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BSI Standards Publication

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

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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- the subject is still under technical development or where, for any other reason, there is the future but no immediate possibility of an agreement on an International Standard.

Technical Specifications are subject to review within three years of publication to decide whether they can be transformed into International Standards.

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

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

Enquiry draft	Report on voting
87/576/DTS	87/592A/RVC

Full information on the voting for the approval of this Technical Specification can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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 publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- transformed into an International Standard,
- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

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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 often critical to patients' well being, it is important that the systems perform consistently at the level provided and accepted in initial tests, e.g. those of IEC 61391-1 and IEC 61391-2. 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 subperformance of a transducer-array element or lens or of a cable or electronic channel. Sensitive image uniformity tests for these transducer- and channel-failures are presented in this document for use monthly (Level 1), biannually (Level 2) and biennially (Level 3). With approximately 14 % transducer-failure rate and 10 % system-failure rate per year on first testing [1],[2],[3],[4],[5],[6],[7],[8],[9],[10],[11],[12], there are, very approximately, 100 000 systems worldwide routinely performing suboptimal diagnostic exams for part of the year.

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

Modern flat-panel display technology is more stable than, and generally far superior to, earlier CRT displays. However, LCD displays can still exhibit luminance drift, as well as problems such as defective pixels. It is still necessary to evaluate them periodically.

ULTRASONICS – PULSE-ECHO SCANNERS –

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

1 Scope

This document specifies requirements and methods for periodic testing of the quality of diagnostic medical ultrasound systems with linear array, curved linear array, single element, annular array, phased array, matrix linear array transducers and two-dimensional arrays. Image interpretation and measurement workstations are included. Usually, "periodic testing" is referred to here as "quality control". This document represents a minimum set of such tests intended for frequent users of medical ultrasound systems, for quality control professionals in their organization, or those hired from other quality-control and/or service-provider organizations. System-manufacturing and repair companies might well employ other or additional tests. The tests are defined in three levels, with the simplest and most cost-effective performed most frequently, similarly to [1]. More complete tests for acceptance testing and for assessment at times of particular importance or concern are specified in IEC 61391-1, IEC 61391-2 and IEC TS 62791 [15]. These more complete tests are categorized as performance evaluation, rather than quality control or frequent periodic testing.

This document also defines terms and specifies methods for measuring (for quality maintenance or quality control) the **maximum relative depth of penetration** of real-time ultrasound B-MODE scanners, though this penetration measure is listed as less frequently applied.

Frequent distance-measurement accuracy tests are recommended only for certain classes of position encoding that are not now known to be highly stable and without bias.

The types of transducers used with these scanners include:

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

Transducers not readily amenable to transducer-element testing by the simple image-uniformity procedures specified (for example, phased array and 2D-array transducers) are tested only partially by maximum relative depth of penetration. 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 program. Dedicated Doppler systems are excluded from coverage here as specialized equipment is required to test them. This test equipment can be specific to the intended application of the Doppler system.

All scanners considered include basic pulse-echo techniques. The failures to be detected by the recommended pulse-echo tests also will affect the operation of other modes, such as colour-flow, harmonic-, elasticity- and compound imaging. The test methodology is applicable for transducers operating in the 1 MHz to 17 MHz frequency range and could be made applicable up to 40 MHz, if the depth of penetration were allowed to be relative, rather than

absolute, and phantom stability were verified [15]. Image-uniformity QC is applicable to transducers operating in the 1 MHz to 40 MHz frequency range as the requirements for phantoms are not stringent.

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 17 MHz.

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>)

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

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

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 terminological databases for use in standardization at the following addresses:

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

3.1
addressable patch
smallest addressable group of transducer elements

3.2
echo from weakly reflecting, background scatterers
echoes from many small targets in which the scattered field is much less intense than the incident field

3.3
maximum depth of penetration
maximum range at which the ratio of the mean, digitized, B-mode-image data corresponding to images displaying **echoes from weakly reflecting, background scatterers** to the mean, digitized, B-mode-image data corresponding to images displaying only electronic noise equals 1,4, when the **echoes from weakly reflecting, background scatterers** are generated in a phantom with properties meeting the specifications of IEC 61391-2.

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

3.4
maximum relative depth of penetration
maximum range at which the ratio of the mean, digitized, B-mode-image data corresponding to images displaying **echoes from weakly reflecting, background scatterers** to the mean, digitized, B-mode-image data corresponding to images displaying only electronic noise equals 1,4, when the **echoes from weakly reflecting, background scatterers** are generated in a phantom with properties meeting specifications more relaxed than those of IEC 61391-2

Note 1 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 2 to entry: For available phantoms and specifications see [16] and for a potential alternative measure of depth of penetration see [17]

Note 3 to entry: The **maximum relative depth of penetration** is expressed in metres (m) and conventionally in centimetres (cm).

3.5
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].

3.6
performance evaluation
tests performed to assess specific absolute performance of the object tested

Note 1 to entry: Typical times for ultrasound system performance evaluation are at pre-purchase evaluation, new and repaired system acceptance testing [19],[20],[21],[22],[1] at time of performance difficulties, and end of useful life evaluations. They are recommended for performance in Level 3 QC tests, though that is not required.

3.7
phantom
device designed to mimic some aspects of the human body for the purposes of testing or training

3.8
specific attenuation coefficient
attenuation coefficient divided by the frequency

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

3.9
quality control
QC
regularly performed procedures to assure consistent performance

Note 1 to entry: A more descriptive term is quality maintenance; quality assurance is also used.

3.10
equivalent sensitivity
sensitivity that is statistically the same or has smaller variance and bias

4 General recommendation

The manufacturer’s specification should allow comparison with the results obtained from the tests described in this document.

5 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 %; 45 % to 75 % for relative depth of penetration;
– atmospheric pressure, 66 kPa to 106 kPa; 86 kPa to 106 kPa for relative depth of penetration.

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 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.

6 Quality control levels

6.1 General

These levels are based on the time required for performance and the interval between tests. Small facilities with a single ultrasound system might not be expected to perform Level 3 tests except for distance-measurement variance and bias or when problems are suspected that are not rapidly addressed by a service call. These levels are similar to those recommended by the European Federation of Societies in Ultrasound in Medicine and Biology [1].

6.2 Level 1 tests

Level 1 tests are short-duration (approximately 5 min) checks, to be performed monthly by the ultrasound system users, which require no special equipment, only record keeping. They are simple to perform and record with limited practice. Alternative methods of proven and at least **equivalent sensitivity**, as well as interpretability to end users, may be employed. See Table 1.

Table 1 – Outline of Level 1 tests

Test	Evaluation	Possible subsequent actions
Inspection for: Damage to transducer face or housing Damage to cable Stable wheel mounts Clean air filters	Visual	Level 2 tests or maintenance (immediately or at interval specified by the manufacturer)
Image uniformity	Visual with clean transducer face held in air	Level 2 tests or maintenance
Monitor function	Visual	Level 3 tests, adjustments or maintenance
Hard copy and image storage function	Visual	Adjustments or maintenance
Performance in clinical use	Ask users whether any changes in or insufficiencies in the system performance have been observed. Record and investigate any observations mentioned by users or interpreters	Level 2 or 3 tests, adjustments or maintenance

While both Level 1 and Level 2 tests are simple, it may be helpful to have a quality control professional, such as a medical physicist or hospital engineer, involved, to assure initiation of the tests and adequate record maintenance over an extended period of time.

