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Edition 2.0 2023-01
REDLINE VERSION

TECHNICAL SPECIFICATION

colour inside

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

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC TS 62736:2016. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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), ~~biannually~~ annually (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)~~ quality-assurance (**QA**) and performance-evaluation procedures to promote improved efficacy of diagnostic examinations through widespread use of effective ~~QC~~ **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 ~~QC~~ **QA**. These practices include tests, such as spatial resolution, which are low-yield and belong in performance-evaluation procedures, rather than ~~QC~~ **QA**.

Modern flat-panel display technology is more stable than, and generally far superior to, earlier cathode ray tube (CRT) displays. However, ~~LCD~~ 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

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

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 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 with linear array, curved linear array, single element, annular array, phased array, matrix linear array transducers and two-dimensional arrays 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 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.

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) ~~curved~~ convex arrays,
d) mechanical ~~probes~~ 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 ~~probes~~ transducers 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.~~

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>)

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

3.2
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. ~~They are recommended for performance in Level 3 QC tests, though that is not required.~~ 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 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.~~

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 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~~

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**~~
~~**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.~~

3.9
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].