected by checking the variation in luminance at different regions of the display of a uniform image as shown in Figure 9. The global uniformity of the display can be evaluated qualitatively by visually inspecting a uniform display, or quantitatively by measuring the luminance using a photometer at the centre and at the four corners of the display and calculating the maximum luminance deviation (Δ_L) as the following, with L_{high} and L_{low} being the highest and lowest luminance, respectively.

$$\Delta_L = 2 \times \frac{L_{high} - L_{low}}{L_{high} + L_{low}} \quad (4)$$

The criterion for maximum luminance deviation is 30 % (IEC 62563-2). Global nonuniformities usually do not interfere with clinical interpretations of the display [33], though such nonuniformities might reduce the displayed dynamic range in parts of the image. However, localized non-uniformities such as burnt-in artifacts or bad pixels are of greater concern as they can interfere with clinical interpretations.

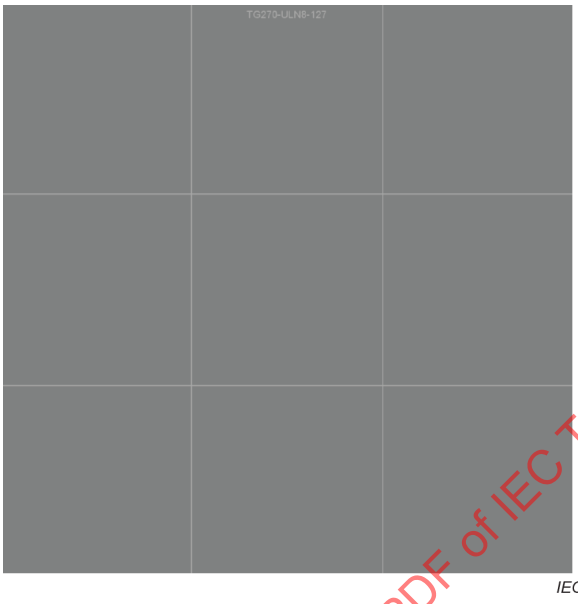


Figure 9 – TG270-ULN uniformity and luminance test pattern (TG270-ULN8-127 with background 8-bit grey level 127 is shown) [33]

Table 5 – Ultrasound image display QA tests

QA tests	Equipment	Patterns	Testing frequency
Visual inspection of display mechanical integrity	None	None	Monthly
Visual assessment of overall display quality	None	TG18-QA	Monthly
Visual assessment of luminance uniformity	None	TG18-UN80	Monthly
Ambient luminance	Photometer	None	Annual
Luminance response function and contrast response function	Photometer	TG18-LN-01 to TG18-LN-18	Annual
Global luminance uniformity	Photometer	TG18-UN80	Annual

A worksheet in the spreadsheet format is available as Table E.3 [41] for display **QA** of which the first sheet is a summary report of visual assessment and quantitative measurement results and the second sheet includes the 18-point luminance measurements and ambient illuminance measurement to assess the GSDF compliance. Additionally, a more comprehensive worksheet is available [41] to include more advanced testing such as chromaticity uniformity evaluation that, using a colour meter, measures the colour coordinates (u', v') at the centre and at the four corners of the display screen and verifies the chromaticity uniformity by checking the colour uniformity index $\Delta(u', v')$ in the (u', v') space [25], see IEC 62563-2. A full analysis of the colour performance over the entire luminance range of a display by measuring the colour coordinates (u', v') for various grey levels and the grey-scale chromaticity can be evaluated [25], see IEC 62563-2. The colour difference between two displays or multiple displays in the same image presentation chain can be evaluated in this way.

11.4 Distance and other spatial measurements

11.4.1 General

To be performed for all systems and transducers in Level 3 tests.