6.3 Level 2 tests

Level 2 tests are performed every six months by users or QC professionals. They are simply Level 1 tests plus a more sensitive version of the image-uniformity test and any other tests indicated for special conditions such as mechanically scanned transducers. This more sensitive image-uniformity test is performed with a phantom and averaging of a cine loop. See Clause 9. Alternative methods of proven and at least **equivalent sensitivity** and interpretability to end users may be employed.

6.4 Level 3 tests

Level 3 tests are performed by QC 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: Levels 1 and 2 tests, plus measurement of **maximum relative depth of penetration,** and system- and interpretation-image displays. Distance-measurement variance and bias tests are required initially on some systems and regularly on others. See Table 2 and Clause 10. 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, but this is not required. 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 control but are treated separately because they are covered by other standards already described. Several Level 3 procedures are specified by reference. In large medical systems with many inexpensive ultrasound systems, 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 Levels 2 and 3 quality control and correction of malfunctions.

Table 2 – Outline of Level 3 tests additional to those in Table 1

Test	Evaluation	Possible subsequent actions
maximum relative depth of penetration	See 10.2; Preferably absolute as in IEC 61391-2:2010, 7.1	Adjustment or maintenance
System- and interpretation-image displays	Tests listed here	Adjustment or maintenance
Distance-measurement and bias	See 10.4 and IEC 61391-1:2006, 7.4	Adjustment or maintenance
Contrast-detail detectability (optional)	IEC TS 61390:1996, 6.3.2.3 [23]	Adjustment or maintenance
Spatial resolution (optional)	IEC TS 62791 [15] or, in lateral, axial and elevational directions, IEC TS 61390:1996, 3.12, 6.3.2 [23], or, in lateral and elevational directions combined, IEC TS 62558 [24].	Adjustment or maintenance
Evaluation of QC program	Assess the QC program, check that appropriate actions are taken to correct problems, identify areas where QC testing may be improved.	Adjustment of procedures

In large hospitals and clinics with many inexpensive, as well as high end, ultrasound systems, 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 Levels 2 and 3 quality control and correction of malfunctions.

7 Equipment and data required

7.1 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.

7.2 Phantoms

7.2.1 Phantoms for Level 2 and/or Level 3 quality control

See 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 [19],[25],[26],[27],[28],[29],[30]. Phantoms without other backscatter generators require particles, such as 40-micrometre-diameter glass beads to provide backscattered signals at a controlled amplitude [31],[32]. Several manufacturers[1)] can produce tissue-mimicking materials and phantoms that comply with the following specifications in 7.2.2 and 7.2.3.

7.2.2 Phantoms for Level 2 quality control only

These specifications should be met in the 1 MHz to 17 MHz frequency range except as noted. More stringent requirements are listed in 7.2.2 for Level 3 tests other than image uniformity:

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, below.
Density:	(1,00 ± 0,3) g cm^{-3}
Specific attenuation coefficient:	(0,3 to 0,9) dB $cm^{-1}MHz^{-1}$ or (1,4 ± 0,4) dB $cm^{-1}MHz^{-1}$ for a compact image-uniformity phantom. The high value minimizes reverberation artifacts.
Backscatter coefficient:	(3×10^{-4} $cm^{-1}sr^{-1}$) ± 10 dB relative to that number at 3 MHz with dependence on "frequency to the n" (f^n), where $1 \leq n < 4$ from 1 MHz to 17 MHz for a combination image-uniformity and relative-depth-of-penetration phantom.
Scanning surface:	The scanning surface should allow acoustic contact of the entire active area of the transducer with the phantom.

1) These include, for example, ATS Labs; Bridgeport, CT, USA (www.atslabs.com); CIRS, Norfolk, VA, USA (www.cirsinc.com); Gammex/RMI, Middleton, WI, USA (www.gammex.com), and Kyoto Kagaku Co., Ltd, Kyoto, Japan (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.

Dimensions: The phantom should provide a uniformly scattering and attenuating field that extends to a depth of at least 6 cm.

7.2.3 Phantoms for both Level 2 and Level 3 quality control

"**Maximum relative depth of penetration**" is used here, rather than "**maximum depth of penetration**", as defined in the referenced standard (IEC 61391-2), because more expensive and perhaps less robust test objects, which are required for the absolute measurements defined in that standard, are not absolutely required for quality control. However, absolute measures are recommended, using phantoms defined 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, similar to those specified in IEC 61391-2 except that a phantom's acoustic-properties 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.

Phantom material requirements for Level 3 QC over 1 MHz to 17 MHz are:

Speed of sound (SOS): (1 540 ± 20) m s^{-1}, to avoid substantial complications.

When 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 control. 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 tracked carefully in quality control. When filaments are included with appropriate spacing to simulate 1 540 m s^{-1} SOS for each of the scan geometries available on the ultrasound system, then (1 500 ± 80) m s^{-1} at 3 MHz is tolerable. This latter extreme flexibility is allowed with great warnings because of the convenience and longevity of urethane rubber phantoms at, typically, 1 450 m s^{-1}. However, for the majority of ultrasound systems, those that assume 1 540 m s^{-1} propagation speed, 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[2)]. In other words, it is impossible for a single set of filaments to provide correct lateral distance measurements for different curved linear-array curvatures or for 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 they are designed. Users should be instructed to use a filament group with curvature close to that (within a certain tolerance) of the transducer, as can be seen easily on the image of the filaments.

Phantom stability:

Specifications should be met for a period of at least 5 years, warranted for that period by the phantom's manufacturer. The warranty can include the expectation of regeneration, for example, via replacement of solution lost to desiccation, if procedures and costs are specified. A method of testing for stability of the phantom within specifications should be provided. In many cases, a manufacturer's labelling of the mass of the phantom and time interval at which weight should be tested can meet this need. When a phantom is starting to desiccate, as water-based phantoms do, or otherwise decay, transition of existing QC

2) Lateral is referred to as azimuthal with phased arrays.

data to that with a new phantom is possible, if the two phantoms have consistent acoustic properties. If such a transition is attempted, note clearly the time of the change.

Density:	(1,00 ± 0,11) g cm^{-3} stable to within ± 0,02 g cm^{-3}
Specific attenuation coefficient:	(0,7 + 0,2 / – 0,05) dB $cm^{-1}MHz^{-1}$ in the 1 MHz to 17 MHz frequency range
Backscatter coefficient:	(3×10^{-4} $cm^{-1}sr^{-1}$) ± 10 dB relative to this number at 3 MHz with dependence on "frequency to the n" (f^n), where $1 \leq n < 4$ from 1 MHz to 17 MHz for a combination image-uniformity and relative-depth-of-penetration phantom. 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 water 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). 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 may 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 61391-1:2006.

