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TECHNICAL SPECIFICATION

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

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FOREWORD

IEC TS 62791 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 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition.

a) It introduces necessary corrections to the analysis methods; these have been published in the literature.

b) It increases the range of contrast levels of **low-echo spheres** in phantoms that meet this Technical Specification. Previous specification was -20 dB, but two additional levels, -6 dB and either -30 dB or, if possible, -40 dB, are now specified.

c) It includes a wider range of uses of the methodology, including testing the effectiveness of scanner pre-sets for specific clinical tasks and detecting flaws in transducers and in beamforming.

d) It decreases the manufacturing cost by decreasing phantoms' dimensions and numbers of low-echo, backscattering spheres embedded in each phantom.

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

Draft	Report on voting
87/776/DTS	87/790A/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 described in greater detail at www.iec.ch/standardsdev/publications.

Terms in **bold** in the text are defined in Clause 3.

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- withdrawn,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

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. Many newer scanners transmit broad, overlapping ultrasound beams, and apply software beam-forming to synthesize narrow, pulse-echo beam patterns.

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 and 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. Some linear- and convex-array models, such as "1,25-D" arrays, incorporate multiple rows of elements to provide additional control of the elevational beam width.

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. The foregoing transducer types commonly operate within the frequency range 1 MHz to 23 MHz, to which this document applies. Medical ultrasound systems exist whose transducers operate at frequencies as high as 33 MHz. Although the procedures specified in this document might be appropriate for these systems, phantoms outlined in this document have not yet been described for use in the 23 MHz to 33 MHz frequency range.

A two-dimensional array (2-D array) is restricted to an array of transducer elements distributed over a rectangular 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 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 (low-echo) sphere is distinguished from the surrounding soft tissue, i.e. the degree to which a small, **low-echo sphere** 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 display and delineate the boundary of an abnormal object, such as a tumour, and the more accurately it will display local acoustic properties.

1 Numbers in square brackets refer to the Bibliography.

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 affect an object's **detectability**. A sphere has no preferred orientation and is therefore the best shape for assessing **detectability** of a low-echo 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 considerably in the case of convex and phased arrays depending on where the object exists in the imaged volume.

Imaging performance can be reduced by:

- beam distortions associated with dead or weak elements in array transducers;
- side lobes and grating lobes that are present with some array transducers;
- unexpected beam changes accompanying variations in the transmit foci applied to multi-row ("1,25-D") arrays; and
- electronic noise.

All can contribute to artifactual echoes on clinical images and on images of phantoms containing **low-echo spheres** or to erroneous echo-signal amplitudes.

It is important that the phantom allow 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 specified in this document 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 document summarizes the requirements for a phantom to provide for determination of **detectability** of small, **low-echo spheres** for any type of pulse-echo transducer, except (perhaps) a 2-D array with a spherical-cap surface.

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

1 Scope

This document, which is a Technical Specification, defines terms and specifies methods for quantifying detailed imaging performance of real-time, ultrasound B-mode scanners. Detail is assessed by imaging phantoms containing small, low-echo spherical targets in a tissue-mimicking background and analysing sphere **detectability** [3]. Specifications are given for phantom properties. In addition, procedures are described for acquiring images, conducting qualitative analysis of sphere **detectability**, and carrying out quantitative analysis by detecting sphere locations and computing their contrast-to-noise ratios. With appropriate choices in design, results can be applied, for example:

- to assess the relative ability of scanner configurations (scanner make and model, scan head and console settings) to delineate the boundary of a tumour or identify specific features of tumours;
- to choose scanner control settings, such as frequency or the number and location of transmit foci, which maximize spatial resolution;
- to detect defects in probes causing enhanced sidelobes and spurious echoes.

The types of transducers used (see sections 7.6 and 10.7 of [1]) with these scanners include:

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

The test methodology is applicable for transducers operating in the 1 MHz to 23 MHz frequency range.

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 – 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*

IEC TS 62736, *Ultrasonics – Pulse-echo scanners – Simple methods for periodic testing to verify stability of an imaging system's elementary performance*