

TECHNICAL SPECIFICATION



Ultrasonics – Pulse-echo scanners – Low-echo sphere phantoms and method for performance testing of gray-scale medical ultrasound scanners applicable to a broad range of transducer types

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CONTENTS

FOREWORD.....	6
INTRODUCTION.....	8
1 Scope.....	10
2 Normative references	10
3 Terms and definitions	10
4 Symbols	12
5 General and environmental conditions	13
6 Equipment required	14
6.1 General.....	14
6.2 Phantom geometries	14
6.2.1 Phantoms for use in the frequency range 2 MHz to 7 MHz	14
6.2.2 Phantoms for use in the frequency range 7 MHz to 15 MHz including "micro-convex" arrays.....	14
6.2.3 Total internal-reflection surfaces.....	15
6.2.4 Spatially random distribution of low-echo spheres.....	15
6.3 Ultrasonic properties of the tissue-mimicking (TM) phantoms.....	15
7 Data acquisition assuming a spatially random distribution of low-echo spheres	16
7.1 Methodology	16
7.2 Storage of digitized image data.....	17
7.3 Digital image files available from the scanner itself	18
7.4 Image archiving systems.....	18
8 Automated data analysis for quantifying low-echo sphere detectability	18
8.1 General.....	18
8.2 Computation of mean pixel values (<i>MPVs</i>)	18
8.3 Determination of the $LSNR_m$ -value for a given depth interval.....	21
8.3.1 Preliminaries	21
8.3.2 Computation of the $LSNR_n$ -values and $LSNR_m$ -value in a given depth interval	21
8.3.3 Standard error corresponding to each $LSNR_n$ -value.....	21
Annex A (informative) Example of a phantom for performance testing in the 2 MHz to 7 MHz frequency range.....	22
Annex B (informative) Illustrations of the computation of $LSNR_m$ -values as a function of depth	24
Annex C (informative) Sufficient number of data images to assure reproducibility of results	29
C.1 General.....	29
C.2 Phantom with low-echo sphere diameter 3,2 mm, having 2 spheres per millilitre	29
C.3 Phantom with 2 mm-diameter, low-echo spheres and 8 spheres per millilitre	32
Annex D (informative) Example of a phantom for performance testing in the 7 MHz to 15 MHz frequency range.....	36
Annex E (informative) Determination of low-echo sphere positions to within $D/8$ in x , y and z Cartesian coordinates.....	39
E.1 Procedure	39
E.2 Argument for the choice of seven <i>MPV</i> nearest-neighbour sites for determining the centres of low-echo spheres	40

