

TECHNICAL REPORT



Ultrasonics – Real-time pulse-echo systems – Test procedures to determine performance specifications

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-5638-1

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

CONTENTS

FOREWORD	5
INTRODUCTION	7
1 Scope	8
2 Normative references	8
3 Terms and definitions	8
4 Environmental conditions	18
5 Recommended equipment	19
6 Test methods	19
6.1 Instruments	19
6.1.1 General	19
6.1.2 Hydrophones	19
6.1.3 Oscilloscope or other transient recorder	19
6.1.4 Spectrum analyzer	20
6.1.5 Pulse generator	20
6.1.6 Tissue-mimicking test objects	20
6.1.7 Tank and degassed water	20
6.1.8 High or low reflective target	20
6.1.9 Target holder and/or positioning system	20
6.1.10 Computing system to run computer-assisted evaluation software	21
6.1.11 Software to evaluate quality parameters	21
6.2 Test settings	21
6.2.1 General	21
6.2.2 Display settings (focus, brilliance, contrast)	21
6.2.3 Sensitivity settings (frequency, suppression, output power, overall gain, TGC, automatic TGC)	21
6.2.4 Final optimisation	22
6.2.5 Recording system	22
6.3 Tested quantities / parameters and procedures	22
6.3.1 General	22
6.3.2 Acoustic working-frequency bandwidth	23
6.3.3 Resolution	23
6.3.4 Contrast-detail resolution	25
6.3.5 Non- or minimally-scattering region detectability	25
6.3.6 Dead zone and proximal and distal working limits	28
6.3.7 Slice thickness	28
6.3.8 Depth of penetration	28
6.3.9 Displayed dynamic range	29
6.3.10 Display error or position recording error	29
6.3.11 Measurement system accuracy	29
6.3.12 M-mode calibration	30
6.3.13 Beam shape	30
6.3.14 Uniformity-degradation (element or channel) test	31
Annex A (informative) Test objects and tissue-mimicking material	32
A.1 Test object structures	32
A.2 Tissue-mimicking materials	32
A.3 Description of test objects	32

A.3.1	Soft tissue-mimicking test object.....	32
A.3.2	Axial resolution test object.....	33
A.3.3	Multi-purpose resolution test object	34
A.3.4	Contrast test objects.....	36
A.3.5	Low-scattering sphere void test object.....	37
A.3.6	Randomly positioned, embedded low-echo spheres phantom	38
A.3.7	Cylindrical-void phantom	39
A.3.8	Edinburgh pipe phantom.....	40
A.3.9	Crossed-threads phantom.....	42
Annex B (informative)	Test procedures	47
B.1	Analysis of random-void phantoms.....	47
B.1.1	Automated segmentation and sorting of voids.....	47
B.1.2	Procedure for detecting voids and assigning contrast-scaled spherical objects to them for display of the best imaging zones	48
B.2	Analysis of beam profiles using cross-threads phantoms	50
B.2.1	Test procedure for crossed-threads phantom.....	50
B.2.2	Analysis of display sonic contrast when using a foam phantom.....	50
Bibliography	53
Figure 1	– Beam geometry.....	11
Figure 2	– Reticulated foam with random voids	26
Figure A.1	– Soft tissue-mimicking test object.....	33
Figure A.2	– Axial resolution test object	34
Figure A.3	– Multi-purpose resolution test object	35
Figure A.4	– Slice-thickness measurement and calculation	36
Figure A.5	– Contrast test object.....	37
Figure A.6	– Non-scattering spheres test object.....	38
Figure A.7	– End view of the phantom applicable for 2 MHz to 7 MHz showing the spatially random distribution of 4-mm diameter spheres	39
Figure A.8	– Essential components of Satrapa's cylindrical-void phantom	40
Figure A.9	– Structures of foams.....	40
Figure A.10	– Schematic of Edinburgh pipe phantom showing anechoic pipes within the tissue mimicking material	41
Figure A.11	– Image from a preclinical ultrasound scanner operating at 55 MHz showing the length over which a 92-micron pipe can be visualised in the scan plane	42
Figure A.12	– 3D-thread phantom	43
Figure A.13	– Beam profiles calculated from the single-filament images	43
Figure A.14	– Thread groups with threads stretched at 45° angles to each other	44
Figure A.15	– (above) Azimuthal and elevational beam profiles obtained from a filament phantom; (below) Constant depth (C-images) from a random-void phantom.....	45
Figure A.16	– Beam profiles calculated for a matrix probe	45
Figure B.1	– Segmentation of voids performed following void contrast (void signal amplitude) ranking and transfer in small spheres like a “container” to the corresponding contrast fraction.....	48
Figure B.2	– WCR-plot for 10 fractions with the reference level set to 70	49
Figure B.3	– Screen shots of rotating volume images of a random-void phantom using gray-scale (left) and VDR_i -levels (right) in transparent mode	49

Figure B.4 – Screen shot of a rotating-volume image of random-void phantom after automatic segmentation	50
Figure B.5 – Determination of display sonic contrast (symbolic)	51
Figure B.6 – Result of 3D-display sonic contrast determination (example)	51
Figure B.7 – A Signal-to-Noise Ratio (SNR) chart, giving only "signal" without "noise", expressed in dB	52

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – REAL-TIME PULSE-ECHO SYSTEMS –**Test procedures to determine performance specifications**

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.