11.4.2 Apparatus and scanning system settings

Employ a **phantom** specified for lateral/axial/elevational-distance measurement accuracy, such as those detailed in IEC 61391-1. Settings can be those used for clinical imaging where absolute measurements are critical, for example, obstetrical, or at settings chosen to minimize the variance and bias in these tests. The latter employ a relatively high-contrast setting, for example, 60 dB or less dynamic range, **TGC** at reproducible settings showing distance targets at approximately uniform brightness, and gain or output to show the targets at moderately low brightness.

11.4.3 Image acquisition

In a test object designed for distance measurements, scan filaments or other targets from the window designed for that group of targets. The largest target separation should be sufficiently large for testing the accuracy over nearly the full range used with the transducer. If a ruler is imaged, scan it as described in 11.4.2. To test distance measurement in the elevational direction for a 3D- or 4D-scanhead, or even a linear array with some form of 3D tracking, align the transducer assembly so that each image scan plane is parallel to a filament or a distance marking on the ruler. Refine the alignment by ensuring that the distance markings on the ruler or the filaments can be visualized clearly, producing the maximum signal from the target that can be achieved by adjusting the tilt of the transducer assembly. Set the gain so that these targets are all visible as the 3D-sweep is performed, but not made larger than necessary in the display by use of a gain setting that is too high. Perform and record a scan and verify that all targets in the 3D field-of-view are seen clearly and fully without coupling artifacts. For distance measurement in the lateral and axial directions, perform the scans with similar alignment and precautions as for elevational measurements, but align so that the image plane is perpendicular to the filaments or markings on the ruler.

Repeat those tests for area and volume measurements when those measurements are automated or precise and unbiased measurements are particularly critical, as in many obstetrical assessment systems.

11.4.4 Analysis

Measure the filament positions or the distance marker positions at every 1 cm marker or some increment providing at least four measurements. Spacings and the distance between the two most distant positions should not differ from the expected values by greater than those set in the manufacturer's specifications. For distance measurements along the axis of the transducer, the measurement should not deviate from the expected value by 1 mm or 2 %, whichever is greater. For lateral and elevational distance measurements, the measurement should not deviate from the expected value by 2 mm or 3 %, whichever is greater.

Results of this immediate analysis should be recorded in a database (IEC 62563-2) as at the end of 10.2.4.

11.5 Performance in clinical use and evaluation of QA programme

Survey the chief user and interpreter of the **QA** tests whether changes or insufficiencies in system performance have been observed. Record and investigate any problems noted.

Assess the **QA** programme, evaluate variance and any bias in the measurements over time and compare with available norms. Check that appropriate actions are taken to correct problems. Identify areas where **QA** testing can be improved.

Annex A
(informative)

Example phantoms for full coupling with curved arrays, particularly for image uniformity tests

A simple method for creating **high-contrast, low-echo-spheres** and a random distribution thereof in a relatively low-cost **phantom** has been described [42]. A **phantom** for linear arrays and curved-linear arrays for image-uniformity tests and allowing for the optional relative-depth-of-penetration measures is illustrated in Figure A.1. This **phantom** is a solid block of gel or urethane with a homogeneous distribution of scatterers. The 9 cm wide well in the top aids coupling of curved-linear arrays. A more compact **phantom** of similar materials, except high attenuation to avoid reverberations, is shown in Figure A.2. Two circular wells are shown for scanning by rotation of the transducer rather than a linear sweep. The large and small wells are for slightly and tightly curved linear arrays, respectively. A versatile **phantom** with a conical well to accommodate various radii-of-curvature (ROC) of arrays is shown in Figure A.3. Two temporally stable, inexpensive **phantoms** for image uniformity tests are shown in Figure A.4.

For more rigorous measurements, with less chance of acoustic-contact problems [3], scatterers in a constantly stirred, well mixed, liquid can be employed. No scanning motion is required. The transducer is lowered into the liquid at the minimum distance to establish good acoustic contact; then cine loops are acquired.

