IEC 61391-2

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Ultrasons – Scanners à impulsion et écho –
Partie 2: Mesure de la profondeur maximale de pénétration et de la plage dynamique locale

IEC 61391-2:2010

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ULTRASONICS –
PULSE-ECHO SCANNERS –

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

FOREWORD

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

This bilingual version, published in 2010-06, corresponds to the English version.

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.

The French version of this standard has not been voted upon.

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 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

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- withdrawn,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

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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]

NOTE This parameter usually differs from the image display rate on the scanner monitor.

3.17
gain
ratio of the output to the input of a system, generally an amplifying system, usually expressed in decibels.

[IEC 61391-1:2006, definition 3.15]

NOTE The ratio applies for a constant and known acoustical system output.

3.18
global dynamic range
ratio of the maximum to the minimum echo-signal amplitude, even with changes of settings, that a scanner can process without distortion of the output signal

3.19
harmonic imaging
method of imaging in which ultrasound is transmitted at a fundamental frequency and is detected at harmonic frequencies

NOTE Harmonics are generated by the propagation medium or by nonlinear reflectors. The resulting harmonic signal is displayed as an image or part of the image.

3.20
local dynamic range
$20 \log_{10}$ of the ratio, of the minimum echo amplitude that yields the maximum grey level in the digitized image to that of the echo that yields the lowest grey level at the same location in the image and the same settings

Unit: dB

NOTE 1 For an 8-bit image memory, the maximum gray level in the digitized image will be 255.

NOTE 2 Some documents refer to **local dynamic range** as the range of echo signals required to vary the display brightness from barely discernible to maximum brightness at a given location [1]. However, this international standard applies the name **local dynamic range** to the digitized image data rather than data viewed on the image monitor. The name **displayed acoustic dynamic range** is the equivalent to **local dynamic range**, but applied to data viewed on the image monitor.

NOTE 3 This quantity is influenced by the grey scale (dynamic) transfer function associated with the echo display.

3.21
maximum depth of penetration
maximum distance in a tissue-mimicking phantom of specified properties for which the ratio of the digitized B-mode image data from background scatterers to the digitized B-mode image data displaying only electronic noise equals 1,4

Unit: m

NOTE The phantom and noise-only images are obtained using identical system settings.

3.22
operating condition
any one of the possible particular control settings for a discrete or a combined operating mode

3.23
operating mode (discrete)
mode of operation of **medical diagnostic ultrasonic equipment** in which the purpose of the excitation of the ultrasonic transducer or ultrasonic transducer element group is to utilize only one diagnostic methodology

NOTE Examples of **discrete operating modes** are A-mode (A), M-mode (M), static B-mode (sB), real-time B-mode (B), continuous wave Doppler (cwD), pulsed Doppler (D), static flow-mapping (sD) and real-time flow-mapping Doppler (rD) generally using only one type of acoustic pulse at a given depth.

[IEC 62127-1:2007, definition 3.39.2]

3.24
operating mode (combined)
mode of operation of a system that combines more than one **discrete operating mode**

[IEC 62127-1:2007, definition 3.39.1]

3.25
perfect planar (or specular) reflector
an interface that has a reflection coefficient of 1,0 and whose dimensions are large compared to the local width of the ultrasound beam

NOTE 1 The pressure-amplitude reflection coefficient of a water-to-air interface is 0,9994 (derived from Zw = 1480 000 $kgm^{-2}s^{-1}$ and Za = 413 $kgm^{-2}s^{-1}$)

NOTE 2 In practical measurements a variety of targets may be used. These can all be referred to the perfect planar reflector by calculation or by careful comparison.

3.26
phantom
a volume of material behaving in essentially the same manner as tissue of the same dimensions, with respect to absorption and scattering of the ultrasound radiation in question, used for dosimetry or for the evaluation of sonographic images in diagnostic sonography (see **tissue mimicking phantom**)

[IEC 60050-881:1983, 881-12-54 modified]

3.27
pulse-echo technique
method of interrogating a region by insonifying it with pulsed sound beams and detecting and displaying echo signals arising from scatterers or reflectors

3.28
reflection coefficient (sound pressure)
ratio of the reflected pressure amplitude to the incident pressure amplitude for plane waves incident perpendicularly on a smooth interface separating two media

3.29
scan line
see **acoustic scan line**

3.30
scan plane
acquired image plane containing the acoustic scan lines

3.31
scan volume
volume from which echo data are acquired and that contribute to a 3D- image

3.32
sensitivity
minimum reflection coefficient in water of a plane reflector, oriented and positioned for maximum response, which produces a **display threshold**

NOTE For the purpose of this standard, the maximum depth of penetration for visualizing background echoes in a phantom is used as an indication of sensitivity.

3.33
specific attenuation coefficient
at a specified frequency, the slope of attenuation coefficient plotted against frequency

Units: dB $m^{-1}MHz^{-1}$

3.34
speckle pattern
image pattern or texture, produced by the interference of echoes from the scattering centres in tissue of tissue-mimicking material

[3.30 of IEC 61391-1:2006]

3.35
statistically independent images
images acquired from planes or directions such that the normalized cross-correlation of the underlying speckle pattern over a fixed region of interest, prior to any speckle reduction smoothing, is less than 0,2

NOTE Statistically independent images are obtained from a phantom containing randomly distributed scatterers by translating the scanning plane, steering the beam, etc., such that the underlying speckle pattern changes sufficiently to reduce the correlation. Images whose speckle target cross-correlation is ~0,2 or lower are sufficiently de-correlated to implement measurements in this standard.

3.36
test object
device containing one or more groups of object configurations embedded in a tissue-mimicking material or another medium (see also **phantom**, **tissue-mimicking phantom**)

[IEC 61391-1:2006, definition 3.33]

3.37
tissue-mimicking material
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, definition 3.36, modified]

3.38
tissue-mimicking phantom
object comprising **tissue-mimicking material**

4 General requirement

The manufacturer's specification shall allow comparison with the results obtained from the tests described in this standard.

5 Environmental conditions

All measurements shall be performed within the following ambient conditions:

– temperature, 23°C ± 3°C;
– relative humidity, 45 % to 75 %;
– atmospheric pressure, 86 kPa to 106 kPa.

Properties of ultrasound phantoms, such as speed of sound and attenuation coefficient, are known to vary with temperature. Consult the specifications published by the phantom manufacturer to determine whether the expected acoustic properties are maintained under the