IEC TS 62736

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



IEC TS 62736:2023-01 RLV(en)

THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2023 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 300 terminological entries in English and French, with equivalent terms in 19 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC TS 62736

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 17.140.50

ISBN 978-2-8322-6369-3

Warning! Make sure that you obtained this publication from an authorized distributor.

® Registered trademark of the International Electrotechnical Commission

CONTENTS

FOREWORD 5
INTRODUCTION 7
1 Scope 9
2 Normative references 10
3 Terms and definitions 11
4 Symbols and abbreviated terms 16
4.1 Symbols 16
4.2 Abbreviated terms 17
5 General recommendation 18
6 Environmental conditions 18
7 Quality ~~control~~ assurance levels 19
7.1 General 19
7.2 Level 1 tests 21
7.3 Level 2 tests 21
7.4 Level 3 tests 22
8 Equipment and data required 22
8.1 Phantoms and software 22
8.1.1 General 22
8.1.2 Phantoms for Level 2 and ~~/or~~ Level 3 quality ~~control~~ assurance 23
8.1.3 Additional phantom specifications for Level 2 quality ~~control~~ assurance ~~only~~ 23
8.1.4 Additional phantom specifications for ~~both Level 2 and~~ Level 3 quality ~~control~~ assurance and optional Level 2 tests 26
8.2 Image data 27
8.2.1 Digital-image data 27
8.2.2 Image-archiving systems 28
8.3 Expectations of system suppliers 29
9 Level 1 test methods 30
10 Level 2 measurement methods 30
10.1 Mechanical inspection 30
10.2 Image uniformity for transducer element and channel integrity 30
10.2.1 General 30
10.2.2 Apparatus scanning procedures and system settings 30
10.2.3 Image acquisition 32
10.2.4 Analysis 32
10.3 Randomly distributed high-contrast sphere visualization 34
10.3.1 Methodology 34
10.3.2 Procedure 36
10.3.3 Data recording 38
10.4 Image displays; system and interpretation; maximum relative depth of penetration; spatial resolution 38
10.5 Distance and other spatial measurements 38
11 Level 3 measurement methods 38
11.1 General 38
11.2 Maximum relative depth of penetration 39
11.2.1 Assessment 39

11.2.2 Scanning system settings 39
11.2.3 Image acquisition 40
11.2.4 Analysis 41
11.2.5 Commentary 42
11.3 System-image display 43
11.3.1 General 43
11.3.2 Level 1 tests of the US system and interpretation-station display 44
11.3.3 Level 2 and Level 3 display tests 45
11.4 Distance and other spatial measurements ~~for mechanically scanned distances~~ 49
11.4.1 General 49
11.4.2 Apparatus and scanning system settings 49
11.4.3 Image acquisition 50
11.4.4 Analysis 50
11.5 Performance in clinical use and evaluation of QA programme 50
Annex A (informative) Example phantoms for full coupling with curved arrays, particularly for image uniformity ~~and/or maximum relative depth of penetration~~ tests 51
Annex B (informative) Available analysis software 55
B.1 Open source software for assessment ~~for QC~~ or tracking of ultrasound image ~~uniformity~~ QA data 55
B.2 Example of ~~QC~~ QA control chart 57
~~Annex C (informative) Display test patterns ..... 61~~
Annex C (informative) Electronic test methods and test methods provided by the manufacturers – Relation to clinical significance 61
Annex D (informative) Special considerations for 3D imaging transducers 62
D.1 General 62
D.2 2D transducers and 3D mechanically driven transducers operating in 2D imaging mode 62
D.3 2D arrays operating in 3D imaging mode for determining $LSNR_{md}$ values for reconstructed images as a function of depth or distance from the central plane 62
D.4 Mechanically driven 3D transducers operating in 3D imaging mode 62
Annex E (informative) Example workbook database for tracking high-contrast, low-echo sphere visibility and luminance of the display 63
Bibliography 70

Figure 1 – Median-averaged image (right) and its lateral profile (left) 33
Figure 2 – Examples of portable apparatus for moving the transducer: a) and c) in equal, chosen increments or b) at a known rate 35
Figure 3 – Example of visual estimation of the two defined depth zones in which spheres can be detected with two degrees of fidelity and clarity 36
Figure 4 – Additional examples of visual estimation of the depth Zone 1 and Zone 2, each of which represents a certain degree of fidelity and clarity (IEC 62791) 37
Figure 5 – Maximum relative depth of penetration – image acquisition 40
Figure 6 – Mean digitized image-data value versus depth for the phantom image data ($A(j)$) and for the noise-image data ($A'(j)$) 42
Figure 7 – TG18-QA test pattern for visual evaluation testing [21],[33] 45
Figure 8 – Examples of TG18-LN luminance patterns for luminance measurements [21] 47

Figure 9 – TG270-ULN uniformity and luminance test pattern (TG270-ULN8-127 with background 8-bit grey level 127 is shown) [33] 48

Figure A.1 – Example phantom for image-uniformity and~~/or~~ maximum relative depth of penetration tests 51

Figure A.2 – Example compact phantom for image uniformity tests 52

Figure A.3 –Photograph and drawing of a three-in-one phantom which provides for determination of distance measurement precision and bias, image-uniformity, very-low-echo sphere visualization, and depth of penetration [39] 53

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

Figure A.4 – Two temporally stable, inexpensive phantoms for image uniformity tests 54

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~~ Example of data analysis for the transducer evaluated to generate Figure 1 56

Figure B.2 – Control chart for a dip in the middle of the profile for one transducer (TD) model, C9-4 and the specified serial number (S/N) 58

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

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

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

Figure E.1 – Current and previous measurements and trendlines providing luminance at various grey levels, fractional slope of luminance and deviation from DICOM GSDF in ΔJND per grey level (IEC 62563-2) 69

~~Table 1 – Outline of Level 1 tests .....~~

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

Table 1 – Overview to the symbols and definitions of the QA terms, other than those for the display 16

Table 2 – Overview of the symbols and definitions of the display QA terms 17

Table 3 – Abbreviated terms 18

Table 4 – Outline of tests by level 19

Table 5 – Ultrasound image display QA tests 49

Table B.1 – Output of image uniformity analysis 57

Table E.1 – Transducer record and baseline high-contrast, low-echo-sphere visualization test data 64

Table E.2 – Database of periodic sphere visualization results 65

Table E.3 – Completed short QA data entry example form for monitor luminance evaluation using test pattern – QA18 66

Table E.4 – Blank, short QA data entry evaluation form for monitor luminance using test pattern – QA18 67

Table E.5 – Analysis of luminance measurements 68

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

ULTRASONICS – PULSE-ECHO SCANNERS –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with can participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication might be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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].

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

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

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

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

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

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

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

[SOURCE: IEC TS 62791:2022, 3.3]

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

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

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

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

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

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

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

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

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

[SOURCE: IEC TS 62791:2022, 3.13]

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

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

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

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

3.21
useable range
$Я_{\mathrm{u}}$
range or ranges over which the negative of $\underline{LSNR}_{\mathrm{m}}$ is ≥ 1,41

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

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

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

3.22
mean useable contrast over the useable range
$|LSNR_{\mathrm{m}Я}|$
mean $|LSNR_{\mathrm{m}}|$ over the **useable range** or combined **useable ranges** of a transducer under given settings

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

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

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

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

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

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

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

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

[SOURCE: IEC TS 62791:2022, 3.9.1]

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

[SOURCE: IEC TS 62791:2022, 3.10]

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

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

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

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

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