IEC TR 61390 has been prepared by IEC technical committee 87: Ultrasonics. It is a Technical Report.

This second edition cancels and replaces the first edition published in 1996. This edition constitutes a technical revision.

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

- a) Several additional phantom designs are included in the main body of the document;
- b) Several additional transducer types are included in the Scope;
- c) Methods of analysis are presented in new Annex B.

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

Draft	Report on voting
87/771/DTR	87/796A/RVDTR

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 Report 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.

NOTE Words 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.

IMPORTANT – The "colour inside" logo on the cover page of this document 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.

INTRODUCTION

An ultrasonic pulse-echo scanner produces images of tissue in a **scan plane** by sweeping a narrow, pulsed beam of **ultrasound** through the section of interest and detecting the echoes generated at tissue boundaries. Furthermore, the number of ultrasonic pulse-echo scanners using plane-wave imaging technology is increasing.

Alternatively, a scanner can transmit a wide-field wave-front or several transmit-beams and record from the whole transducer array the echoes backscattered from tissue boundaries [1] [2]¹. The latter is followed by software beamforming, picking several parts of the wide beam or in this way selecting one of the simultaneously transmitted beams to obtain adequate resolution. Plane-wave techniques cannot compete with physical, transmit beam-forming for maximum depth of imaging at a given **bandwidth**, maximum resolution and minimum acoustic exposure.

Ultrasonic scanners are widely used in medical practice to produce images of many soft-tissue organs throughout the human body. A variety of transducer types is employed to operate in a transmit/receive mode for generating/receiving the ultrasonic signals.

This document describes test procedures that should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use this document to prepare their own specifications, while users should use this document to check manufacturers' specifications. The measurements can be carried out without interfering with the normal working conditions of the machine. The structures of the **test objects**, **test equipment** and measuring systems have not been specified in detail; rather, suitable types of overall and internal structures are described, together with typical **test objects**, in Annex A. The specific structure of a **test object** and **test equipment** should be reported, together with the results obtained using them. Similar commercial versions of these **test objects** are available.

The performance parameters selected and the corresponding methods of measurement have been chosen to provide a basis for comparison with the manufacturers' specifications and between similar types of apparatus of different makes, intended for the same kind of diagnostic application. The manufacturers' specifications should allow comparison with the results obtained from the tests described in this document. Specific values of parameters and the tolerances on them have not been recommended, since these are constantly changing. Furthermore, it is intended that the sets of results and values obtained from the use of the recommended methods will provide useful criteria for predicting the performance of equipment in appropriate diagnostic applications.

The procedures recommended in this document are in accordance with IEC 60601-1:2005. Where a diagnostic system accommodates more than one option in respect of a particular system component, for example the transducer, it is intended that each option be regarded as a separate system. However, it is considered that the performance of a machine is adequately specified, if measurements are undertaken for the most significant combinations of machine-control settings and accessories. Further evaluation of equipment is obviously possible but this should be considered as a special case rather than a routine requirement.

Data relating to measuring methods, principles and equipment that are common to two or more sections of this report are given in Annex A. Specific test procedures are given in Annex B.

The measurement of acoustic output power levels and the assessment of electrical safety are dealt with in other IEC standards; they are therefore specifically excluded from this document.

¹ Numbers in square brackets refer to the Bibliography.

ULTRASONICS – REAL-TIME PULSE-ECHO SYSTEMS –

Test procedures to determine performance specifications

1 Scope

This document describes representative methods of measuring the performance of complete real-time medical ultrasonic imaging equipment in the frequency range 0,5 MHz to 23 MHz.

NOTE The frequency range given represents, in general, the widely used range in hospitals at the date of publication; special medical applications use higher frequencies for imaging but mainly in research or pre-clinical imaging.

This document is relevant for real-time ultrasonic scanners based on the pulse-echo principle, for the types listed below:

- mechanical sector scanner;
- electronic phased array sector scanner;
- electronic linear array scanner;
- electronic curved array sector scanner;
- water-bath scanner based on any of the above four scanning mechanisms;
- plane-wave/fast imaging scanners;
- combination of several of the above methods (e.g. a linear array phased at the edge to produce a sector there to enlarge the field of view).

The methods described are based on evaluation of:

- sonograms obtained by scanning of tissue mimicking objects (phantoms);
- sonograms obtained by scanning of artificial, low- or highly reflective **targets** in suitable environments;
- parameters of the **ultrasound** field transmitted by the measured scanner.

This document does not relate to methods for measuring electrical parameters of the scanner's electronic systems.

2 Normative references

There are no normative references in this document.