IEC TS 62791

Edition 1.0 2015-09

TECHNICAL SPECIFICATION

colour inside

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

IEC TS 62791:2015-09(en)

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

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
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 corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
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 It also gives information on projects, replaced and withdrawn publications.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 also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
More than 60 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

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: csc@iec.ch.

IEC TS 62791

Edition 1.0 2015-09

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50; 17.140.50

ISBN 978-2-8322-2902-6

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

CONTENTS

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

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 may 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 should 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 should 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.

The main task of IEC technical committees is to prepare International Standards. In exceptional circumstances, a technical committee may propose the publication of a Technical Specification when

- the required support cannot be obtained for the publication of an International Standard, despite repeated efforts, or
- the subject is still under technical development or where, for any other reason, there is the future but no immediate possibility of an agreement on an International Standard.

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
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication 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.

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.

IEC takes no position concerning the evidence, validity and scope of this patent right.

The holder of this patent right has assured the IEC that he/she is willing to negotiate licences under reasonable and non-discriminatory terms and conditions with applicants throughout the world. In this respect, the statement of the holder of this patent right is registered with IEC. Information may be obtained from:

Wisconsin Alumni Research Foundation,
614 Walnut Street, 13th Floor,
Madison, WI 53726,
USA

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those identified above. IEC shall not be held responsible for identifying any or all such patent rights.

ISO (www.iso.org/patents) and IEC (http://patents.iec.ch) maintain on-line data bases of patents relevant to their standards. Users are encouraged to consult the data bases for the most up to date information concerning patents.

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-802, IEC 61391-1 and the following apply.

3.1
active area of a transducer
area over which transducer transmitting and/or receiving elements are distributed

3.2
backscatter coefficient
intrinsic backscatter coefficient
BSC
intrinsic property of a material at some frequency, equal to the differential scattering cross-section per unit volume for a scattering angle of 180°

Note 1 to entry: See [4], [5], [6].

[SOURCE: IEC 61391-1:2006, 3.6, modified]

3.3
low-echo sphere
spherical inclusion in a phantom with **backscatter coefficient** much lower than that of the background tissue-mimicking material

Note 1 to entry: All low-echo spheres in a phantom have the same diameter with a tolerance of ±1 %.

3.4
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 spheres** in a particular phantom have the same diameter D. The diameter tolerance is ±1 %.

3.5
pixel
smallest spatial unit or cell size of a digitized 2-dimensional array representation of an image

Note 1 to entry: Each **pixel** has an address corresponding to its position in the array.

Note 2 to entry: **Pixel** is a contraction of 'picture element'.

[SOURCE: IEC 61391-1:2006, 3.23, modified]

3.6
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 gray-scale display the pixel value is converted to a luminance by some, usually monotonic, function. The set of integer values representing the gray 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.

3.7
digitized image data
two-dimensional set of **pixel values** derived from the ultrasound echo signals that form an ultrasound image

3.8
mean pixel value
MPV
mean of **pixel values** detected over an area A in a phantom image, where A is somewhat smaller than the area of a circle of diameter D

Note 1 to entry: The phrase "somewhat less than" is introduced as partial compensation for the partial volume effect in the elevational dimension [3].

Note 2 to entry: The partial volume effect is a term common in CT and MR imaging, namely if an object is smaller than the slice thickness, then the signal will include the contribution of that object and the material around it. For example, if the object is a sphere, then contribution to the signal will occur from material surrounding the sphere and in a cylinder with radius equal to that of the sphere and perpendicular to the slice. In the ultrasound case, the slice corresponds to the elevational beam profile.

3.9
depth interval
interval in depth of area segments into which an image area is subdivided for computation of $LSNR_{\mathrm{m}}$-values as a function of depth

Note 1 to entry: Experience determining $LSNR_{\mathrm{m}}$-values for numerous cases has led to the conclusion that a 5 mm-**depth interval** is adequate for the phantoms containing 3,2 mm-diameter and 4 mm-diameter, low-echo spheres, and a 2 mm-**depth interval** is adequate for the phantoms containing 2 mm-diameter, low-echo spheres.

Note 2 to entry: The maximum depth (depth of field) is the sum of a set of contiguous **depth intervals**; thus, if the depth of field is 14 cm and each depth interval spans 5 mm = 0,5 cm, then there are 14 cm/0,5 cm = 28 **depth intervals**.

