IEC 61391-2

Edition 1.0 2010-01

INTERNATIONAL STANDARD

Ultrasonics – Pulse-echo scanners – Part 2: Measurement of maximum depth of penetration and local dynamic range

IEC 61391-2:2010(E)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

PRICE CODE W

ICS 17.140.50

ISBN 978-2-88910-513-7

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PULSE-ECHO SCANNERS –

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FOREWORD

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International Standard IEC 61391-2 has been prepared by IEC technical committee 87: Ultrasonics.

The text of this standard is based on the following documents:

Enquiry draft	Report on voting
87/400/CDV	87/426/RVC

Full information on the voting for the approval of this standard 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.

Terms in **bold** in the text are defined in Clause 3.

A list of all parts of the IEC 61391 series, published under the general title *Ultrasonics – Pulse-echo scanners,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

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 by reflection at tissue boundaries and by scattering within tissues. Various transducer types are employed to operate in a transmit/receive mode to generate/detect the ultrasonic signals. Ultrasonic scanners are widely used in medical practice to produce images of soft-tissue organs throughout the human body.

This standard is being published in two or more parts:

- Part 1 deals with techniques for calibrating spatial measurement systems and measurement of system point spread function response;
- Part 2 deals with measurement of system sensitivity (maximum depth of penetration) and local dynamic range.

This standard describes test procedures for measuring the **maximum depth of penetration** and the **local dynamic range** of these imaging systems. Procedures should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use the standard to prepare their specifications; users should employ the standard to check performance against those specifications. The measurements can be carried out without interfering with the normal working conditions of the machine.

Typical phantoms are described in Annex A. The structures of the phantoms are not specified in detail; instead, suitable types of overall and internal structures for phantoms are described. Similar commercial versions of these test objects are available. The specific structure of a test object selected by the user should be reported with the results obtained when using it.

The performance parameters described herein and the corresponding methods of measurement have been chosen to provide a basis for comparison between similar types of apparatus of different makes but intended for the same kind of diagnostic application. The manufacturer's specifications of **maximum depth of penetration** and **local dynamic range** must allow comparison with the results obtained from the tests described in this standard. It is intended that the sets of results and values obtained from the use of the recommended methods will provide useful criteria for predicting performance with respect to these parameters for equipment operating in the 1 MHz to 15 MHz frequency range. However, availability and some specifications of test objects, such that they are similar to tissue in vivo, are still under study for the frequency range 10 MHz to15 MHz.

The procedures recommended in this standard are in accordance with IEC 60601-1 [1] and IEC 61391-1.

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 for a specific task 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.

The paradigm used for the framework of this standard is to consider the ultrasound imaging system to be composed architecturally of a front-end (generally consisting of the ultrasound transducer, amplifiers, digitizers and beamformer), a back-end (generally consisting of signal conditioning, image formation, image processing and scan conversion) and a display (generally consisting of a video monitor but also including any other output device). Under ideal conditions it would be possible for users to test performance of these components of the system independently. It is recognized, however, that some systems and lack of some laboratory resources might prevent this full range of measurements. Thus, the specifications and measurement methods described in this standard refer to image data that are provided in

a digitalized format by the ultrasound machine and that can be accessed by users. Some scanners do not provide access to digitized image data. For this group of scanners, tests can be done by utilizing frame grabbers to record images. Data can then be analyzed in a computer in the same manner as for image data provided directly by the scanner.

ULTRASONICS – PULSE-ECHO SCANNERS –

Part 2: Measurement of maximum depth of penetration and local dynamic range

1 Scope

This part of IEC 61391 defines terms and specifies methods for measuring the **maximum depth of penetration** and the **local dynamic range** of real-time ultrasound B-MODE scanners. The types of transducers used with these scanners include:

– mechanical probes;
– electronic phased arrays;
– linear arrays;
– curved arrays;
– two-dimensional arrays;
– three-dimensional scanning probes based on a combination of the above types.

