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TECHNICAL REPORT

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

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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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- withdrawn,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 **target**s 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.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
A-scan
class of data acquisition geometry in one dimension, in which echo strength information is acquired from points lying along a single **beam axis** and displayed as amplitude versus time of flight or distance

[SOURCE: IEC 61391-1:2006, 3.1]

3.2
A-mode
amplitude-modulated display
method of presentation of **A-scan** information in which the **ultrasonic transducer-target** distance is represented on one axis (normally horizontal) and the echo amplitude on the other axis

[SOURCE: IEC TR 60854:1986, 3.17, modified – Replacement of "echo information" with "**A-scan** information" and "transducer to **target** distance" with "**ultrasonic transducer-target** distance"]

3.3
acceptance testing
evaluation of system performance after delivery of a purchased or repaired system and before authorisation for payment

3.4
acoustic clutter
noise artifact in **ultrasound** images that appears as diffuse echoes overlying signals of interest

Note 1 to entry: Sources of **acoustic clutter** include sound reverberation in tissue layers, scattering from off-axis structures, **ultrasound** beam distortion, returning echoes from previously transmitted pulses and random acoustic or electronic noise

3.5
acoustic scan line
one of the component lines that form a **B-mode** image on an **ultrasound** monitor, where each line is the envelope-detected **A-scan** line, in which the echo amplitudes are converted to brightness values

[SOURCE: IEC 61391-1:2006, 3.26]

3.6
acoustic-working frequency
centre frequency
arithmetic mean of the frequencies f_1 and f_2 at which the amplitude of the acoustic pressure spectrum is 3 dB below the peak amplitude

[SOURCE: IEC 61391-1:2006, 3.3]

3.7
axial resolution
minimum separation along the **beam axis** of two equally scattering volumes or **target**s at a specified depth for which two distinct echo signals can be displayed

[SOURCE: IEC 61391-1:2006, 3.5]

3.8
B-scan
brightness-modulated display scan
class of data-acquisition geometry in which echo information is acquired from points lying in an ultrasonic **scan plane** containing interrogating ultrasonic beams

Note 1 to entry: **B-scan** is a colloquial term for **B-mode** scan or image.

3.9
B-mode
brightness-modulated display
method of presentation of **B-scan** information, in which a particular section through an imaged object is represented in a conformal way by the plane of the display and echo amplitude is represented by local brightness or optical density of the display

[SOURCE: IEC 61391-1:2006, 3.10, modified – Replacement of "**scan plane**" with "plane"]

3.10
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

Note 1 to entry: The frequency dependency should be addressed at places where **backscatter coefficient** is used, if frequency influences results significantly.

Note 2 to entry: **Backscatter coefficient** is expressed in units of 1 per metre times 1 per steradian ($m^{-1}sr^{-1}$)".

[SOURCE: IEC 61391-1:2006, 3.6, modified – In the definition, addition of "at a specified frequency", and addition of two new Notes to entry]

3.11
backscatter contrast
ratio between the **backscatter coefficients** of two objects or regions

[SOURCE: IEC 61391-2:2010, 3.8]

3.12
bandwidth
difference in the most widely separated frequencies f_1 and f_2 at which the magnitude of the acoustic pressure spectrum drops 3 dB below the peak magnitude, at a specified point in the acoustic field

Note 1 to entry: **Bandwidth** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.6, modified – Replacement of "becomes" with "drops"]

3.13
beam axis
straight line that passes through the **beam centrepoints** of two planes perpendicular to the line which connects the point of maximal **pulse-pressure-squared integral** with the centre of the **external transducer aperture**

Note 1 to entry: See Figure 2 .

Note 2 to entry: The location of the first plane is the location of the plane containing the maximum **pulse-pressure-squared integral** or, alternatively, is one containing a single main lobe which is in the focal Fraunhofer zone. The location of the second plane is as far as is practicable from the first plane and parallel to the first with the same two orthogonal **scan line**s (x and y axes) used for the first plane. This alternative definition, eliminating reference to the centre of the **external transducer aperture**, is necessary when the pressure distribution among the transducer elements is not symmetric about the **external transducer aperture**.

Note 3 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, for examples:

a) in the case of a continuous wave signal, the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689:2022, 3.29.;

b) in cases where signal synchronisation with the scan frame is not available, the term **pulse-pressure-squared integral** can be replaced by **temporal average intensity**.

Note 4 to entry: Definition is modified compared to 4.2.14 of IEC 61828:2020 – "**aperture**" replaces "**surface plane**".

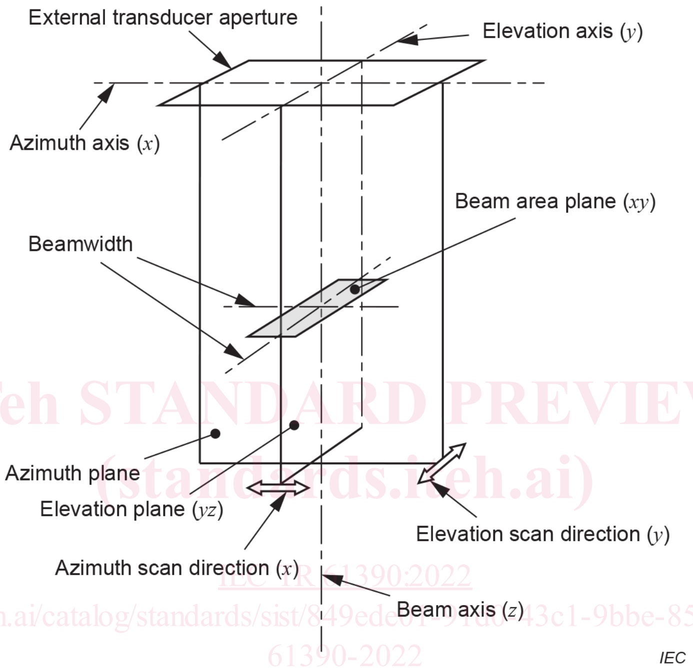

Figure 1 – Beam geometry

3.13.1
beam centrepoint
position determined by the 2D centroid of a set of **pulse-pressure-squared integrals** measured over the -6 dB beam-area in a specified plane