Note 3 to entry: A rectangular scan area will be subdivided into horizontal bands; a sector scan area will be subdivided into annular ring segments, the angular limits being determined by the sector angle [see Figure B.2 d)]. Rectilinear projection of these area segments in the elevational direction will create volume segments analogous to slabs and partial cylindrical shells with thickness equal to the **depth interval**, respectively.

Note 4 to entry: **Depth interval** is expressed in millimetres (mm).

3.10
detectability
numerical value quantifying the probability that a human observer will detect an object in an image having background speckle

3.11
lesion signal-to-noise ratio for the *n*th low-echo sphere
$LSNR_n$
numerical value quantifying the **detectability** of a macroscopically uniform, low-echo sphere in a macroscopically uniform, surrounding-background material and having its centre in a volume segment determined by a given **depth interval** in the phantom

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

3.12
mean lesion signal-to-noise ratio
$LSNR_{\mathrm{m}}$
mean value of **lesion signal-to-noise ratios** for **low-echo spheres** whose centres lie in a volume segment determined by a given **depth interval** in the phantom

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

4 Symbols

Symbol	Meaning	Clause
A	area in an image plane selected for calculation of MPV	3.8
BSC_{obj}, BSC_{bkg}	backscatter coefficient	3.2
D	low-echo sphere diameter	3.4
d	integer for counting depth intervals	E.1
i, j, k	integers corresponding to rows and columns and the elevational direction of the cubic array, respectively	8.2
i (in Annex F)	index taking values 1 or 2 to indicate one side or opposite side of a phantom, where a reflector is situated	Formula (F.1)

Symbol	Meaning	Clause
$LSNR_{\mathrm{m}}$	mean lesion signal-to-noise ratio	3.12
$LSNR_n$	lesion signal-to-noise ratio for the nth low-echo sphere	3.11
M_d	mean of all MPVs with centres lying within volume segment, d, using the entire image set	E.1
MPV	mean pixel value	3.8
$(MPV)_{ijk}$	MPV at the ijk-site of the cubic array	8.2
$(MPV)_n = S_{\mathrm{L}n}$	MPV calculated over area A centred at the projection of $(x_{\mathrm{CM}n}, y_{\mathrm{CM}n})$ onto the image plane nearest to z_{CM}	8.2
N	total number of detected low-echo spheres with centres in the volume segment determined by a depth interval (including all image frames)	8.3.2
n	integer for counting low-echo spheres	3.11
$P(u)$	probability of there being u low-echo sphere centres in an arbitrarily chosen 1 ml volume	6.2.4
q	exponent of the frequency dependence of the backscatter coefficient	6.3
R_i and N_i	**mean pixel values** on the reflector side and non-reflector side of phantom	Formula (F.1)
$S_{\mathrm{L}n} = (MPV)_n$	MPV calculated over area A centred at the projection of $(x_{\mathrm{CM}n}, y_{\mathrm{CM}n})$ onto the image plane nearest to z_{CM}	8.3.2
$S_{\mathrm{mB}n}$	mean of all MPVs in the specified image plane whose centres are within the annulus defined by radii equal to (3/4)D and 2D and centred at the coordinates of $S_{\mathrm{L}n}$	8.3.2
SD_d	standard deviation of all MPVs with centres lying within volume segment, d, using the entire image set	E.1
$x_{\mathrm{CM}n}, y_{\mathrm{CM}n}, z_{\mathrm{CM}n}$	coordinates of the centre of mass of the nth low-echo sphere	E.1
x_n, y_n	projections onto the nearest image plane of the x- and y-coordinates of the centre of mass of the nth low-echo sphere $(x_{\mathrm{CM}n}, y_{\mathrm{CM}n})$	8.2
v	mean number of low-echo sphere centres per millilitre	6.2.4
$\sigma_{\mathrm{B}n}$	standard deviation of all MPVs contributing to $S_{\mathrm{mB}n}$	8.3.2

NOTE Additional symbols used only in relation to Figure F.4 are defined in the text below that figure.

5 General and environmental conditions

The manufacturer's specification should allow comparison with the results obtained from the tests described in this Technical Specification.