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TECHNICAL SPECIFICATION

colour inside

Ultrasonics – Real-time pulse-echo scanners – Phantom with cylindrical, artificial cysts in tissue-mimicking material and method for evaluation and periodic testing of 3D-distributions of void-detectability ratio (VDR)

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ULTRASONICS – REAL-TIME PULSE-ECHO SCANNERS – PHANTOM WITH CYLINDRICAL, ARTIFICIAL CYSTS IN TISSUE-MIMICKING MATERIAL AND METHOD FOR EVALUATION AND PERIODIC TESTING OF 3D-DISTRIBUTIONS OF VOID-DETECTABILITY RATIO (VDR)

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IEC 62558, which is a technical specification, has been prepared by IEC technical committee 87: Ultrasonics.

The text of this technical specification is based on the following documents:

Enquiry draft	Report on voting
87/434/DTS	87/458/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.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site 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- withdrawn,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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INTRODUCTION

This technical specification provides an example of a measurement method and of a test phantom. The specified method and test equipment permit operation without knowledge of proprietary information of the diagnostic ultrasonic equipment manufacturer.

This technical specification describes desirable specifications and performance characteristics of a tissue-mimicking material (TMM) 3D artificial-cyst phantom. An example including design of a realized and conforming phantom is given. The described results are independent of applied electronic and design architecture of diagnostic ultrasound systems and related transducers suitable for testing with the phantom.

Medical diagnostic ultrasound systems and related transducers need periodic testing as the quality of medical decisions based on ultrasonic images may decrease over time due to progressive degradation of essential systems characteristics. The TMM phantom is intended to be used to measure and to enable documentation of changes in void-detectability ratio in periodic tests over years of use.

The example of phantom design uses sliced TMM arranged as alternating "cyst-slices" and "attenuation-slices". It allows measurement along all three axes of the ultrasonic beam (axial, azimuthal and elevation) to determine the void-detectability ratio depending on the depth in the image generated from a transducer. The basis of the design concept and measurement method is anechoic, artificial cysts, representing idealized pancreatic ducts in the human body, and the measurement of the void-detectability ratio inside the images of these artificial cysts. The images of the artificial cysts should appear anechoic. The measurement of void-detectability ratio quantifies the diagnostic ultrasound system's ability to properly represent these objects. Increased artifactual signals appearing within images of these artificial cysts indicate a degradation of certain image parameters. A certain level of artifactual signals is to be expected for any ultrasound system, due to the emitted beam's shape and the transducer's receive characteristics. Any increase in these artifactual signals may be caused, for example, by grating- and side-lobes that may occur due to, for example, partial or total depolarisation of elements, delamination between transducer elements and lens, or corrosion. The measurement procedure allows a reliably and reproducible determination of the visibility limits of small voids, an important image parameter of an ultrasound diagnostic system over the time of use, by applying dedicated acquisition, processing and documentation software.

Four informative annexes are provided: Annex A – Description of construction of an example phantom and test results; Annex B – System description; Annex C – Rationale; Annex D – Uniformity measurement.

ULTRASONICS – REAL-TIME PULSE-ECHO SCANNERS – PHANTOM WITH CYLINDRICAL, ARTIFICIAL CYSTS IN TISSUE-MIMICKING MATERIAL AND METHOD FOR EVALUATION AND PERIODIC TESTING OF 3D-DISTRIBUTIONS OF VOID-DETECTABILITY RATIO (VDR)

1 Scope

This technical specification specifies essential characteristics of a phantom and method for the measurement of void-detectability ratio for medical ultrasound systems and related transducers. It is restricted to the aspect of long-term reproducibility of testing results.

This technical specification establishes:

– important characteristics and requirements for a TMM 3D artificial cyst phantom using anechoic voids;

– a design example of a 3D artificial cyst phantom, the necessary test equipment and use of relevant computer software algorithms.

This technical specification is currently applicable for linear array transducers. A uniformity test prior to void-detectability ratio (VDR) measurement is recommended.

NOTE The basic concept of the 3D artificial-cyst phantom may also be valid for other types of ultrasound transducers; however there is a need for further verification (see Annex D).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including amendments) applies.

IEC 60050-802, *International Electrotechnical Vocabulary, Part 802: Ultrasonics*

3 Terms and definitions

For the purposes of this document, the terms and definitions contained in IEC 60050-802 as well as the following terms and definitions apply.

3.1
acoustic coupling medium
medium, usually fluid or a gel, that allows echo-free coupling of the transducer to the coupling window of the phantom.