Dimensions in centimetres

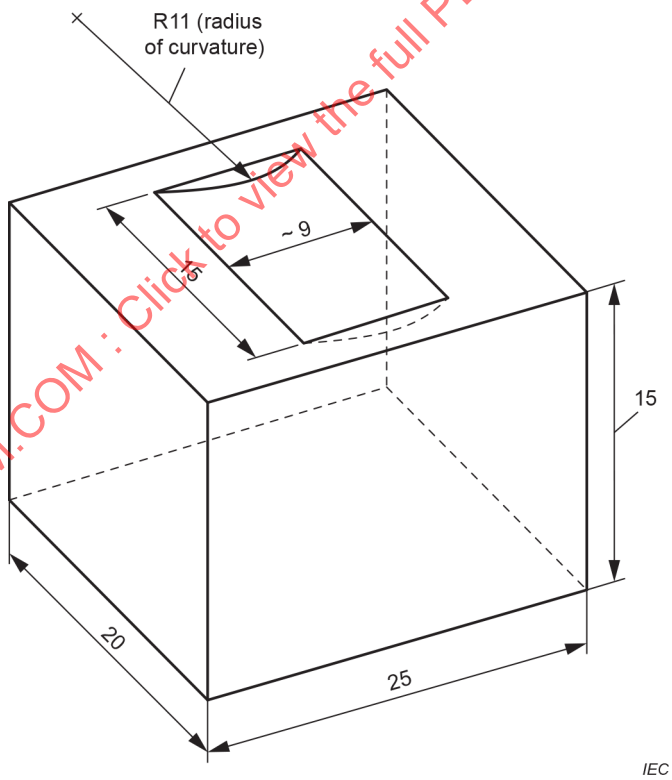


Figure A.1 – Example phantom for image-uniformity and maximum relative depth of penetration tests

