

Ultrasonics — Real-time pulse-echo systems — Guide for test procedures to determine performance specifications

ICS 11.040.50

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- Association of British Health-Care Industries
- British Dental Association
- British Institute of Radiology
- British Medical Ultrasound Society
- British Society for Rheumatology
- Department of Health
- Institution of Electrical Engineers
- Institution of Physics and Engineering in Medicine and Biology
- National Physical Laboratory
- Institute of Laryngology and Otology

This British Standard, having been prepared under the direction of the Electrotechnical Sector Board, was published under the authority of the Standards Board and comes into effect on 15 March 1997

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The following BSI references relate to the work on this standard:
Committee reference EPL/87
Draft for comment 91/20276 DC

ISBN 0 580 26627 3

Amendments issued since publication

Amd. No.	Date	Comments

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National foreword

This British Standard has been prepared by Technical Committee EPL/87 and is identical with Technical Report IEC 1390:1996 *Ultrasonics — Real-time pulse-echo systems — Test procedures to determine performance specifications*, published by the International Electrotechnical Committee (IEC).

Cross-references

International standard	Corresponding British Standard
IEC 50 (801):1994	BS 4727 <i>Glossary of electrotechnical power, telecommunications, electronics, lighting and colour terms</i> Part 3: <i>Terms particular to telecommunications and electronics</i> Part 3:Group 08:1995 <i>Acoustics and electroacoustics</i> (Identical)
IEC 866:1987	BS 7041:1989 <i>Specification for characteristics and calibration of hydrophones for operation in the frequency range 0.5 MHz to 15 MHz</i> (Identical)
IEC 1102:1991	BS EN 61102:1994 <i>Specification for measurement and characterisation of ultrasonic fields using hydrophones in the frequency range of 0.5 MHz to 15 MHz</i> (Identical)
IEC 1157:1992	BS EN 61157:1995 <i>Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment</i> (Identical)

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 18, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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

This technical report describes test procedures which should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use the report to prepare their specifications, the users should use the report to check specifications. The measurements can also be carried out without interfering with the normal working conditions of the machine. The structures of the **test objects** 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** should be reported, together with the results obtained using it. Similar commercial versions of these **test objects** are also available.

The performance parameters specified, and the corresponding methods of measurement have been chosen to provide a basis for comparison with the manufacturer's specifications and between similar types of apparatus of different makes, intended for the same kind of diagnostic application. The manufacturer's specifications should allow comparison with the results obtained from the tests in this report. 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 application.

The procedures recommended in this report are in accordance with IEC 601-1 [9]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 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.

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

1 Scope

This technical report describes methods of measuring the performance of real-time medical ultrasonic imaging equipment in the frequency range 0,5 MHz to 15 MHz. This report 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.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this technical report. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this Technical report are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 50(801):1994, *International Electrotechnical Vocabulary (IEV) — Chapter 801: Acoustics and electroacoustics*.

IEC 854:1986, *Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment*.

¹⁾ Figures in square brackets refer to the bibliography given in annex B.

IEC 866:1987, *Characteristics and calibration of hydrophones for operation in the frequency range 0,5 MHz to 15 MHz*.

IEC 1102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*.

Amendment 1 (1993)

IEC 1157:1992, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*.

3 Definitions

For the purpose of this technical report, the following definitions apply:

3.1

A-scan

class of data acquisition geometry in one dimension, in which echo information is acquired from points lying along a single **ultrasonic beam axis** [3.20 of IEC 854 modified]

3.2

acoustic scan lines

lines in a **B-mode** image, related directly to the transmission/reception cycle of echo collection

3.3

acoustic-working-frequency bandwidth

difference in the frequencies f_1 and f_2 at which the amplitude of the acoustic pressure spectrum is 3 dB below the peak amplitude [3.62 of IEC 1102 modified]

3.4

acoustic-working frequency

frequency of an acoustic signal based on the observation of the output of a hydrophone placed in an acoustic field at the position corresponding to the spatial-peak temporal-peak acoustic pressure. The signal is analyzed either using the zero-crossing frequency technique or using a spectrum analysis method [3.4 of IEC 1102 modified]

3.5

amplitude-modulated display (A-mode)

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 [3.17 of IEC 854 modified]

3.6

automatic time gain compensation (ATGC)

compensation for the attenuation in ultrasonic pulse amplitude with depth by deriving a compensating gain control function from the observed decrease in echo amplitudes

3.7

axial resolution

minimum separation along the **ultrasonic beam axis** of two targets at a specified depth in a tissue-mimicking **test object** for which two echo signals can be displayed

3.8

backscatter coefficient

mean acoustic power scattered in the 180° direction by a specified object with respect to the direction of the incident beam, per unit solid angle per unit volume, divided by the incident beam intensity. The scatterers are considered to be randomly distributed. The mean power is obtained from different spatial realisations of the scattering volume. This is commonly referred to as the differential scattering cross-section per unit volume in the 180° direction

3.9

backscatter contrast

difference between the **backscatter coefficient** of two objects divided by the greater of the two **backscatter coefficients**

3.10

B-scan

class of data acquisition geometry in which echo information is acquired from points lying in a scanned plane insonated by an interrogating ultrasonic beam [3.21 of IEC 854 modified]

3.11

brightness-modulated display (B-mode)

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 [3.18 of IEC 854 modified]

3.12

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

3.13

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**. The specified properties include shape, size or speed of sound

3.14**dead zone**

distance from the **test object scanning surface** to the nearest **test object** wire which can be unequivocally imaged