All scanners considered are based on pulse-echo techniques. The test methodology is applicable for transducers operating in the 1 MHz to 15 MHz frequency range operating both in fundamental mode and in harmonic modes that extend to 15 MHz. However, testing of harmonic modes above 15 MHz is not covered by this standard.

NOTE Phantom manufacturers are encouraged to extend the frequency range to which phantoms are specified to enable tests of systems operating at fundamental and harmonic frequencies above 15 MHz.

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 any amendments) applies.

IEC 61391-1:2006, *Ultrasonics – Pulse-echo scanners – Part 1:Techniques for calibrating spatial measurement systems and measurement of system point spread function response*

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

3 Terms and definitions

For the purposes of this document the following terms and definitions apply:

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

[IEC 61391-1:2006, definition 3.1]

3.2
acoustic scan line (scan line)
one of the component lines which 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

[IEC 61391-1:2006, definition 3.26]

3.3 acoustic working frequency
arithmetic mean of the frequencies f_1 and f_2 at which the amplitude of the acoustic pressure spectrum first falls 3dB below the main peak amplitude.

[IEC 61391-1:2006, definition 3.3, modified]

3.4
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.)

NOTE 1 When describing the attenuation properties of a material, the variation of attenuation with frequency should be given. This may be done by expressing $a(f)$, the attenuation coefficient at frequency f, as $a(f) = a_0 f^b$, where f is in MHz, a_0 is the attenuation coefficient at 1 MHz and b is a constant determined by least-squares fitting to experimental data points.

NOTE 2 This parameter specifies the medium's attenuation only; it excludes reflective losses at interfaces enclosing the medium and signal decreases due to diffraction.

NOTE 3 See also **specific attenuation coefficient**.

3.5
B-mode
method of echo-signal display in which the amplitude of the echo signal is represented by modulation of the brightness of the corresponding point on the display

NOTE The location of the point is determined from the transit time of the acoustic pulse and an assumed value for sound speed in tissues; for B-mode imaging, it is also determined from the relative position and orientation of the **acoustic scan line**.

3.6
B-scan
class of data acquisition geometry in which echo information is acquired from points lying in an ultrasonic scan plane containing interrogating ultrasonic beams

[IEC 61391-1:2006, definition 3.9]

3.7
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]

3.8
backscatter contrast
ratio between the backscatter coefficients of two objects or regions

[IEC 61391-1:2006, definition 3.7, modified]

3.9
beam axis
the longitudinal axis of the pulse-echo response of a given acoustic scan line, a pulse-echo equivalent to the transmitted beam axis of IEC 62127-1

[IEC 61391-1:2006, definition 3.8, modified]

3.10
digitized image data
two-dimensional set of pixel values derived from the ultrasound echo signals that form an ultrasound image

3.11
displayed acoustic dynamic range
20 $\log_{10}$ of the ratio of the amplitude of the maximum echo that does not saturate the display to that of the minimum echo that can be distinguished in the same or similar location of the display under the scanner test settings

Unit: dB

NOTE On most B-mode scanners echo-signal compression is applied in the receiver, so the **displayed acoustic dynamic range** exceeds the input-signal dynamic range capabilities of the monitor.

3.12
display threshold (B-mode)
display luminance just above the luminance when no echo signal is present

3.13
display saturation (B-mode)
display luminance at which an increase in echo-signal level or an increase in system sensitivity produces no change in luminance

3.14
dynamic range
see **local dynamic range**; see also **displayed dynamic range** and **global dynamic range**

3.15
field-of-view
area in the ultrasonic **scan plane** from which ultrasound information is acquired to produce one image frame

NOTE 1 This area can correspond to a two-dimensional or three-dimensional field.

NOTE 2 Definition differs from that of 61391-1 in that it is restricted to the region from which information is acquired.

[IEC 61391-1:2006, definition 3.13 modified]

3.16
frame rate
number of sweeps comprising the full-frame refresh rate that the ultrasonic beam makes per second through the field-of-view

[IEC 61391-1:2006, definition 3.14]