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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

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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.

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- transformed into an International standard,
- reconfirmed,
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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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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*