Annex F (informative) Test of total internal reflection produced by alumina and plate-glass, plane reflectors	41
Annex G (informative) Results of a test of reproducibility of $LSNR_m$ versus depth for a phantom with 4 mm-diameter low-echo spheres and 2 spheres per millilitre	48
Annex H (informative) Results for low-echo sphere-concentration dependence of $LSNR_m$ versus depth for phantoms with 4 mm-diameter spheres	50
Annex I (informative) Results for low-echo sphere-concentration dependence of $LSNR_m$ versus depth for phantoms with 3,2 mm-diameter spheres	53
Annex J (informative) Comparison of two different makes of scanner with similar transducers and console settings	57
Annex K (informative) Special considerations for 3-D probes	59
K.1 3-D probes operating in 2-D imaging mode	59
K.2 2-D arrays operating in 3-D imaging mode for determining $LSNR_m$ -values as a function of depth for reconstructed images	59
K.3 Mechanically driven 3-D probes operating in 3-D imaging mode	59
Bibliography	60
Figure 1 – Flow chart	17
Figure 2 – Schematic of an image plane	20
Figure A.1 – End view of the phantom applicable for 2 MHz to 7 MHz showing the spatially random distribution of 4-mm diameter low-echo spheres	22
Figure A.2 – Top view of phantom with 4 mm-diameter, low-echo spheres	23
Figure B.1 – Convex-array image of a prototype 4 mm-diameter low-echo sphere phantom for use in the 2 MHz to 7 MHz frequency range	24
Figure B.2 – Auxiliary figures relating to Figure B.1	25
Figure B.3 – Results corresponding to Figures B.1 and B.2, demonstrating reproducibility	25
Figure B.4 – Results corresponding to Figures B.1, B.2 and B.3	26
Figure B.5 – One of 80 parallel linear-array images of the phantom containing 4 mm-diameter, low-echo spheres, at 4 MHz with focus at 3 cm	26
Figure B.6 – Three successive images of the set of 80, separated by $D/4$ equal to 1 mm	27
Figure B.7 – Results for the 4 cm-wide, 3 cm-focus, linear array addressed in Figures B.5 and B.6	27
Figure B.8 – Results for the 4 cm-wide, 3 cm-focus, linear array addressed in Figures B.5, B.6 and B.7, using all 80 image frames corresponding to Figure B.7	28
Figure C.1 – One image obtained from a phantom containing 3,2 mm-diameter, low-echo spheres by using a 4 MHz linear array focused at 3 cm	29
Figure C.2 – Reproducibility result for two independent sets of 70 images with a mean number of low-echo sphere centres that is about 15 per 5 mm-depth interval	30
Figure C.3 – Results obtained by using both sets of 70 independent images corresponding to Figure C.2	30
Figure C.4 – Sector image (curved array) at 4,5 MHz with multiple foci at 4 cm, 8 cm and 12 cm depths; the low-echo spheres are 3,2 mm in diameter	31
Figure C.5 – Reproducibility results for a multiple-lateral-focus (4 cm, 8 cm and 12 cm) case corresponding to Figure C.4	31
Figure C.6 – Reproducibility results for the case corresponding to Figure C.5, except that there is a single focus at 10 cm depth	32
Figure C.7 – Reproducibility results for the case corresponding to Figure C.5, except that there is a single focus at 4 cm depth	32

Figure C.8 – Image of the phantom containing 2 mm-diameter, low-echo spheres, made with a curved array having 1,5 cm radius of curvature, with its focus at 3 cm	33
Figure C.9 – Reproducibility results corresponding to Figure C.8	33
Figure C.10 – Results using all 100 images in the image set that gave rise to Figure C.9.....	34
Figure C.11 – Image of the phantom containing 2 mm-diameter, low-echo spheres, made with a high-frequency (15 MHz) linear array, laterally focused at 4 cm.....	34
Figure C.12 – Reproducibility results corresponding to Figure C.11	35
Figure C.13 – Results using all 200 images in the image set that gave rise to Figure C.12.....	35
Figure D.1 – End- and top-view diagrams of the phantom containing 2 mm-diameter, low-echo spheres for use in the 7 MHz to 15 MHz frequency range.....	37
Figure D.2 – Image obtained by using the phantom containing 2 mm-diameter, low-echo spheres and a pediatric transducer with a radius of curvature of about 1,5 cm	38
Figure F.1 – Average of 10 images obtained by using a phased array.....	42
Figure F.2 – Plot of the data with blue data computed in the left rectangle in Figure F.1 and red data computed in the right rectangle	42
Figure F.3 – Plot of the data when the reflector is on the right side with blue computed in the left rectangle and red computed in the right rectangle	43
Figure F.4 – The percentage by which the mean pixel values resulting from reflections differ from the mean pixel values not involving reflections.....	44
Figure F.5 – Wide sector (153°), 1 cm-radius-of-curvature transducer with alumina reflector on the left.....	45
Figure F.6 – Plot of the data with blue computed in the left rectangle in Figure F.5 and red computed in the right rectangle	45
Figure F.7 – Plot of the data when the reflector is on the right side with blue computed in the left rectangle and red computed in the right rectangle	46
Figure F.8 – The percentage by which the mean pixel values resulting from reflections differ from the mean pixel values not involving reflections.....	46
Figure G.1 – Example image of the phantom with a 4,2 MHz curved array and two low-echo spheres per millilitre	48
Figure G.2 – Reproducibility results corresponding to the image set, one of which is shown in Figure G.1.....	49
Figure H.1 – Example of an image from the image set giving rise to the results in Figure H.2; the phantom contained an average of one 4 mm-diameter, low-echo sphere per millilitre	50
Figure H.2 – Results corresponding to an image set, one of which is shown in Figure H.1	51
Figure H.3 – Example of an image from the data set giving rise to the results in Figure H.4; the phantom contained an average of two 4 mm-diameter, low-echo spheres per millilitre	51
Figure H.4 – Results corresponding to an image set, one of which is shown in Figure H.3	52
Figure I.1 – Example of an image from the 4 ml ⁻¹ data set producing the results shown in Figure I.2	53
Figure I.2 – Results for the phantom containing four 3,2 mm-diameter, low-echo spheres per millilitre.....	54
Figure I.3 – Example of an image from the 2 ml ⁻¹ data set producing the results shown in Figure I.4	54
Figure I.4 – Results for the phantom containing two 3,2 mm-diameter, low-echo spheres per millilitre.....	55