Dimensions in centimetres

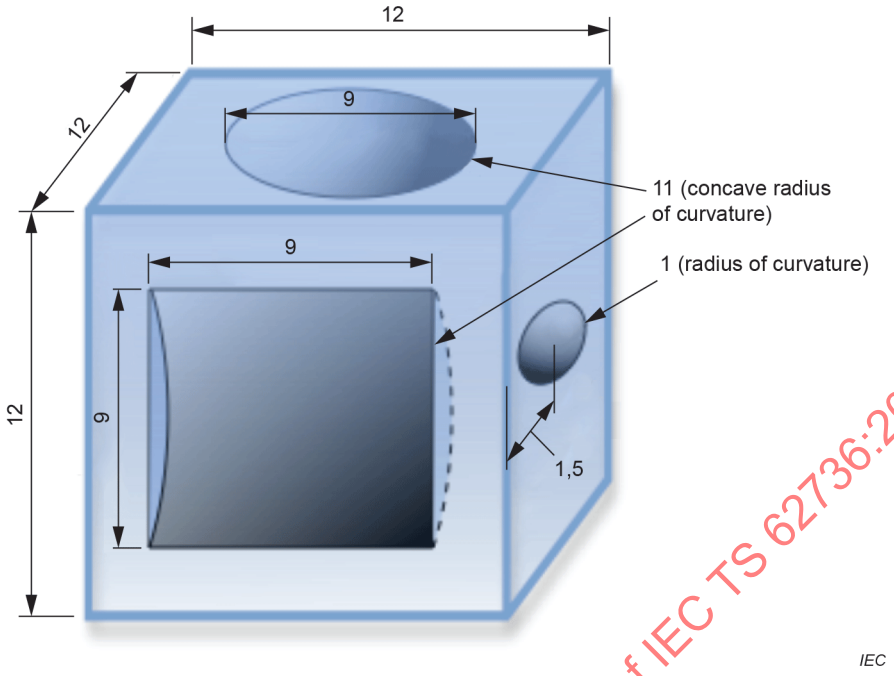


Figure A.2 – Example compact phantom for image uniformity tests

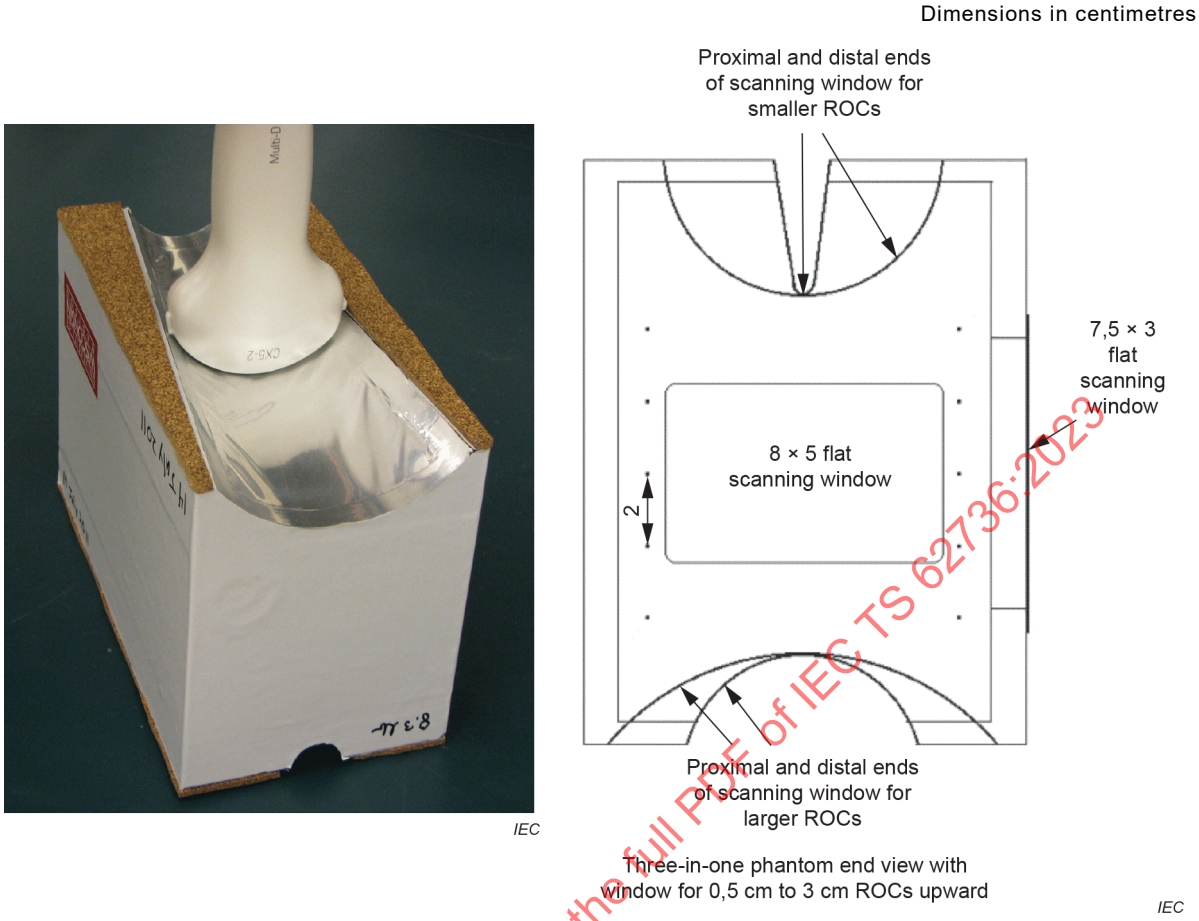
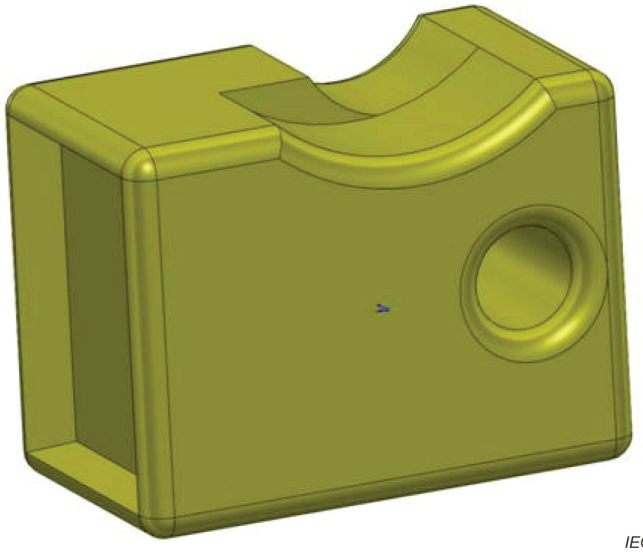