7.3 Image data

7.3.1 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 300 × 300 pixels and at 8 bits (255 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 data are desired by many users. As described in Annex B, software is offered commercially and free that is purported to simplify acquisition of these data, their recording, storage and immediate and long-term analysis.

Scanners for which this document applies may 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 [33] – images from the scanner.

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

b) Other digital-image files available from the scanner itself, lossless 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 QC 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 has to be provided under stable conditions to minimize signal distortions. Specific care and attention has to be taken for the following aspects.

- 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 8 bits or 256 grey levels is necessary.
- Conversion-function linearity has to be assured.
- The display spatial resolution (given by the pixel size) of the digital picture shall be at least as good as 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 has to be used to avoid reflections in the line.
- Image test patterns are required for scanner display testing.

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, but this is more difficult to control quantitatively.

7.3.2 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 a minimally compressed 'tiff' (Tagged Image File Format), or an uncompressed format, such as a raw or a DICOM-format, to work stations that have access rights to the image data.

Clips are sometimes only sent from the ultrasound scanner in compressed format. Those clips can be sent with compression minimized and eliminated, if possible. Or, as long as compression ratio/quality factor is kept constant over time, useful QC measurements can be made from compressed clips, as long as all system settings affecting the measures such as gain, output, focal zones, are kept constant. It is strongly recommended that all such settings be maintained consistently through all QC-testing between the same and similar systems through use of QC-presets.

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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, but this is more difficult to control quantitatively.

7.4 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 (N ≈ 1 to 10) of sequential elements. 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. This 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 5 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 QC-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 electrical tests for which there are strong data showing a good correlation with these QC-measures and which provide a mapping and summary of element performance may be employed by the user. However, the QC-tests 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 employed by the end user. The capability for calibrating the system display to the DICOM grey-scale standard display function should also be provided [33]. Optimal display calibration is appropriate and important for the ultrasound-scanner display since, in practice, this display is used for diagnostic interpretation.

For compliance with this document, manufacturers should provide a description of how to recover presets (reference settings with complicated sets of parameters), since such settings are affected by software updates. They should provide a capability to rapidly recover such settings.

8 Level 1 test methods

See 6.2 and [1] for additional information on those tests which should be performed and results recorded at least monthly. 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, casing for cracks as a potential shock hazard, and cable insulation and grommets for wear. Adjust settings at 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. Adjust settings as in the Level 2 tests, except increase the gain such that electronic noise can be barely seen, if possible. 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 may be possible to do so in engineering/service settings.

In the hard copy and image storage, 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 QC-record book in paper or digital form and should be acted upon in a timely manner.

9 Level 2 measurement methods

9.1 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, casing for cracks as a potential shock hazard, and cable insulation and grommets for wear.

9.2 Image uniformity for transducer element and channel integrity

9.2.1 General

The image-uniformity test is primarily a test of ineffective transducer elements or their signal channels. Measurement results will depend on the system transducer, frequency, and the operating conditions and mode. These shall be specified and repeated for consistent QC-measurements that can be repeated for detection of change as well as detection of unacceptable image uniformity.

9.2.2 Apparatus scanning procedures and system settings

These 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 that meets either of the sets of specifications in 7.2. 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 probe, 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 depth of imaging tests are provided in 10.2.2.

- Set the imaging to the shortest focal zone possible, with no spatial compounding.
- Set the displayed dynamic range to a relatively low value; ~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) algorithms, if possible.
- Except as otherwise noted, settings, such as frequency, should be in typical positions that are used clinically, preferably at the preset (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.
- While the choice of the particular grey-scale characteristic curve is not very important for these tests, the setting shall be reproducible. If possible, without having to measure the characteristic curve as detailed in IEC 62563-1 [34] and [35], the grey-scale characteristic display curve should be set to the one which has the most purely logarithmic compression, a straight line in image-pixel value as a function of logarithmic received signal level, with a 50 dB displayed dynamic range. If these settings are not available, characteristic curve choice and dynamic range settings always should be set the same.
- Obtain help, if necessary, on finding these and other settings affecting QC-results and record them, so that they can be reset, if another operator has changed them.
- All settings should be recorded and stored in QC-uniformity- and penetration-test preset 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.
- 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-arrays require special imaging sequences from the system manufacturer as specified in 7.4. 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 QC-uniformity- and penetration-test preset 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.

9.2.3 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 100 or more images.
- 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 61391-2:2010).
- When cine loop capabilities are not available, record images as rapidly as possible as the transducer is scanned slowly over the phantom.

9.2.4 Analysis

For high sensitivity, compute the median-averaged image value $a_{i,j}$ over all images, k = 1 to N, in the sweep and/or sweep and tilt, for each pixel at coordinate i,j. The resulting, highly averaged image should 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 ray 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)].

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 is 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 or a complete electrical test of the elements (Annex D). Other specifics of measurement with available specialized software, including production of profiles with convex linear arrays, are given in Annex B.

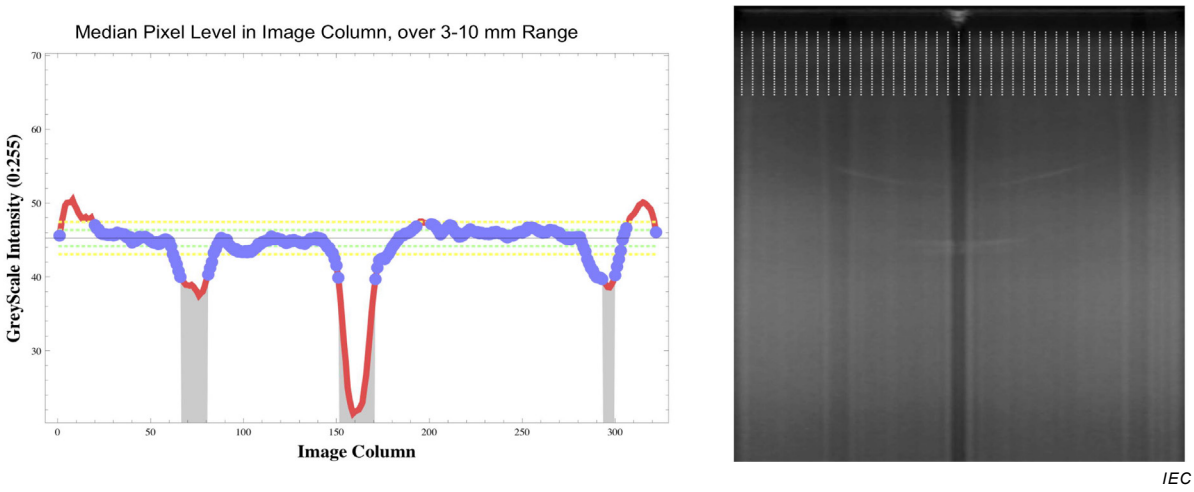


Figure 1 – Median-averaged image (right) and its lateral profile (left)

On the right side 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

4) For example, Matlab, or 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.

