

FINAL VERSION

VERSION FINALE



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

**Ultrasons – Scanners à impulsion et écho –
Partie 1: Techniques pour l'étalonnage des systèmes de mesure spatiaux et
des mesures de la réponse de la fonction de dispersion ponctuelle du système**

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references.....	7
3 Terms and definitions	7
4 Symbols and abbreviated terms	15
5 General conditions.....	16
6 Techniques for calibrating 2D-measurement systems.....	17
6.1 Test methods	17
6.2 Instruments	17
6.3 Test settings.....	18
6.4 Test parameters	19
7 Methods for calibrating 3D-measurement systems.....	21
7.1 General	21
7.2 Types of 3D-reconstruction methods.....	21
7.3 Test parameters associated with reconstruction problems.....	22
7.4 Test methods for measurement of 3D-reconstruction accuracy.....	23
8 Measurement of point-spread and line-spread function (high-contrast spot size)	27
8.1 General	27
8.2 Test methods	28
8.3 Instruments	28
8.4 Test settings.....	28
8.5 Test parameters	30
Annex A (normative) Test objects – Calibration of 2D-spatial measurement systems.....	35
Annex B (normative) Test objects – Measurement and calibration of 3D-image reconstruction accuracy	38
Annex C (normative) Test objects – Measurement of point-spread function response.....	42
Annex D (informative) Quality parameters derived by PSF-mapping analysis.....	47
Bibliography	63
Figure A.1 – Concentric circular arrays of nylon filaments	36
Figure A.2 – Regular 2D-array of nylon filaments	37
Figure B.1 – Tissue mimicking ovoid target phantom	39
Figure B.2 – Composite of two cross-sectional views of test object shown in Figure B.1	39
Figure B.3 – Projection view from top of test object shown in Figure B.1	40
Figure B.4 – Projection view from end window of test object shown in Figure B.1	41
Figure C.1 – Filament test object for measuring the LSF.....	43
Figure C.2 – Axial resolution test object.....	44
Figure C.3 – Movable single filament in water.....	45
Figure C.5 – Slice thickness measurement and calculation	46
Figure D.1 – Principal schematic of the PSF-analyser function.....	50
Figure D.2 – Principle of elimination of internal multi-reflections in the spherical target using filtration in time domain.....	53

Figure D.3 – A pixel maximum level and PSF-trace estimation in ROI stored digital data.....	55
Figure D.4 – The derivation of FWHM-value from the lateral-amplitude profile of PSF received-echo signal ($a_{r,\max}(x_i, z_k) = 221$) with reflector positioned on axis of the ultrasound beam in point (x_i, z_k) of the measuring grid.....	56
Figure D.5 – The FWHM-derivation from the elevational (transversal) profile of MER in one point of the measuring grid.....	57
Figure D.6 – The derivation of the reflected-signal axial-profile from the ROI.....	58
Figure D.7 – The enumeration of the $W_{H, HM}$ parameter from the axial-profile line: $a_{r,\max}(x, z) = 243$	58
Figure D.8 – The distribution of FWHM over a scan area of width 20 mm to depth 80 mm, made with a monofocal scan using a linear 5 MHz transducer.....	59
Figure D.9 – The distribution of FWHM over a scan area of width 20 mm to depth 80 mm, made with the same system as for Figure D.7 but using three focal points (F1, F2 and F3) for the scan.....	59
Figure D.10 – Plot of the distribution of MER-intensity over the scanning area 30 mm wide and 40 mm deep.....	60
Figure D.11 – The elevational profile recorded from $a_{r,\max}(x_i, y, z_k)$ values for a spherical target passing perpendicularly to the scanning plane in one point (x_i, z_k) of the measuring grid.....	61
Table 1 – Expected values for the two ellipsoidal objects in Figure D.3.....	26
Table 2 – Suggested table of reported values.....	27

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PULSE-ECHO SCANNERS –

**Part 1: Techniques for calibrating spatial measurement systems
and measurement of system point-spread function response**

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, accept 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.

DISCLAIMER

This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 61391-1 bears the edition number 1.1. It consists of the first edition (2006-07) [documents 87/336/FDIS and 87/343/RVD] and its amendment 1 (2017-07) [documents 87/650/FDIS and 87/653/RVD]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International Standard IEC 61391-1 has been prepared by IEC technical committee 87: Ultrasonics.

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.

This standard is intended to be 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 will deal with measurement of system sensitivity, dynamic range, and low-contrast resolution.

The committee has decided that the contents of the base publication and its amendment 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

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication 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 an ultrasonic **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 **ultrasonic transducer** types are 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 standard describes test procedures that should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use the standard to prepare their specifications; the users should employ the standard to check specifications. The measurements can be carried out without interfering with the normal working conditions of the machine. Typical **test objects** are described in the annexes. The structures of the **test objects** have not been specified in detail, rather suitable types of overall and internal structure are described. The specific structure of a **test object** should be reported with the results obtained using it. Similar commercial versions of these **test objects** are available.

The performance parameters specified and the corresponding methods of measurement have been chosen to provide a basis for comparison with the manufacturer's specification and between similar types of apparatus of different makes, intended for the same kind of diagnostic application. The manufacturer's specification should allow comparison with the results obtained from the tests in this standard. 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. This standard concentrates on measurements of images by digital techniques. Methods suitable for inspection by eye are covered here as well. Discussion of other visual techniques can be found in IEC 61390 [1]¹⁾.

Where a diagnostic system accommodates more than one option in respect of a particular system component, for example the **ultrasonic 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.

1) Figures in square brackets refer to the Bibliography.

ULTRASONICS – PULSE-ECHO SCANNERS –

Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response

1 Scope

This International Standard describes methods of calibrating the spatial measurement facilities and **point-spread function** of ultrasonic imaging equipment in the ultrasonic frequency range 0,5 MHz to 15 MHz. This standard is relevant for ultrasonic scanners based on the pulse-echo principle of the types listed below:

- mechanical sector scanners;
- electronic phased-array sector scanners;
- electronic linear-array scanners;
- electronic curved-array sector scanners;
- water-bath scanners based on any of the above four scanning mechanisms;
- 3D-volume reconstruction systems.

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 60050-801:1994, *International Electrotechnical Vocabulary – Chapter 801: Acoustics and electroacoustics*

IEC 60050-802:2011, *International Electrotechnical Vocabulary – Part 802: Ultrasonics*

IEC 61685:2001, *Ultrasonics – Flow measurement systems – Flow test object*

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 terms and definitions given in IEC 60050-801:1994, IEC 60050-802:2011, IEC 62127-1:2007 and the following apply. See also related International Standards, Technical Specifications and Technical Reports for definitions and explanations [1] [2] [3] [4] [34] [35] [36] [37] [38] [39].

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