Figure A.3 – Photograph and drawing of a three-in-one phantom which provides for determination of distance measurement precision and bias, image-uniformity, very-low-echo sphere visualization, and depth of penetration [39]

Two cone-shaped scanning windows are on opposite sides; together the two windows allow direct contact of convex (curved) arrays with any radius of curvature (ROC) from 3,5 cm through 6 cm. The scanning window that accommodates ROCs from 2 cm through 6 cm is directed upward in the photograph; the windows have a metallic appearance because they consist of plastic-coated aluminium foil, which transmits the ultrasound beam but suppresses desiccation of the tissue-mimicking **phantom** material. The cork layers are for preventing sliding of the **phantom** when on a smooth surface. A third flat scanning window is shown on the side of the **phantom** for accommodating other transducer shapes such as linear arrays and phased arrays. More specific **phantom** designs for **very-low-echo spheres** are presented in IEC TS 62791.

Figure A.4a) depicts a uniformity **phantom** of rubber material flexible enough to fit many transducer shapes, but too flexible for built-in distance calibration points or filaments unless a rigid plate with ridges are attached to the bottom and right end. This **phantom** would serve better if a bit thicker. Figure A.4b) depicts a fast, reliable uniformity **phantom** that is almost as compact and robust as that in Figure A.4a)



IEC

a) A compact uniformity phantom of durable rubber material for many transducer shapes[5]

IEC

b) A uniform phantom with soft scanning surface to conform to all diagnostic transducer shapes[6]

Figure A.4 – Two temporally stable, inexpensive phantoms for image uniformity tests

5 Gammex Sun Nuclear Model Sono TE (https://www.sunnuclear.com/products/sono-ultrasound-phantom accessed 2021). This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products.

6 CIRS Model 551 Uniformity Phantom (https://www.cirsinc.com/product-category/ultrasound/ accessed 2021). This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products.

Annex B
(informative)

Available analysis software

B.1 Open source software for assessment or tracking of ultrasound image QA data

Some examples of known software for **QA** purposes are listed below[7][1]:

– UltraIQ™ (Cablon Medical, NL)

  This company has developed a software application for automated evaluation and reporting of ultrasound systems dedicated to Level 2 and Level 3 applications, including image uniformity. (http://www.ultraiq.com); accessed 2021-06-24.

– QA4US™

  G. Weijers, J. M. Thijssen, and C. L. de Korte. Quality Assurance 4 medical UltraSound equipment. (Radboud University, Nijmegen, NL) MUSIC QA4US website; accessed 2020-06-24; a modular software package that can be used for Level 2 and Level 3 test requirements.

– CIRS QA Portal

  Software included with the purchase of any of four general-purpose **phantom** models (CIRS, Inc. Norfolk, VA, USA. https://www.cirsinc.com/software/qa-portal/ , accessed 2020-06-24).

– QA Track Module, Ultrasound

  Tracking of QA data and bar code-based tracking of transducers and systems, Attrix Medical Systems, Minneapolis, MN, USA.

  https://www.atirix.com/Products/QC-Track/Modalities/Ultrasound.aspx

– Nottingham USQA

  Nottingham University Hospitals, Medical Physics & Clinical Engineering, UK; software developed by the ultrasound group to evaluate Level 2 and Level 3 tests.