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, and/or the product of amplitude and dip width, as a function of time in a control chart [36]. The control chart can help define deviations exceeding two or three standard deviations from the mean of the previously recorded values, These are typical thresholds for declaring a clear degradation and usually.obtaining corrective action. See B.2.

10 Level 3 measurement methods

10.1 General

These tests should be performed and results recorded at least every other year using phantoms defined in 7.2.3. 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 9.2.4, the results of tests should be plotted in control charts to aid selection of significant deviations from the mean of the measurements. See B.2.

10.2 Maximum relative depth of penetration

10.2.1 Assessment

The **maximum depth of penetration** is the best imaging method devised at time of writing for simple tests of ultrasound system sensitivity. Similarly, after that, the **maximum relative depth of penetration** is the next best imaging method at time of writing for assessing changes in system sensitivity and requires only a stable phantom without narrowly defined acoustic properties. Visual measurements of depth of penetration might be too inconsistent to document modest changes in system sensitivity and procedures have been developed to quantify this measure.

10.2.2 Scanning system settings

The following is adapted with minor changes from IEC 61391-2:2010, 6.1.1 and 7.1. **Maximum relative depth of penetration** should be measured at the preset (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

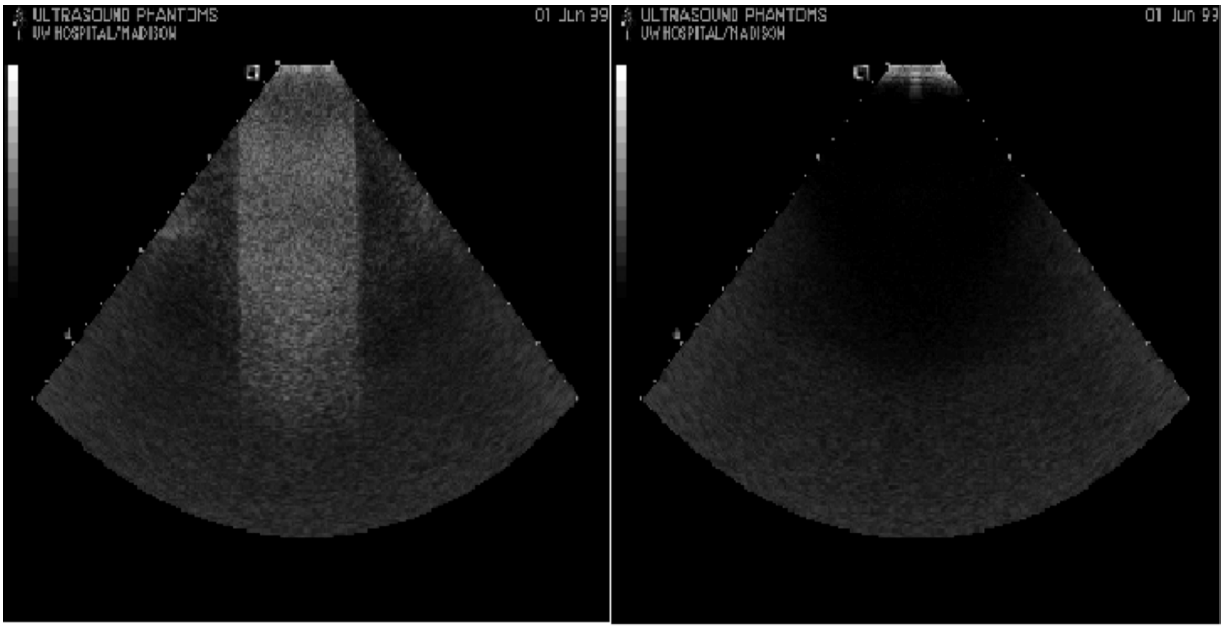
verify that image pixels are not saturated or that a real signal is not displayed as zero, i.e. pegged high or low.

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 preset (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 preset is used, the intended clinical application for the preset as well as the above control setting values should be recorded.

These tests are performed in the most common mode employed, e.g. 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.

10.2.3 Image acquisition

The **maximum relative depth of penetration** is determined from the image-pixel signal-to-noise ratio vs. 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 2A). This optimization usually results in the background echo-signals from the phantom fading into the displayed electronic noise.



A B

IEC

Figure 2 – A) Image of a uniform section in a tissue-mimicking phantom, 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: University of Wisconsin]

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 2B. It has been conjectured that transducer mechanical loading, when the probe is coupled to the phantom, can result in different noise levels than when the probe 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.

10.2.4 Analysis

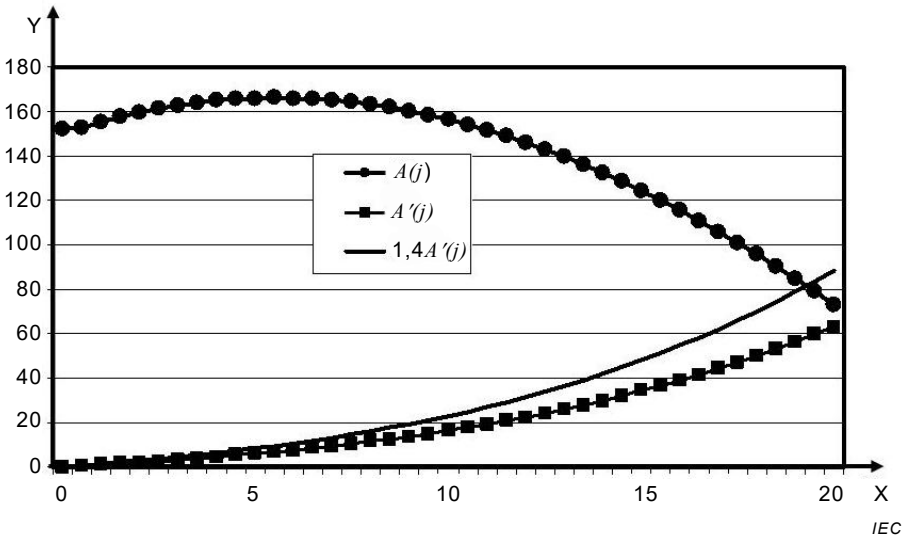
The digitized image data for a rectangular region-of-interest (ROI) extending from the near field to the bottom of the image form a matrix, $a(i,j)$, where i refers to the column (horizontal position) and j refers to the row (vertical position) in this matrix. Acquire a full cine loop of independent 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) vs. depth, $A(j)$ is then computed by averaging pixel values corresponding to a constant depth from the transducer. With sector transducers such as phased arrays and curved-linear arrays, it may be necessary to apply a more complex ROI when computing the $A(j)$ values, unless the width of the ROI is narrow, such as less than one-tenth of the sector width at the maximum depth. Similarly, $A'(j)$, the mean pixel value (numerical grey level) vs. depth should be determined for the image containing noise only.

Typical plots of $A(j)$ and $A'(j)$ vs. depth are illustrated in Figure 3. 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 vs. depth in the image in the absence of any electronic noise. Assuming the signal and noise are not correlated, and that the B-mode image is a display of echo-signal level, it may be shown that the average signal vs. depth for the image of the phantom is

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

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

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



Key

X depth into phantom (cm)

Y mean image pixel (data) value

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.