3.15**depth of penetration**

maximum depth in the **tissue-mimicking material** of the **test object** beyond which the **speckle pattern** echoes are no longer detectable

3.16**display error**

distance between the centre of the image of a wire in the overall image of a **test object** and its correct position, as specified by the **test object** dimensions

3.17**display frame rate**

rate at which complete images are presented on the output display

3.18**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 in the display under the scanner test settings

3.19**field-of-view**

area in the **scan plane** which is insonated by the **ultrasound** beam during the acquisition of echo data to produce one image frame

3.20**frame rate**

number of sweeps the ultrasonic beam makes per second through the **field-of-view**

3.21**gray scale**

range of values of image brightness, being either continuous between two extreme values or, if discontinuous, including discrete values [3.14 of IEC 854 modified]

3.22**lateral resolution**

minimum separation in the **scan plane** of two line targets perpendicular to the **ultrasonic beam axis** at a specified depth in a tissue-mimicking **test object** for which two distinct echo signals can be displayed

3.23**line density**

number of **acoustic scan lines** of echo information at a specified point in the image which cross a line of 1 cm length perpendicular to the beam and centred on the point

3.24**M-scan (time-motion scan)**

class of acquisition geometry in which echo information from moving structures is acquired from points lying along a single beam axis. The echo information is presented using an **M-mode** display

3.25**maximum depth of penetration**

maximum depth at which the **speckle pattern** related to the scatterers in the tissue-mimicking **test object** can be displayed

3.26**nominal frequency**

ultrasonic frequency of operation of a system as quoted by the designer or manufacturer [3.7 of IEC 854]

3.27**real-time B-scan**

class of data acquisition and presentation in which **B-scans** are automatically and repetitively performed at **display frame rates** typically greater than five per second

3.28**recording error**

distance between the centre of the image of a wire in the overall record of a **test object** and its correct position, as specified by the **test object** dimensions

3.29**scan plane**

plane containing **ultrasonic scan lines** [3.38 of IEC 1102 modified]

3.30**slice thickness**

thickness, perpendicular to the **scan plane** and at a stated depth in the **test object**, of that region of the **test object** from which acoustic information is displayed

3.31**speckle pattern**

image pattern produced by the interference of echoes from the scattering centres in **tissue-mimicking material**

3.32**spherical void**

sphere of material containing no scattering centres

3.33**test object**

device containing one or more groups of object configurations embedded in a **tissue-mimicking material**

3.34**test object scanning surface**

surface on the tissue-mimicking **test object** recommended for **ultrasonic transducer** location during a test procedure

3.35**time gain compensation (TGC)**

change in amplifier gain with time introduced to compensate for loss in echo amplitude with increasing depth due to attenuation in tissue

3.36**time-motion mode (M-mode)**

method of presentation of **M-scan** information in which the motion of structures along a fixed **ultrasonic beam axis** is depicted by presenting their positions on a vertical line which moves across a display to show the variation with time of the echo

3.37**tissue-mimicking material**

material in which the propagation velocity (speed of sound), reflection, scattering and attenuating properties are similar to those of soft tissue for **ultrasound** in the frequency range 0,5 MHz to 15 MHz

3.38**ultrasonic transducer**

device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and, reciprocally, of converting mechanical energy to electrical energy

NOTE For the purposes of this report, **ultrasonic transducer** is taken to refer to a complete assembly which includes the transducer element or elements, and mechanical and electrical damping and matching provisions.

3.39**ultrasonic transducer element group**

group of elements of an **ultrasonic transducer** which are excited together in order to produce a single acoustic pulse

3.40**transmitted ultrasound field**

three-dimensional distribution of **ultrasound** energy emanating from the **ultrasonic transducer**

3.41**ultrasound**

acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 16 kHz) [IEV 801-21-04]

3.42**ultrasonic beam axis**

line fitted to points of maximum sensitivity measured at increasing distances in the direction of propagation of a **transmitted ultrasound field**

3.43**ultrasonic scan line**

for automatic scanning systems, the beam-alignment axis either for a particular **ultrasonic transducer** element or for a single or multiple excitation of an **ultrasonic transducer** or of an **ultrasonic transducer element group** [3.27 of IEC 1157]

4 Environmental conditions

The tests should be performed within the following ambient conditions:

- temperature: $23\text{ °C} \pm 2\text{ °C}$;
- relative humidity: 45 % to 75 %;
- atmospheric pressure: 86 kPa to 106 kPa.

5 Equipment required

To carry out the test procedures, the following items are required:

- a) a hydrophone;
- b) an oscilloscope;
- c) a spectrum analyzer;
- d) a tissue-mimicking **test object**;
- e) a pulse generator to drive an **ultrasonic transducer** for the injection of acoustic pulses into the system **ultrasonic transducer**;
- f) a tank containing degassed water.

The specifications of these devices are given in clause 6.

6 Test methods**6.1 Instruments**

The instruments specified have been selected to permit testing of real-time ultrasonic scanners performing as in clinical usage, and without requiring electronic signals to be output from, or input to, the scanners.

6.1.1 Hydrophones

A class A hydrophone in accordance with IEC 866 with a piezoelectric element of less than 1 mm diameter and with a flat frequency response ($\pm 3\text{ dB}$) from 0,5 MHz to 15 MHz is required. A second hydrophone (which may be a class B hydrophone in accordance with IEC 866) may also be required to trigger an oscilloscope if the ultrasonic pulses, in a scanning beam which cannot be stopped, are to be detected for examination by the first hydrophone.

6.1.2 Oscilloscope

An oscilloscope of bandwidth at least 40 MHz and sensitivity 5 mV/div is required.