Image Uniformity Quantification Software: One algorithm is described here as an example of quantitative measurements of image uniformity and as a convenience to users of this document. This multi-platform software is available as a plug-in to NIH ImageJ. (Free at https://github.com/sclarsonmp/Ultrasound-uniformity. Maintenance for latest operating systems might be demanding.) TIFF images and stacks and uncompressed DICOM data containing rectangular and arc scan regions are processed. A median image of the image stack is created with one plug-in and the data are analysed with either the linear array or convex curved-linear array plug-in. The operator positions and resizes the analysis window below the main transducer ring-down and for a distance of approximately one-eighth of the total depth of the image. Additionally, one can reposition the window to catch any variations of concern. Output of the analysis is shown in Figure B.1.

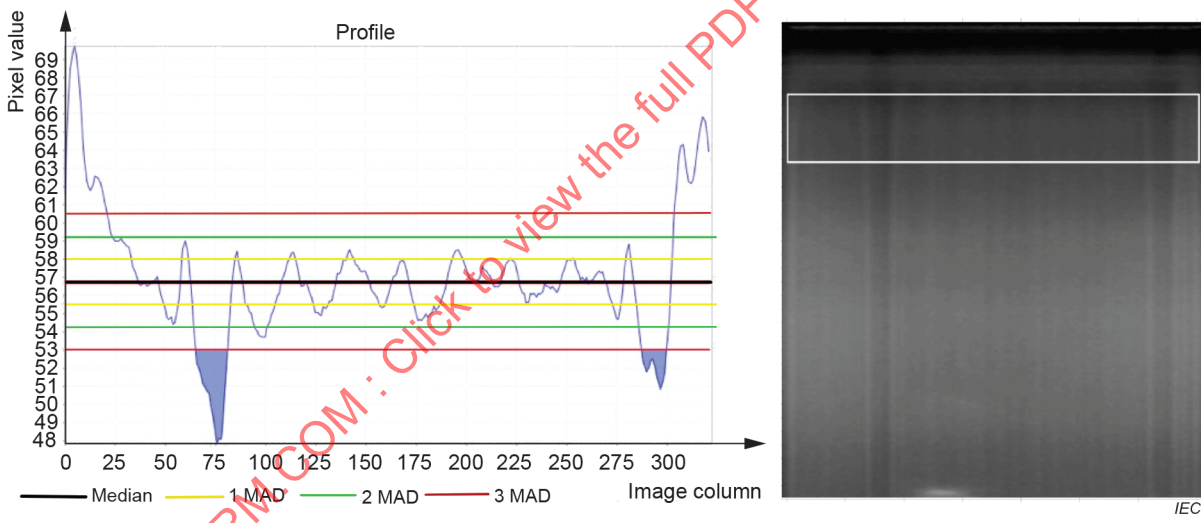
Before exporting the profile to a spreadsheet, the threshold for defect detection is considered. The threshold should be at the institution's standard value (recommended three times the **median absolute deviations** from the data's median, 3 MADs). The MAD is similar to the standard deviation.

7 This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products.

Before the profile is exported from the plug-in, the number of transducer elements in the tested array should be set at the known value (set at 128, if unknown). This gives, as in Table B.1, the normalized signal below 3 *MAD*s integrated over all scan lines in each signal valley, as well as the same integration over columns one-element wide.

In Figure B.1 data are analysed for the transducer in Figure 1 but without the nylon filament obstructing some central elements. On the left, the profile of median **pixel value** is plotted for each image column in the white analysis box in the median image on the right. Tentative recommended action thresholds are as follows:

A signal valley of area (in columns one-element wide) divided by a mean greater than 0,4 is worth counting as a defect of possible concern. More than two such defects are worthy of recommending repair, replacement or further testing. A finding of normalized area greater than 0,9 in a single valley is worthy of an "unacceptable" rating and a request for repair, replacement or further testing. A strong justification should exist for a recommendation of no further action. These recommendations are yet to be verified on a large number of transducers and, in any case, might be subject to the individual institution's assessment of the importance of the defect to clinical practice. These quantitative criteria assume correct entry of the number of transducer elements. If this number is unknown, a reasonable guess for high-end systems in 2021 is (128 + 192)/2 = 160. Taking the area of the dip in **pixel values** is like taking a certain number of decibels assuming a standard dynamic range setting and a purely logarithmic characteristic curve. This latter assumption is most accurate in the middle of the image brightness range.