Figure 3 – Mean digitized image-data value vs. depth for the phantom image data ($A(j)$) and for the noise-image data ($A'(j)$)

The depth at which the signal-to-noise ratio decreases to 1 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. 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 as referenced at the end of 9.2.4 [36].

10.2.5 Commentary

Unlike the performance evaluation standard IEC 61391-2:2010, 7.1.3, this measurement of relative depth of penetration into an attenuating phantom may not be used to compare imaging performance of similar systems, unless the tests are performed on the same phantom or with a phantom meeting the specifications in that standard. If the same phantom is employed, the **maximum relative depth of penetration** may 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. However, 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/or 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 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.

10.3 System-image display

10.3.1 General

All test patterns referred to below are specified in detail in [35] and their equivalents in IEC 62563-1 [34] are available as digital images. All of the assessments described below should be performed more frequently than specified here if so recommended by the ultrasound (US) system and interpretation-station manufacturers. Full tests for display-system performance evaluation, including grey-scale calibration, might be appropriate, particularly for displays without luminance-stabilization circuitry.

10.3.2 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 scratches, cracks, pen marks, mechanical stability of the display support.

10.3.3 Level 2 and 3 tests

The tests for contrast transfer characteristics associated with the display device should be performed as part of Level 3 QC-tests and a quick visual check with same is recommended for Level 2 tests. See Annex C. Visual assessments by low-contrast detectability, employing the low-contrast pattern of TG18-CT [35] (Figure C.1) should be performed in good lighting conditions and in the usual or worst conditions in which the ultrasound system is used typically. The latter will demonstrate the bad effects of poor viewing conditions and perhaps

motivate the use of improved ambient light. The row/column numbers of the lowest contrast blocks in which both curved edges of the circular hemispheres in the centre can be resolved visually should be recorded.

It is recommended to test the display for pixel defects (dead/stuck pixels) and overall display uniformity by first disconnecting the power, to drain static electricity, restarting, and viewing the TG18-UN10 and TG18-UN80 test images [35] (Figure C.1). Detected non-uniformities should be recorded precisely in words, such as “lost pixels or larger non-uniformity at Row (1-4), Column (1-4)” and photographic recording of display defects with a digital camera is recommended. IEC 62563-1:2009, 7.2 and [35] give specifics for more complete evaluations. The number of dysfunctional pixels that is acceptable for medical diagnosis depends on the distraction caused by the dysfunction and is a function of the pixel size compared with the size of the imaging point spread function.

Results of these immediate analyses should be recorded in a database as at the end of 9.2.4 [36]. These test patterns are for monitors calibrated to the DICOM standard. Most ultrasound system displays use the gamma 2.2 curve, which typically will not allow discrimination of the full range of grey levels possible with 8 bit image values. These test patterns will normally reveal those limitations.

Availability of these or equivalent test patterns in the ultrasound system should be requested for existing systems and specified for systems selected more than two years after release of this document.

As with other QC-tests herein, these and more complete tests should be performed upon acceptance of new or refurbished ultrasound systems and when significant changes (greater than 2 standard deviations from mean of previous measurements) are detected in these measurements. Ideally, quantitative display performance evaluation should be performed according to IEC 62563-1. For example, the grey-scale calibration should be assured through luminance measurements at multiple, digital-driving levels, using a calibrated photometer and a selection of the TG18-LN test patterns [35].

A more pressing problem in large imaging services, those with reading stations other than the display on the ultrasound system, is that the digital image output is not designed to provide the same image on a standard DICOM reader station as that presented on the ultrasound system. It is critical that the interpreting physician see the same features as the person acquiring the study. Further standardization is needed.

10.4 Distance measurements for mechanically scanned distances

10.4.1 General

To be performed for Level 3 tests and, if need is suspected, Level 2 tests. In initial QC testing of a system, testing of distance measurements in all dimensions is recommended.

Performance of distance measurements in Level 2 QC is of particular importance:

- 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 scanheads. 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 QC-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 verified.

10.4.2 Apparatus and scanning system settings

Employ a phantom specified for lateral/elevational-distance measurement accuracy, described in IEC 61391-1. Settings can be those used for clinical imaging where absolute measurements are critical, for example, obstetrical, or at settings particularly to minimize the variance and bias in these tests. The latter employ a relatively high contrast setting, for example, 60 dB 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.

10.4.3 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 10.4.2. 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.

10.4.4 Analysis

Measure the filament positions or the distance marker positions at every 1 cm marker or some increment providing at least 4 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.

Results of this immediate analysis should be recorded in a database as at the end of 9.2.4 [36].

Annex A
(informative)

Example phantoms for image uniformity and/or maximum relative depth of penetration

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 urethane with a homogeneous distribution of scatterers. The 9 cm-wide well in the top aids coupling of curved-linear arrays. A less expensive and more compact phantom, probably 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 is shown in Figure A.3 and a temporally stable, inexpensive one in Figure A.4.

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

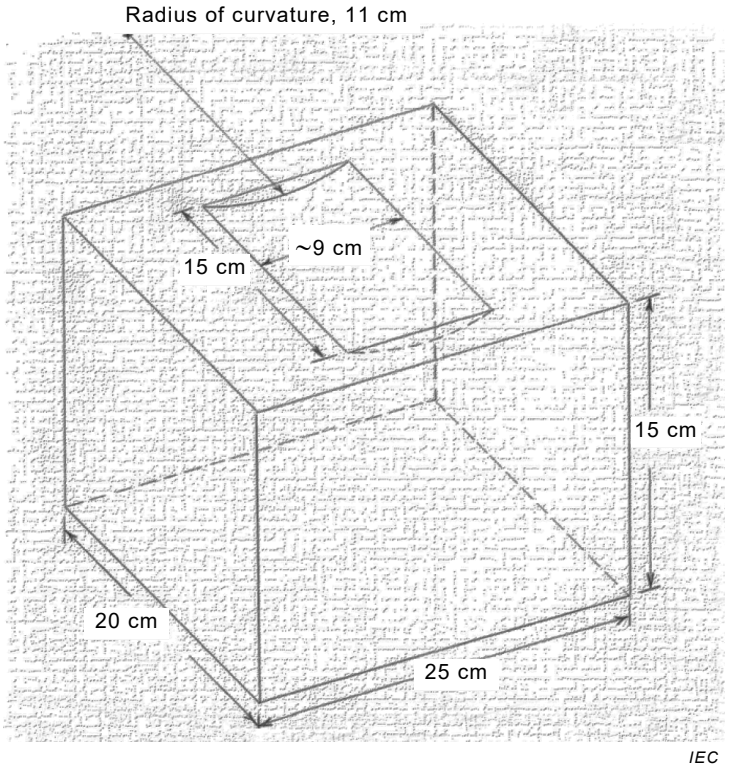


Figure A.1 – Example phantom for image-uniformity and/or maximum-relative-depth-of-penetration tests