3.2
artifactual signal
signal at a specific region in an image where no signal is expected (e.g. inside the image of a void)

3.3
attenuation coefficient
at a specified frequency, the fractional decrease in plane wave amplitude per unit path length in the medium, specified for one-way propagation

Units: m^{-1} (attenuation coefficient is expressed in dB m^{-1} by multiplying the fractional decrease by 8,686 dB)

[IEC 61391-2:2010, definition 3.4]

3.4
backscatter coefficient
at a specified frequency, the mean acoustic power scattered by a specified object in the 180° direction with respect to the direction of the incident beam, per unit solid angle per unit volume, divided by the incident beam intensity, the mean power being obtained from different spatial realizations of the scattering volume

Units: $m^{-1}steradian^{-1}$

NOTE The frequency dependency should be addressed at places where backscatter coefficient is used, if frequency influences results significantly.

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

3.5
backscatter contrast
ratio between the backscatter coefficients of two objects or regions

[IEC 61391-2:2010, definition 3.8]

NOTE Backscatter contrast can be frequency-dependent but it is independent of any image system.

3.6
B-, C-, D-image
basic cross sectional presentations of 3D-images:

B-image is in a plane that is created by the acoustic scan-lines (scan plane);

C-image is in a plane perpendicular to the acoustic scan lines in the B-image;

D-image is in a plane perpendicular to B-image–plane and C-image-plane

3.7
B-, C-, D-(image) plane
B-plane: scan plane;

C-plane: reconstructed image plane that is perpendicular to acoustic scan lines in the B-plane;

D-plane: reconstructed image plane that is perpendicular to the scan plane and the C-plane

3.8
coupling window
portion of the phantom’s enclosure provided for entrance and exit of the transmitted ultrasound waves to/from the tissue-mimicking material without significant attenuation or distortion

NOTE The coupling window usually consists of a thin membrane which protects the tissue-mimicking material from evaporation, leakage and mechanical damage by the transducer and which does not significantly alter the ultrasound signals

3.9
detection limit
smallest true value of the measurement, which is detectable by the measuring method

[IEC 60761-1:2002, definition 3.10, modified]

3.10
digitized image data
two-dimensional or three-dimensional set of pixel (voxel) values derived from the grey-level values of the B-mode images that are sent to the monitor screen

3.11
documentation
human-readable information about a device instance

[IEC 62453-1:2009, definition 3.1.18]

NOTE Within the context of this TS, the printed documentation and the documentation provided via Extended Markup Language (XML) are also meant. The documentation can consist of several documents and images.

3.12
fixed pattern
parts of the B-mode image that remain in the same position relative to the image frame when the transducer is moved

3.13

grey-level value
number determining the brightness of the pixels of a B-mode image (as derived from the signal amplitude of the signal reflected from the corresponding position in the body)

NOTE The grey level values determine the brightness of specific pixels in the image and they historically range from 0 (black) to 255 (white). Black indicates a weak signal, white a strong signal, This convention holds throughout this document for calculations. In images an inverted display can be used, where black indicates the level 256 and white 0.

3.14
(acoustic) scan line
one of the component lines that form a B-mode image on an ultrasound system monitor, where each line is the envelope-detected A-scan line in which the echo amplitudes are converted to brightness values

[IEC 61391-1:2006, definition 3.26, modified]

3.15
scan plane
acquired image plane containing the acoustic scan lines

[IEC 61391-2:2010, definition 3.30]

3.16
specific attenuation coefficient
at a specified frequency, the slope of attenuation coefficient plotted against frequency

Units: m^{-1} Hz^{-1}

3.17
Tissue-mimicking material
TMM
material in which the propagation velocity (speed of sound), reflection, scattering, and attenuation properties are similar to those of soft tissue for ultrasound in the frequency range 1 MHz to 15 MHz

[IEC 61391-1:2006, 3.36, modified]

3.18
TMM 3D artificial anechoic cyst phantom
phantom containing tissue-mimicking material, in which there are well-defined regions whose backscatter contrast is lower than -60 dB relative to the regions containing TMM

3.19
uniformity test procedure
procedure to test the uniformity of the transmitted signals of all the elements of array transducers

3.20
void
artificial anechoic cyst
region of defined geometry in a tissue-mimicking material that generates no scattered acoustic waves

NOTE Saline solution in specified concentration is known to produce extremely low levels of scattered signals and therefore it is an optimal approximation to a perfect void.