Figure I.5 – Example of an image from the 1 ml⁻¹ data set producing the results shown in Figure I.6 55

Figure I.6 – Results for the phantom containing one 3,2 mm-diameter, low-echo sphere per millilitre 56

Figure J.1 – Results for System A scanner and 7CF2 3-D (swept convex array) transducer focused at 4 cm and operated at 4,5 MHz in 2-D mode..... 57

Figure J.2 – Results for System B scanner with a 4DC7-3 3-D (convex array) transducer, operated at 4 MHz in 2-D mode and focused at 4 cm. The sector angle and all other console settings mimicked those for the System A case (Figure J.1) 57

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS – PULSE-ECHO SCANNERS – LOW-ECHO
SPHERE PHANTOMS AND METHOD FOR PERFORMANCE
TESTING OF GRAY-SCALE MEDICAL ULTRASOUND SCANNERS
APPLICABLE TO A BROAD RANGE OF TRANSDUCER TYPES**

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

Technical Specification IEC TS 62791 has been prepared by IEC technical committee 87 Ultrasonics.

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

DTS	Report on voting
87/554/DTS	87/570/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.

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

INTRODUCTION

Ultrasonic pulse-echo scanners are widely used in medical practice to produce images of soft tissue organs throughout the human body. Most ultrasonic pulse-echo scanners produce real-time images of tissue in a scan plane by sweeping a narrow, pulsed beam of ultrasound through the tissue section of interest and detecting the echoes generated by reflection at tissue boundaries and by scattering within tissues. Generally, the sweep that generates an image frame is repeated at least 20 times per second, giving rise to the real-time aspect of the displayed image. The axes of the pulsed beams generally lie in a plane that defines the scan plane.

Various transducer types are employed to operate in a transmit/receive mode to generate/detect the ultrasonic signals. Linear arrays, in which the beam axes are all parallel to one another, resulting in a rectangular image, consist of a line of hundreds of parallel transducer elements with a subset of adjacent elements producing one pulse at a time. Convex arrays are similar to linear arrays but the element arrangements define part of the surface of a short right circular cylinder with the array elements parallel to the axis of the cylinder. The radius of curvature of the cylinder (and therefore the array) can have values between 0,5 cm and 7 cm. The convex array generates a sector image since the beam axes fan out over the scan plane. A phased array has a linear arrangement of elements, where all elements act together to form a pulse and the direction and focus of an emitted pulse is determined by the timing of excitations of the elements. The phased array generates a sector image. Another type of sector scanner is the mechanical sector scanner in which a single element transducer or an annular array transducer is rotated about a fixed axis during pulse emissions. All the foregoing transducer types commonly operate within the frequency range 2 MHz to 15 MHz, to which this Technical Specification applies.