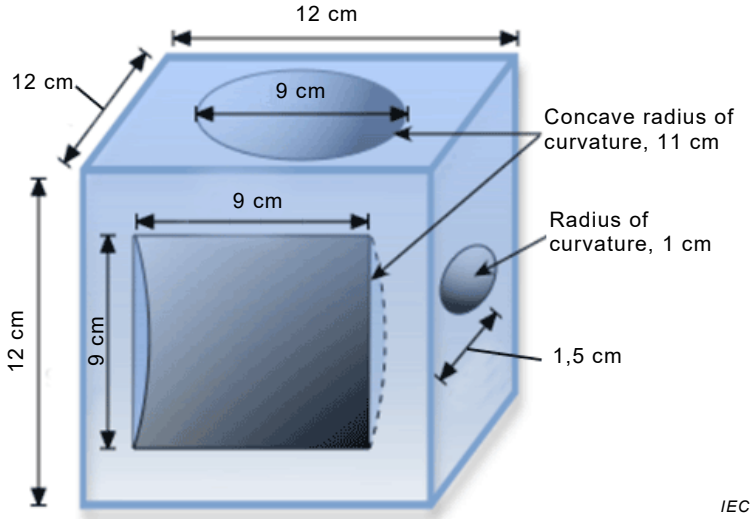
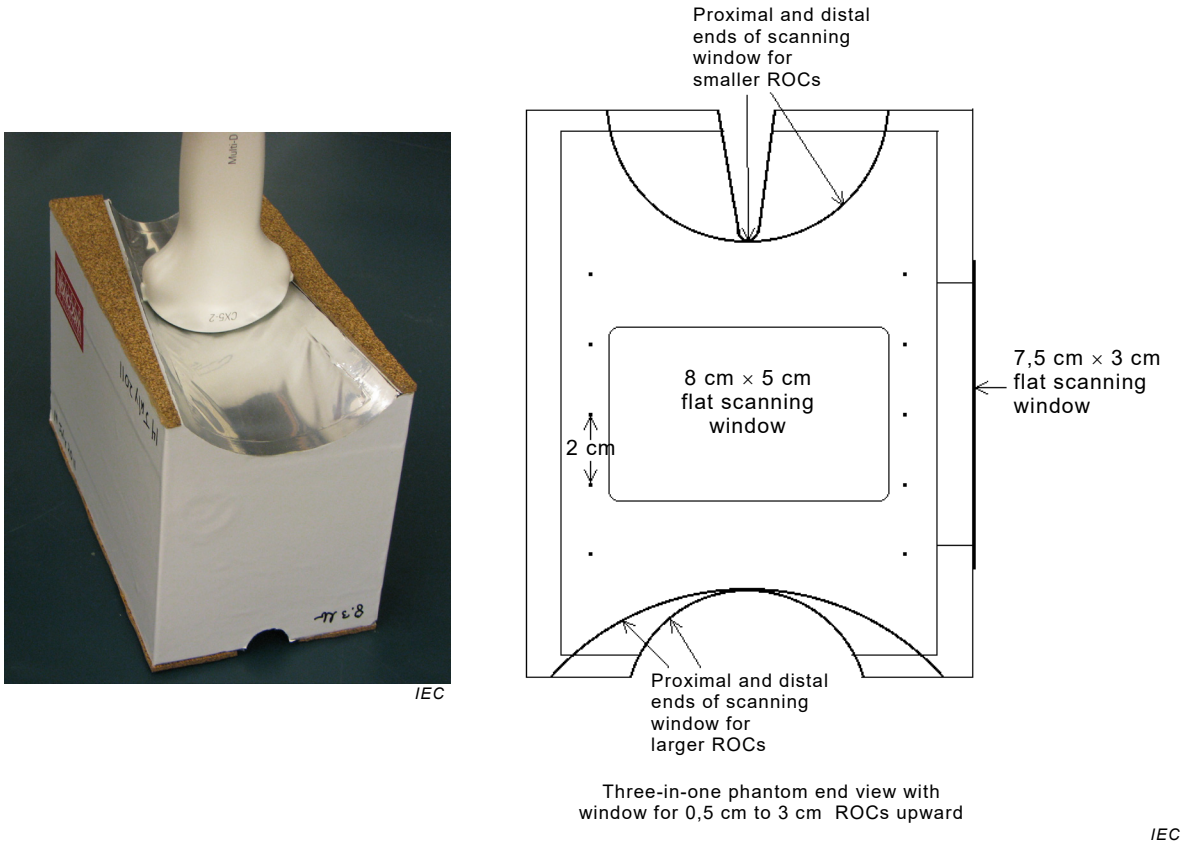


Figure A.2 – Example compact phantom for image-uniformity tests



Key

ROC radius of curvature

Figure A.3 – Photograph and drawing of a three-in-one phantom which provides for determination of distance measurement precision and bias, image uniformity and depth of penetration [37]

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.

Figure A.4 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 were attached to the bottom and right end. This phantom would serve better if a bit thicker.

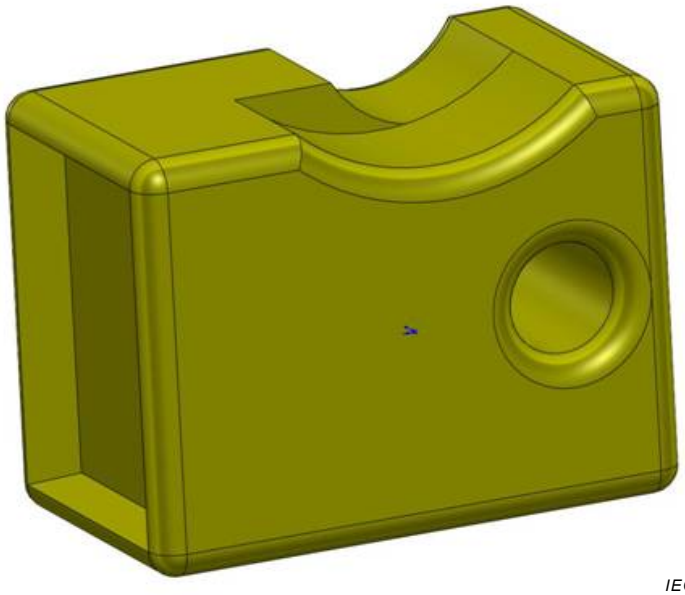


Figure A.4 – A compact uniformity phantom of relatively durable rubber material

Annex B
(informative)

Available analysis software

B.1 Open source software for assessment for QC of ultrasound image uniformity

Some examples of known software for QA purposes are listed below[5] (from [1]):

- UltraIQ™ (Cablon Medical, NL)

  This company has developed a software application for automated evaluation and reporting of ultrasound systems dedicated to Levels 2 and 3 applications. (http://www.ultraiq.com); accessed 29.6.2015

- QA4US™

  (Radboud University, Nijmegen, NL)

  a modular software package that can be used for Levels 2 and 3 test requirements (www.qa4us.eu); accessed 26.6.2012

- FirstCheck™

  (UltraSound-Lab, ZMPBMT, Medical University Vienna, Austria) Java-based software that is dedicated to support simple user tests/documentation of Level 1 (http://www.zmpbmt.meduniwien.ac.at/1/science/ultrasound-lab/projects/firstcheck/); accessed 30.6.2016

- Nottingham USQC

  (Nottingham University Hospitals, Medical Physics & Clinical Engineering, UK) software developed by the ultrasound group to evaluate Levels 2 and 3 tests

One set of software is described here as an example of the newer quantitative measurements of image uniformity and as a convenience to users of this document. This multi-platform software will be available shortly as a plug-in to NIH ImageJ[5)] (free at http://rsbweb.nih.gov/ij/). 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 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.