Note 1 to entry: Methods for determining 2D centroids are described in Annex C of IEC 61828:2020.

[SOURCE: IEC 62359:2010, 3.14]

3.13.2
external transducer aperture
part of the surface of the **ultrasonic transducer** or **ultrasonic transducer element group** assembly that emits ultrasonic radiation into the propagation medium

Note 1 to entry: This surface is assumed to be either directly in contact with the patient or in contact with a water or liquid path to the patient.

Note 2 to entry: The **ultrasonic transducer element group** is usually offset from this surface by a lens, matching layers and possibly fluid.

[SOURCE: IEC 62127-1:2007, 3.27, modified]

3.13.3
pulse-pressure-squared integral
ppsi
time integral of the square of the **instantaneous acoustic pressure** at a particular point in an acoustic field integrated over the **acoustic pulse waveform**

Note 1 to entry: The **pulse-pressure-squared integral** is expressed in pascals squared second (Pa^2s).

Note 2 to entry: Definition adapted from 3.50 of IEC 62127-1:2007.

3.14
contrast detail

3.14.1
contrast detail detectability
minimum diameter of an object, at specified control settings and range, which can be distinguished on the display with a specified level of confidence, as a function of the **backscatter contrast** of the object with respect to the background, said contrast being varied in steps over a wide range

3.14.2
contrast-detail resolution
minimum difference in echo amplitude, which can be detected for a scattering or reflecting structure of specified properties, embedded in a particular **tissue-mimicking material**

Note 1 to entry: The specified properties include shape, size or speed of sound.

3.15
dead zone
distance from the **test object scanning surface** to the nearest **test-object target** that can be unequivocally imaged

Note 1 to entry: This concept is now rarely useful unless the transducer is damaged. It was defined historically for **line targets** lying parallel to the length of linear array elements. **Dead zone** has been superseded by **proximal** and **distal working limits.**

3.15.1
proximal working limit
distance from the **test object scanning surface** to the nearest depth at which **spherical low-scattering masses** can be unequivocally detected

3.15.2
distal working limit
distance from the **test object scanning surface** to the furthest depth at which **spherical low-scattering masses** can be unequivocally detected

3.16
depth of penetration
maximum distance from the scanning surface of **tissue-mimicking material** to the embedded **test object** beyond which the **speckle pattern** echoes are no longer detectable

3.17
display curve
curve of signal level amplitude sent to the display as a function of the **linear signal**

3.18
linear signal
amplitude of the voltage generated across the transducer element, that is assumed, generally correctly, to be proportional to the integrated pressure across the element face

3.19
display frame rate
rate at which complete images are presented on the output display

3.20
display sonic contrast
display acoustic contrast
C_{DS}
relative difference between any **pixel value** in a resolved void without inclusions and the mean **pixel value** over a region in the image corresponding to background material at approximately the same depth and lateral location

$$C_{DS} = f_{NL} \times px \times R_D / R_{Dp} \mathrm{d} \quad (1)$$

where

R_D is the dynamic range in dB;

R_{Dp} is the dynamic range in pixel-values;

px is the difference between main- and side-lobe **maxima** in pixel-values;

f_{NL} is a correction factor for non-linear image processing; for linear image processing, f_{NL} = 1.

Note 1 to entry: **Display sonic contrast** as treated here assumes that the **display curve** is the log of the signal pressure amplitude and thus can be expressed in decibels by accounting for the **displayed dynamic range**, ignoring other nonlinear image processing in the system prior to the display. It is best to test for **display sonic contrast** using an available **display curve** most closely approximating that logarithmic relationship.

Note 2 to entry: See B.2.2.

3.21
displayed dynamic range
ratio, expressed in decibels, of the amplitude of the maximum echo that does not saturate the display to the minimum echo that can be distinguished electronically from the background under the scanner test settings

[SOURCE: IEC 61391-1:2006, 3.11, modified – Replacement of "in the display" with "from the background"]

3.22
elevational resolution
transversal resolution
for two **line-target**s parallel to the scanned plane, minimum separation of two **line-targets** at a specified depth in a **test object** made of **tissue-mimicking material** for which two distinct echo signals can be displayed

Note 1 to entry: The plane of separation between the **target**s should be perpendicular to the beam-alignment axis.

3.23
field-of-view
area in the **scan plane** that is insonated by the **ultrasound** beam during the acquisition of echo data to produce one image frame

[SOURCE: IEC 61391-1:2006, 3.13, modified – Deletion of "ultrasonic" before "**scan plane**"]

3.24
frame rate
number of sweeps comprising the full-frame refresh rate that the ultrasonic beam makes per second through the **field-of-view**

[SOURCE: IEC 61391-1:2006, 3.14]