IEC/TS 62558

Edition 1.0 2011-03

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)

IEC/TS 62558:2011(E)

AVA Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2011 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.
If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.
Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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.

- Catalogue of IEC publications: www.iec.ch/searchpub
The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub
Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv
If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: csc@iec.ch
Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00

Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

IEC/TS 62558

Edition 1.0 2011-03

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)

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE X

ICS 17.140.50

ISBN 978-2-88912-377-3

® Registered trademark of the International Electrotechnical Commission

Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope 7
2 Normative references 7
3 Terms and definitions 7
4 Symbols 11
5 Ambient conditions of measurement with the phantom 12
6 Specification of TMM 3D artificial anechoic-cyst phantom 12
6.1 3D-phantom concept 12
6.2 General phantom specification 12
6.3 TMM specifications: 12
6.4 Anechoic targets 13
6.5 Phantom enclosure 13
6.6 Scanning surface: 13
6.7 Dimensions 13
6.8 Phantom stability 14
6.9 Digitized image data 14
7 Principle of measurement using the 3D anechoic void phantom 15
7.1 General 15
7.2 Analysis 15
Annex A (informative) Description of construction of an example phantom and test results 17
Annex B (informative) System description 37
Annex C (informative) Rationale 38
Annex D (informative) Uniformity measurement 41
Bibliography 48

Figure A.1 – Example of measurement test equipment 17
Figure A.2a) – Package of TMM slices containing alternating void slices and attenuation slices of polyurethane foam 19
Figure A.2b) – Holes of different diameters in the void slices allow the use of the phantom with different ultrasound frequencies (1 – 15 MHz) 19
Figure A.2 – TMM slices 19
Figure A.3 – Structure of foam 19
Figure A.4 – C-images of voids 20
Figure A.5 – Experimental confirmation of Rayleigh distribution with attenuating TMM 21
Figure A.6 – Speed of sound in saltwater 22
Figure A.7 – Phantom with motor drive and two types of adapters 22
Figure A.8 – B-, D-, C- images and grey scale 24
Figure A.9 – Illustration of the VDR calculation for a ROI consisting of a single line 25
Figure A.10 – B-C-D planes 26
Figure A.11 – Principle of the ultrasound scanning array and beam 27
Figure A.12 – Schematic of B-D-C planes 28

AVA Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

Figure A.13 – 3D-Phantom images 29
Figure A.14 – B-D-C images and VDR 30
Figure A.15a) – Example: Curved Array, 40-mm radius, 3,5MHz with good VDR-values..... 31
Figure A.15b) – Example: Curved Array, 40-mm radius, 3,5MHz with poor VDR-values 31
Figure A.15 – VDR-values 31
Figure A.16 – Example: Linear array transducer 13 MHz..... 32
Figure A.17 – Interpretation of VDR parameter 33
Figure A.18 – Explanation of saturation (0-255 grey-scale range) 34
Figure A.19a) – Voids 2,5 mm..... 35
Figure A.19b) – Voids 3,0 mm..... 35
Figure A.19c) – Voids 4 ;0 mm..... 35
Figure A.19 – Saturation effect 35
Figure A.20 – Void spot analysis..... 35
Figure A.21a) – Local dynamic curve 36
Figure A.21b) – Expected envelope of VDR 36
Figure 21 – Local dynamic range 36
Figure C.1 – Autocorrelation function..... 39
Figure C.2a) – Autocorrelation function at 4,06 cm depth..... 40
Figure C.2b) – Autocorrelation function at 9,08 cm depth..... 40
Figure C.2 – Autocorrelation function – dependence on depth 40
Figure C.3 – Autocorrelation function at 10,94 cm depth 40
Figure D.1a) – Uniformity test with related linear or curved array transducer..... 42
Figure D.1b) – Fixed pattern in B-image 42
Figure D.1 – Uniformity test 42
Figure D.2a) – B-D-C image and fixed pattern in C-image..... 43
Figure D.2b) – Grey scale display of full array 43
Figure D.2 – Uniformity test – Additional features 43
Figure D.3 – Linear transducer with reference tape..... 44
Figure D.4 – Interpretation of simulated transducer failure when half of the probe is covered by five layers of 50-mm fabric tape 45
Figure D.5 – Disconnected elements, example with linear transducer 46
Figure D.6 – Example with curved array transducer and reference tape 47

Documents
Document Sharing Hub
Full document details: IEC TS 62558 2011

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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)

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 shall 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 shall 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.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

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

AVA Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

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
- amended.

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

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.

Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

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.

Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

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

AVA Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

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]

Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

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]

Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

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

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

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.

Documents
Document Sharing Hub
Full document details: IEC TS 62558 2011

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

Documents
Document Sharing Hub
Full document details: IEC TS 62558 2011

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

AVA Documents
Document Sharing Hub
Full document details: IEC TS 62558 2011

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,

AVA Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

ultrasound system that provides a 24 cm imaging depth requires a phantom of at least 16 cm depth. This is generally at least four times the size of the transducer transmit-receive aperture, so any degradation caused by side lobes or by poor lateral resolution would be manifested within this range.

6.8 Phantom stability

The manufacturer shall state the duration of stability and indicate criterion of use.