3.21
void-detectability ratio
VDR
number characterizing the visibility of an image area corresponding to a void of defined diameter surrounded by tissue-mimicking material (TMM) in the phantom

$VDR = (\mu_1 - \mu_2) / \sigma_1 = (1/n)(\Sigma_{i=1..n}(VDR_i))$

where

μ_1 = mean image pixel value of the TMM in the region surrounding the void for a given C-plane;

μ_2 = mean value of the image pixel values from within the image area representing a void;

σ_1 = standard deviation of mean pixel values over separate TMM areas equal to the void area and lying in the region of the void, for a given C-plane;

n = number of voxels (pixels) from a given C-plane or from a specific part of this C-plane (e.g. the image area of a single void or the image area of all voids within the C-plane)

NOTE 1 The image of the surrounding TMM material is expected to show modulated grey levels (i.e. an ultrasound speckle image) due to the ultrasound interference patterns).

NOTE 2: The VDR formula is derived from [4][1]

3.21.1
detectability ratio for a single voxel
detectability ratio for a single voxel is defined by:

$VDR_i = (\mu_1 - g_i) / \sigma_1$

where

μ_1 = mean image pixel value of the TMM in the region surrounding the void for a given C-plane;

g_i = grey level value of the i-th voxel (pixel) from a given C-plane or from a specific part of this C-plane (e.g. the image area of a single void or the image area of all voids within the C-plane);

σ_1 = standard deviation of mean pixel values over separate TMM areas equal to the void area and lying in the region of the void, for a given C-plane

1 Numbers in square brackets refer to the Bibliography.

NOTE The VDR formula is derived from [4].

3.21.2
maximum VDR within a void
VDR_v
maximum VDR within a void is defined by

$$VDR_v = (\mu_1 - g_v) / \sigma_1 = \max_{i=1..n} (VDR_i)$$

where

μ_1 = mean image pixel value of the TMM in the region surrounding the void for a given C-plane;

g_v = minimum grey-level value of the image region corresponding to the interior of a void;

σ_1 = standard deviation of mean pixel values over separate TMM areas equal to the void area and lying in the region of the void, for a given C-plane

NOTE The VDR formula is derived from [4].

maximum VDR in a ROI in a C-plane
VDR(max)
maximum value of VDR in a specified region of interest (ROI) within a C-plane

3.21.3
absolute maximum VDR in a ROI in a volume
VDR_{absmax}
absolute maximum value of all VDR_i-values in a volume comprising the evaluated region of interest (ROI), i.e. in a display of the function VDR(max) over the total depth z in the evaluated ROI

3.22
VDR limit
minimum value of the VDR for which there is visualization of a void on an ultrasound image

NOTE In [4] the detection limit for the detection of voids of the defined void sizes (see A.10.1) for a noise level independent of electronic noise was stated to be around VDR = 2,5 for spherical voids.

4 Symbols

c	=	speed of sound
$g_{i...}$	=	grey level value of the i-th voxel (pixel) from a given C-plane or from a specific part of this C-plane (e.g. the image area of a single void or the image area of all voids within the C-plane)
g_v	=	minimum grey-level value of image region corresponding to the interior of a void
T	=	temperature
S	=	salinity
$S_{g\ max}$	=	maximum value of the digitized image data (grey-level values)
VDR	=	void detectability ratio -- averaged value over the image of a void
VDR_i	=	detectability ratio for a single voxel (pixel) i, measured over a region in the digitized image data
VDR_v	=	void detectability ratio -- maximum value within the image of a void
VDR(max)	=	maximum value of VDR in a specified ROI in a C-plane
VDR_{absmax}	=	absolute maximum value of VDR in a display of the functional range of VDR(max) over depth

z	=	depth
μ_1	=	mean image pixel value of the TMM in the region surrounding the void for a given C-plane
μ_2	=	mean value of the image pixel values from within the image area representing a void
μ_3	=	mean value of the image pixel values from a 3D region of interest (ROI)
σ_1	=	standard deviation of mean pixel values over separate TMM areas equal to the void area and lying in the region of the void, for a given C-plane

5 Ambient conditions of measurement with the phantom

Typical ambient conditions during measurements should be similar to those specified in IEC 61319-1 and IEC 61319-2:

Temperature: 20 °C to 24 °C;

Relative humidity: 45 % to 75 %;

Atmospheric pressure: 86 kPa to 106 kPa.

6 Specification of TMM 3D artificial anechoic-cyst phantom

6.1 3D-phantom concept

The 3D phantom shall be composed of TMM that contains an arrangement of voids of a specified shape (i.e. cylindrical) and sizes specified in relation to the defined frequency range of transducers to be tested.

