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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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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.

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- withdrawn,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.

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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