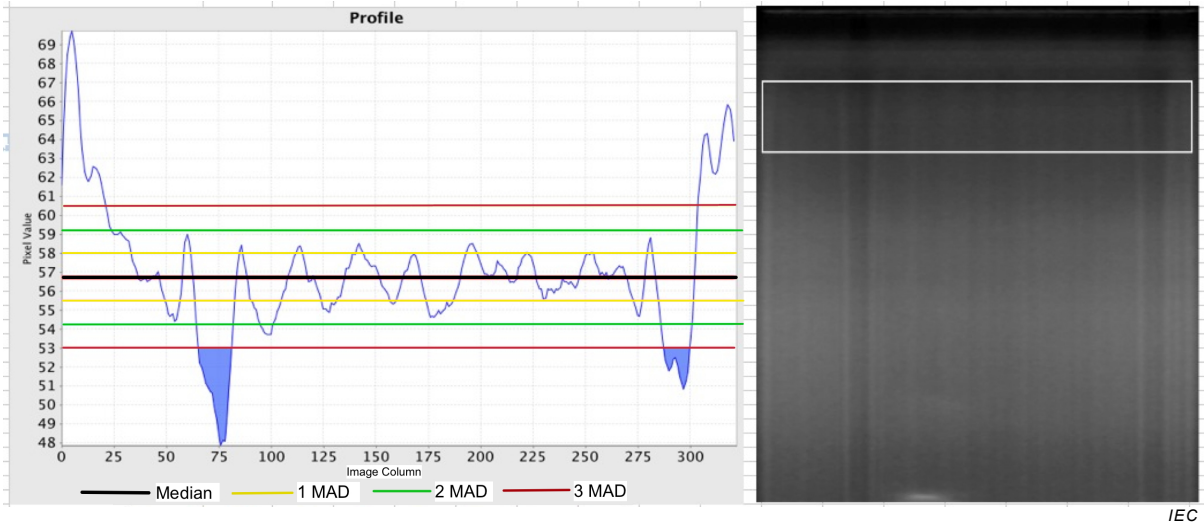
Before exporting the profile to a spreadsheet, the threshold for defect detection is considered. The threshold should be at the institution's standard value (recommended 3 times the **median absolute deviations** from the data's median, 3 MADs). The MAD is similar to the standard deviation.

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 integrated over all scan lines in each signal valley, as well as the same integration over columns 1-element wide. Tentative recommended action thresholds are as follows.

A signal valley of area (in columns one element wide)/mean $>$ 0,4 is worth counting as a defect of possible concern. More than two such defects are worthy of recommending

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

repair/replacement or further testing. A finding of normalized area > 0,9 in a single valley is worthy of an unacceptable rating and a request for repair/replacement or further testing with strong justification of no further action. These recommendations are yet to be verified on a large number of transducers and, in any case, may be subject to the individual institution's assessment of the importance of the defect to clinical practice. A classification guide is that a dip > 3 dB (–3 dB relative to the mean) and more than two elements wide is worth counting as a defect of possible concern. If the dynamic range of the display is not known and cannot be estimated reasonably, "A signal valley of area (in columns 1 element wide)/mean > 0,4" can be used as a guide. This is the area of the dip in pixel values integrated over the number of columns of one transducer element width, taken from the –3 MAD level. This criterion assumes correct entry of the number of transducer elements. If this number is unknown, a reasonable guess for high-end systems in 2016 is (128 + 192)/2 = 160. Taking the area of this 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 MADs (median absolute deviations) are shown in blue.

Figure B.1 – On the left the profile of median pixel value is plotted for each image column in the analysis box shown in the median image on the right for the transducer in Figure 1, but without the nylon filament obstructing some central elements

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. Below, see a step-by-step example of performing this analysis.

Table B.1 – Output of analysis

Filename:	/Volumes/Englewood/Users/pcarson9b/locoHills2/ASmallFryles/_AAPM_ACR_AIUM_IEC/IE						
Institution	U of M	Test Date	8/9/09	Analaysis D	2/10/013		
Scanner model	GE Logiq 9	S/N					
Transd. Model	7L	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

The bottom two rows 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 analysed area of the image. Dip depth in dB is 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 dB. 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.

B.2 Example of QC control chart:

A control chart can plot results of a series of measurements over time. Confidence 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 3 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. [SOURCE: spreadsheet from [36], plotted with modifications]

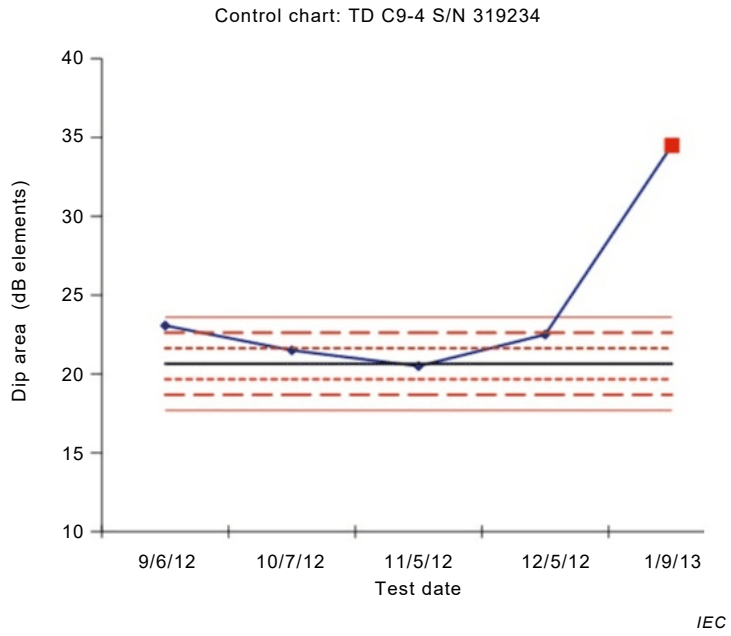
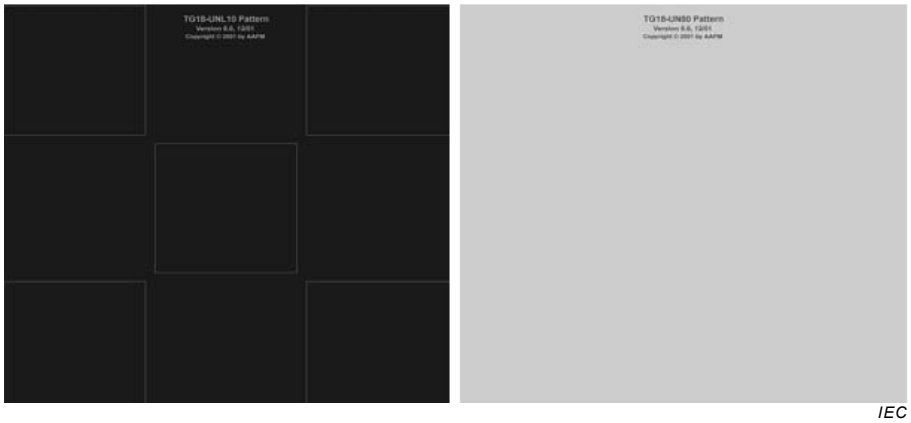