NOTE An example of a phantom that conforms to this technical specification is presented in Annex A.

6.2 General phantom specification

The phantom shall allow implementing the test procedures described in this document by providing anechoic targets at known locations within tissue-mimicking material. Analysis of images is done from digitized image data that are acquired during scans of the phantom. The manufacturer shall provide an instruction manual with advice regarding reliable use and maintenance.

6.3 TMM specifications:

The following parameters of the TMM shall lie within the specified limits:

Speed of sound: (1 540 ± 10) m s^{-1} at 3 MHz

Density: (1,00 ± 0,11) g cm^{-3}

Specific attenuation coefficient: (0,7 + 0,2/ - 0,05) dB cm^{-1}MHz^{-1} in the 1 MHz to 15 MHz range. If a phantom is manufactured by using layered materials as in Annex A, for example, the specific attenuation coefficient corresponding to the mean value of the specific attenuation shall apply.

Backscatter coefficient: (3 × 10^{-4} cm^{-1}sr^{-1}) ± 10 dB at 3 MHz; with a “frequency to the *n*” (f^n**)** dependence, where $2 < n < 4$ from 1 MHz to 15 MHz. The value of the backscatter coefficient of the phantom shall be reported as a function of frequency, together with the results obtained with the phantom. Scatterers within the phantom should be of a sufficient number density to provide Rayleigh statistics in the echo-amplitude distribution (see Figure A.2.2). The scatterer number density needed will depend on the frequency and focusing characteristics of the transducer and ultrasound system to be tested under this technical specification. For guidance, around 10 scatterers per cubic millimetre are sufficient for most transducers operating up to 15 MHz.

Phantoms manufactured to these TMM specifications can be constructed using, for example, open pore sponges or polyurethane foam immersed in saline. The materials have microscopic inhomogeneities that are uniformly distributed throughout to produce the desired attenuation level.

6.4 Anechoic targets

Anechoic targets shall be provided whose backscatter contrast is at least -60 dB relative to that of the background TMM material. Degassed saline solution is an adequate material for filling anechoic targets. The saline shall be adapted in concentration to achieve sound speed of (1 540 ± 10) m s^{-1}. The sound speeds in saltwater as a function of saline concentration and temperature is shown Figure A.2.3.

Anechoic targets shall be placed at different depths throughout the phantom volume. Targets of a given diameter shall be positioned with their centres coplanar, so that in the scan plane at least 6 such targets are viewed at different lateral locations at each depth from the transducer. Targets shall be positioned in lateral locations so that they can be viewed from different locations within the scanning plane. Targets in the phantom presented in Annex A are cylinders whose faces are parallel to the scanning surface.

At each depth and lateral location, various sizes of anechoic targets shall be available. For each frequency region two sizes of voids shall be present. Dimensions of voids shall be selected in regard to realistic azimuthal and elevational beam width and frequency of the transducer, as follows:

– Voids of 4 mm and 2,5 mm diameter are satisfactory for transducers operating in the 1 MHz to 4 MHz range.
– Voids of 3 mm and 1,5 mm diameter are satisfactory for transducers operating in the 4 MHz to 8 MHz range
– Voids of 2,5 mm and 1 mm diameter are satisfactory for transducers operating in the 8 MHz to 15 MHz range

One important reason for the occurrence of artifactual signals inside of anechoic voids are side-lobes of the ultrasonic beam [9], A prerequisite to detect artifactual signals caused by side-lobes and/or grating-lobes in images of anechoic voids is an echo-amplitude difference better than -60 dB compared to the surrounding tissue-mimicking material.

6.5 Phantom enclosure

The purpose of this enclosure is to protect the contents from degradation (fluid evaporation) with time during use and storage. The material used for the enclosure walls shall be such as to prevent degradation of the contents.

6.6 Scanning surface

The scanning surface shall allow acoustic contact of the entire active surface of the transducer with the phantom. If the scanning surface includes a window material, such as a foil or membrane, to prevent desiccation of the TMM or to protect the TMM contents from damage from the transducer, the membrane properties, including material contained therein, thickness, density, and specific attenuation coefficient, shall be provided. Alternatively, transmission losses as a function of frequency shall be provided.

6.7 Dimensions

The dimensions of the phantom shall be suitable to evaluate transducers by assessing VDR at least 2/3 of the imaged field for which the transducer is typically used. For example, a