Profile columns below 3 *MAD*s (**median absolute deviations**) are shown in blue.

Figure B.1 – Example of data analysis for the transducer evaluated to generate Figure 1

After being made aware of these defects by this procedure and having quantitative measures to test, the user can follow minor acceptable defects until replacement, if further degradation occurs. Alternatively, on a servicer contract allowing a certain transducer replacement rate, the most defective transducers currently in the user's possession can be replaced as the no-cost opportunity arises. See below for a step-by-step example of performing this analysis.

The bottom two rows of Table B.1 provide a listing and measured characteristics of the signal dips. "Min" and "Signal at half max" are in **pixel values**. "Area" is integrated **pixel value** in the dips and "mean" in "Area/mean" is the **mean pixel value** in the analyzed area of the image. "Dip depth (dB)" is the maximum depth calculated assuming a purely logarithmic compression and the entered dynamic range of 70 in this case. "Dip Area (dB elements)" is just the integrated dip area in decibels. Another column should be added, giving the distance of each dip from the end of the transducer that has the bump or ridge provided on it to aid orientation in clinical use. *MAD* is defined as the median of the absolute deviations from the data's median. These sheets can be worksheets in a workbook for the given transducer, scanner or facility. A master spreadsheet should keep the results for a given transducer in a column for documentation and analysis of change.

Table B.1 – Output of image uniformity analysis

Filename:	/Volumes/Englewood/Users/pearson9b/locoHills2/ASmallFryies/_AAPM_AQB_AIUM_IEC/IE						
Institution	U of M	Test Date	8/9/09	Analaysis D	2/10/013		
Scanner model		S/N					
Transd. Model	7	S/N					
Uncompounded (Y/N)?		Scanner Preset					
Settings: Gain		TGC		Focal depth	5 mm		
Other Settings:							
Dip Threshold (-MAD below mean):	53.29						
MAD is defined as the median of the absolute deviations from the data's median							
MAD	1.24						
Mean	57.01						
MAD/Mean	0.02						
Dynamic Range (dB)	70.00	<-- Enter local dynamic range setting					
# elements:	128.00	<-- Enter number of elements in array					
Horizontal scale (image pix/elt)	2.54						
Dips:	Min	Signal at half max	Area at FWHM	Area/mean	Area in elements/mean	Dip depth (dB)	Dip Area (dB elements)
1.00	47.84	52.43	104.76	1.84	0.73	2.51	11.49
2.00	50.82	53.92	66.50	1.17	0.46	1.69	6.60

B.2 Example of QA control chart

A control chart can plot results of a series of measurements over time. Confidence limits or control limits or standard deviations of the data are plotted as horizontal lines showing the likelihood that a point is deviating from the mean due to other than the fluctuations in the data, assuming a random, Gaussian measurement error. In the example of Figure B.2, the sudden increase in the area of the dip, if reproducible, indicates transducer, cable or electronic degradation that warrants repair, replacement or further diagnosis. The dip is shown as stable for several months within three standard deviations from the mean before jumping to a more serious defect. This apparent change is more cause for concern than a modest stable defect. The dip area is labelled in depth of the dip in decibels integrated over the number of involved transducer elements.