Figure B.2 – Control chart for a dip in the middle of the profile for one transducer (TD) mode C9-4 and the specified serial number (S/N)

Annex C
(informative)

Display test patterns

Two types of display test patterns, Figure C.1 and Figure C.3, are chosen for this document because of their simplicity for visual and, if desired, photometric analysis. Both of the test patterns in Figure C.1 are recommended. These are simple dark field and light field patterns. One is shown with and one without a grid to aid reporting of sections of reduced or accentuated brightness. The grid pattern is recommended to simplify data entry as in Figure C.2 (left). It is important that each pattern fills the screen. Evaluate each for visibly acceptable uniformity when viewed from each side, above and below, and from straight ahead. Unlike most patterns, it is not essential for those in Figure C.1 and Figure C.3 to have a one-on-one relationship between the image pixels and the display pixels. Patterns in DICOM and 16-bit TIFF formats should be displayed with a window and level set to cover the range from 0 to 4 095 (WW = 4 096, WL = 2 048). For 8-bit patterns, the displayed range should be from 0 to 255 (WW = 256, WL = 128).



Lined (left) or unlined (right) patterns may be used.

Figure C.1 – AAPM TG18-UN10 (left) and TG18-UN80 (right) patterns for luminance uniformity, colour uniformity, and angular response evaluations [35]

For the required assessments of the contrast transfer characteristics associated with the luminance response of a device, the low contrast test pattern [35] represented in Figure C.3 is employed. The pattern includes 16 adjacent regions varying in luminance from levels 8 to 248 with an 8-bit display and 128 to 3 968 with 12 bits. Each region differs in pixel value by the same amount from the adjacent ones. Each patch contains four small corner patches at ±4 [±64 with 12 bits] pixel value difference from the background, identical to those in the TG18-QC test pattern. In addition, at the centre of each patch is a half-moon target with the two sides of the target at ±2 [±32] pixel value difference from the background. For Figure C.2 (right), state the lowest contrast pattern in each row at which the central split circle can be distinguished. A similar pattern OIQ (IEC 62563-1 [34]) is perhaps even better for this purpose for LED displays.

A. Display Uniformity by Image Segment			
Row/Column	A	B	C
1			S
2			
3	P		
Code	P = failed pixels		
	S = shading (more less bright)		
	Blank = OK		

B. Display Luminance Response				
Row/Column	A	B	C	D
1				x
2			x	
3		x		
4				
Column of minimum resolved split circe, each row				

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Figure C.2 – Example data entry form for visual display evaluation: left for Figure C.1; right for Figure C.3

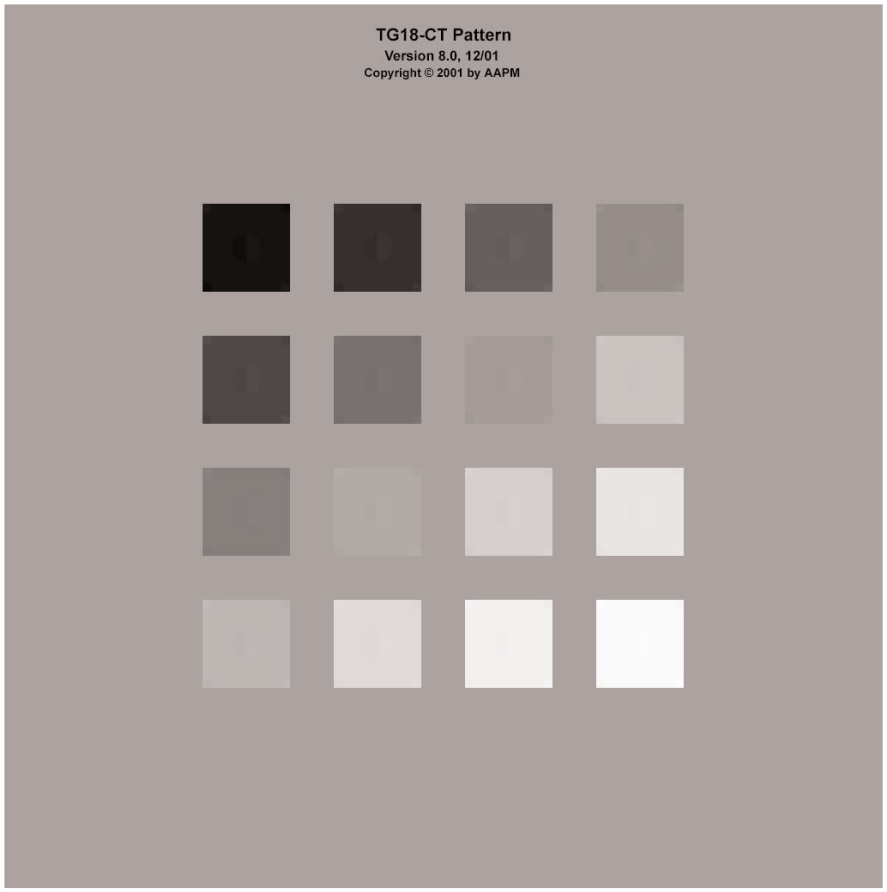

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Figure C.3 – TG18-CT low-contrast test pattern for the evaluation of the luminance response of display systems [35]

Annex D
(informative)

Electronic test methods and test methods provided by the manufacturers; relation to clinical significance

Two methods are discussed in 9.2.4, including electronic test methods from an independent supplier and test methods provided by the manufacturers. Writers are unaware of transducer tests provided by the system manufacturers with results provided to the users, but this testing is done internally in some systems. A device for complete electrical tests of the transducer cable and the elements (FirstCall aPerio™ [6]) was sold commercially but has since been 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.[7]

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 with existing performance evaluation standards and Technical Specification is recommended (IEC 61391-1, IEC 61391-2, and IEC TS 62791 [15] or IEC TS 62558 [24]). 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. A full-blown clinical trial in various clinical applications with defective and properly functioning transducers is not worth the cost. 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.

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[6] FirstCall aPerio™ is the trademark of a product supplied by Unisyn Medical Technologies, Golden, CO, USA. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.

[7] Aureon™ is an example of a suitable product available commercially (supplied by Acertara Acoustic Laboratories, Longmont, CO, USA, http://www.acertaralabs.com/products/for-hospitals/aureon/). This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.

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