A 2-dimensional array (2-D array) is restricted to an array of transducer elements distributed over a square area or a spherical cap. Such an array receives echoes from a 3-D volume and can produce images corresponding to any planar surface in that volume. A 3-D mechanically driven, convex array (3-D MD convex array) means a convex array that acquires images as it is rotated mechanically about an axis lying in its image plane or an extension of that plane. A 3-D mechanically driven, linear array (3-D MD linear array) is similar to a 3-D MD convex array, where the array radius of curvature is infinite and the array is either rotated about an axis or is translated perpendicularly to the scan plane of the linear array. For an overview of current 3-D and 4-D systems, see sections 1.5 and 10.2.2 of [1]¹.

One means for testing the imaging performance of an ultrasound pulse-echo scanner is to quantify the degree to which a small cyst-like (low-echo) object is distinguished from the surrounding soft tissue, i.e. the degree to which a small cyst-like (low-echo) object is detectable in the surrounding soft tissue. It is reasonable to assume that the smaller the **low-echo sphere** that can be detected at some position, the better the resolution of the scanner, i.e. the better it will delineate the boundary of an abnormal object, such as a tumour. There are three components of resolution defined in pulse-echo ultrasound:

- axial resolution (parallel to the local pulse propagation direction);
- lateral resolution (perpendicular to the local pulse propagation direction and parallel to the scan plane); and
- elevational resolution (perpendicular to the local pulse propagation direction and also to the scan plane).

Axial resolution usually – but not always – is better than lateral and elevational resolutions. Thus, all three components should be given equal weight in measuring **detectability**. A sphere has no preferred orientation and is therefore the best shape for a cyst-like object for two reasons. First, all three components of resolution are weighted equally no matter what the beam's incident direction is. Second, the incident beam's propagation direction will vary

¹ The numbers in square brackets refer to the Bibliography.

considerably in the case of convex and phased arrays depending on where the object exists in the imaged volume.

It is important that the phantom allows quantification of **detectability** to be carried out over the entire depth range imaged; thus, it is important that the low-echo spheres exist up to the entire scanning window. A phantom limited to a flat scanning surface is acceptable for a linear array, phased array, or a flat 2-D array, but not for the remaining types of arrays. Each of the phantoms described in this Technical Specification contains a random distribution of equal diameter [2], low-echo spheres existing at all depths, including the case of those designed for testing convex (curved) arrays.

This Technical Specification summarizes the requirements for a phantom to provide for determination of **detectability** of low-echo (cyst-like) objects for any type of pulse-echo transducer, except (perhaps) a 2-D array with a spherical-cap surface.

The International Electrotechnical Commission (IEC) draws attention to the fact that it is claimed that compliance with this document may involve the use of US Patents 5,574,212 and 8,887,552, concerning an “Automated System and Method for Testing Resolution of Ultrasound Scanners” and an “Ultrasound Phantom Having a Curved Surface”, respectively, given in 8.2 and 8.3, and Annexes A and D.

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ULTRASONICS – PULSE-ECHO SCANNERS – LOW-ECHO SPHERE PHANTOMS AND METHOD FOR PERFORMANCE TESTING OF GRAY-SCALE MEDICAL ULTRASOUND SCANNERS APPLICABLE TO A BROAD RANGE OF TRANSDUCER TYPES

1 Scope

This Technical Specification defines terms and specifies methods for quantifying the imaging performance of real-time, ultrasound B-mode scanners. The types of transducers used (see sections 7.6 and 10.7 of [1]) with these scanners include

- a) phased array,
- b) linear arrays,
- c) convex arrays,
- d) mechanical sector scanners,
- e) 3-D probes operating in 2-D imaging mode (see Annex K),
- f) 3-D probes operating in 3-D imaging mode for a limited number of sets of reconstructed 2-D images (see Annex K).

The test methodology is applicable for transducers operating in the 2 MHz to 15 MHz frequency range.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 – 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 61391-2:2010, *Ultrasonics – Pulse-echo scanners – Part 2: Measurement of maximum depth of penetration and local dynamic range*