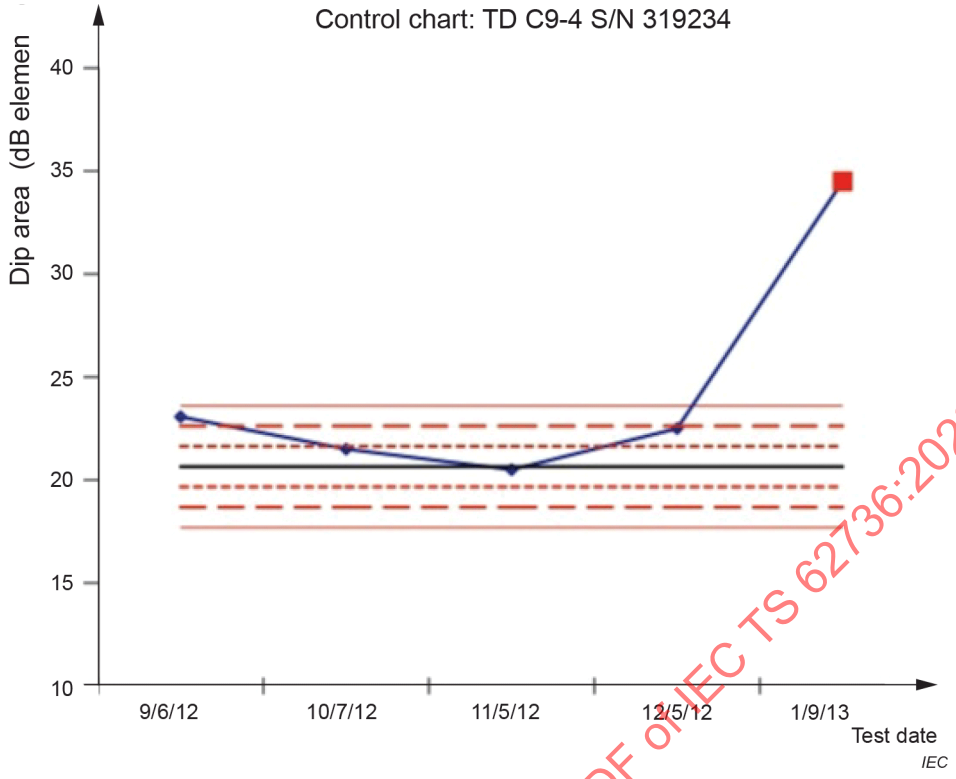


Figure B.2 – Control chart for a dip in the middle of the profile for one transducer (TD) model, C9-4 and the specified serial number (S/N)

Annex C
(informative)

Electronic test methods and test methods provided by the manufacturers – Relation to clinical significance

Two methods are discussed in 8.3, namely electronic test methods from an independent supplier and test methods provided by the manufacturers. Manufacturers are encouraged to supply detailed results of transducer tests performed internally by the system. A device for complete electrical tests of the transducer cable and the elements was sold commercially as Sonora FirstCall[8] but its availability has been subsequently restricted. A system for imaging the surface vibrations of a transducer array can fully check the transmission capabilities of even a 2D imaging array without requiring electrical connections and pin-to-element knowledge [36], see IEC 61390.[9]

The test methods in this document for transducer element and channel malperformance are quite sensitive, but their connection to image quality at the depths of interest in the image plane are not fully understood. Professional judgement is used to determine actual thresholds for various actions to improve the system performance after defects and, possibly, evolution thereof have been documented by these tests. When questionable defects are detected, further testing should be carried out with existing IEC **performance evaluation** documents (IEC 61391-1, IEC 61391-2, and IEC TS 62791 or IEC TS 62558). More specific image-quality performance-evaluation methods can help elucidate the importance of various transducer defects in relation to the various costs of transducer replacement or repair.[10]

8 This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products.

9 This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products.

10 A full-blown clinical trial in various clinical applications with defective and properly functioning transducers would be useful but extremely expensive. A useful test method, however, could involve use of the simulated ideal observer and simulated image artifacts on databases of borderline pathologies with adjustable lesion contrast and simulated element/channel dropout.