6.9 Digitized image data

Test and analysis methods described in this technical specification are applied to digitized image data derived from the ultrasound system and related transducer being evaluated. In all cases, grey level values for all spatial locations in the image must be available. Image data typically are in a matrix consisting of about 300 × 300 pixels and at least 8 bits (256 levels) of amplitude (directly proportional to grey-scale) resolution.

Digitized image data may be obtained using a video frame grabber to digitize images from output connectors normally used to transfer images to analogue monitors or to recording devices. The video signal digitization must be provided under exactly specified conditions to avoid or minimize signal distortions. Specific care and attention shall be taken for the following parameters:

- The input dynamic range of the video-frame grabber shall be adjusted according to the maximum signal amplitude of the video output.
- The digitizing amplitude resolution (given by the pixel byte size) shall be better than that of the grey-scale resolution of the ultrasound image video-output signal. A minimum of 8 bits or 256 grey levels is required.
- Ultrasound image signal to TV conversion-function linearity has to be assured. The spatial resolution (given by the voxel size) of the digital picture must be better than the original video line density of the image.
- The video-capture frame rate of the video-frame grabber must be high enough to allow acquisition of data to keep up with input data rates, if the imaged field is moved. Keep in mind the difference between scanning frame rate and output video frame rate.
- A cable matched for input/output impedance has to be used to avoid reflections in the line. A cable length of 1 m to 2 m is generally not critical.
- The digitized image data must be representative of those on the display monitor of the diagnostic ultrasound system. The digitized image data derived from the diagnostic ultrasound system shall not undergo any post-processing modifications between the point of data processing and the monitor output signal of the system before being subjected to analysis as described in this technical specification.

Data also can be acquired using DICOM-images (Digital Imaging and Communications in Medicine) [13] or images in other formats from the ultrasound system. This method is used by most ultrasound system manufacturers for in-house quality-control testing and image-processing development. Capabilities often exist to extend the method for use by clinical personnel using, for example, file-transfer-protocol (ftp) resources.

Alternatively, many diagnostic ultrasound systems provide image files on removable media, such as USB-thumb drives, magneto-optical disks, zip disks, or CD-ROM, and these are appropriate sources of digital images data as well.

In addition, many imaging centres use commercially available Picture Archiving and Communication Systems (PACS) for viewing and storing ultrasound-image data. Manufacturers of PACS systems usually provide means to acquire images in an uncompressed format, such as a tiff (Tagged Image File Format) or a DICOM format, to workstations that have access rights to the image data.

Documents
Document Sharing Hub

Full document details: IEC TS 62558 2011

In any case, where image data are not acquired from the (analogue or digital) video output but from data derived within the ultrasound system, it must be ascertained that the digitized amplitude provided in this case really corresponds to the grey-levels shown on the viewing screen.

Until DICOM offers a standard for 3D-images the best procedure is to use a VGA or DVI converter to digitize the video output signal of the ultrasound system.

7 Principle of measurement using the 3D anechoic void phantom

7.1 General

The measurement equipment for the VDR measurement consists of the phantom, the transducer and ultrasound system to be tested, and a means to acquire digitized image data from scan planes that extend over that volume of the phantom that contains voids.

An acceptable method for acquiring the 3D data is to apply the mechanical transducer positioner described in Annex A, then to record digitized image data from closely positioned scan planes. The scan plane spacing should be equal to the voxel separation within the scan-planes, however; it should be less than 1/4 times the diameter of the void from which VDR will be computed.

Other approaches to 3D data acquisition are to use special transducers, such as those with built-in mechanical translation of the probe, or to use manual translation of the transducer while recording image data in a cine image loop, such as those provided within the ultrasound system. However, the latter approach does not allow for ensuring an appropriate B-plane spacing.

A uniformity measurement of transducers is essential. It should be done prior to VDR measurement. One possible method is described in Annex D.

7.2 Analysis

The following is an acceptable method of analysis:

VDR is computed for anechoic targets (i.e., voids) of a given diameter, depth, and lateral location in planes parallel to accessible C-planes, as described in Annex A. However, for this technical specification, results shall be reported for C-planes containing voids.

Within images reconstructed from the acquired 3D data a region of interest (ROI) is defined.

The data in this region shall provide cubic voxels (i.e. the dimensions of the voxel should be identical in all three directions) of known size. To achieve this objective, information on the image scale must be acquired. The 3D-ROI data are stored in a matrix to allow viewing and processing of this 3D-data set.

For each C-plane within the 3D-ROI the mean (μ_1) and the standard deviation (σ_1) values for the TMM are calculated. Different approaches for excluding void regions from these calculations have been proposed. Some of these approaches make use of the additional information from the knowledge of the void distribution; others just use the local grey-scale compared to the other voxel amplitudes within the C-plane to decide whether or not the individual voxel is part of a void. Different approaches to exclude void regions from the calculation of the TMM-mean and standard deviation are described in Annex A.

The μ_1 and σ_1 values are used to calculate VDR_i for each individual voxel according to the expression

Documents
Document Sharing Hub
Full document details: IEC TS 62558 2011