

TECHNICAL SPECIFICATION



**Ultrasonics – Pulse-echo scanners –
Simple methods for periodic testing to verify stability of an imaging system's
elementary performance**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references.....	8
3 Terms and definitions	8
4 General recommendation	9
5 Environmental conditions	10
6 Quality control levels	10
6.1 General.....	10
6.2 Level 1 tests	10
6.3 Level 2 tests	11
6.4 Level 3 tests	11
7 Equipment and data required	12
7.1 General.....	12
7.2 Phantoms	12
7.2.1 Phantoms for Level 2 and/or Level 3 quality control	12
7.2.2 Phantoms for Level 2 quality control only.....	12
7.2.3 Phantoms for both Level 2 and Level 3 quality control.....	13
7.3 Image data.....	14
7.3.1 Digital-image data.....	14
7.3.2 Image-archiving systems.....	15
7.4 Expectations of system suppliers.....	16
8 Level 1 test methods.....	16
9 Level 2 measurement methods.....	17
9.1 Mechanical inspection	17
9.2 Image uniformity for transducer element and channel integrity.....	17
9.2.1 General	17
9.2.2 Apparatus scanning procedures and system settings	17
9.2.3 Image acquisition	18
9.2.4 Analysis.....	19
10 Level 3 measurement methods.....	20
10.1 General.....	20
10.2 Maximum relative depth of penetration.....	20
10.2.1 Assessment	20
10.2.2 Scanning system settings	20
10.2.3 Image acquisition	21
10.2.4 Analysis.....	22
10.2.5 Commentary	23
10.3 System-image display	23
10.3.1 General	23
10.3.2 Level 1 tests of the US-system and interpretation-station display	23
10.3.3 Level 2 and 3 tests.....	23
10.4 Distance measurements for mechanically scanned distances	24
10.4.1 General	24
10.4.2 Apparatus and scanning system settings	25

10.4.3	Image acquisition	25
10.4.4	Analysis.....	25
Annex A (informative) Example phantoms for image uniformity and/or maximum relative depth of penetration.....		26
Annex B (informative) Available analysis software		29
B.1	Open source software for assessment for QC of ultrasound image uniformity	29
B.2	Example of QC control chart:.....	31
Annex C (informative) Display test patterns		33
Annex D (informative) Electronic test methods and test methods provided by the manufacturers; relation to clinical significance		35
Bibliography		36
Figure 1 – Median-averaged image (right) and its lateral profile (left).....		19
Figure 2 – A) Image of a uniform section in a tissue-mimicking phantom, bright rectangle; B) Image displaying electronic noise only, obtained with the operating controls set the same as for A but with the transducer decoupled from the phantom [SOURCE: University of Wisconsin].....		21
Figure 3 – Mean digitized image-data value vs. depth for the phantom image data ($A(j)$) and for the noise-image data ($A'(j)$)		22
Figure A.1 – Example phantom for image-uniformity and/or maximum-relative-depth-of-penetration tests.....		26
Figure A.2 – Example compact phantom for image-uniformity tests		27
Figure A.3 – Photograph and drawing of a three-in-one phantom which provides for determination of distance measurement precision and bias, image uniformity and depth of penetration [37]		27
Figure A.4 – A compact uniformity phantom of relatively durable rubber material.....		28
Figure B.1 – On the left the profile of median pixel value is plotted for each image column in the analysis box shown in the median image on the right for the transducer in Figure 1, but without the nylon filament obstructing some central elements		30
Figure B.2 – Control chart for a dip in the middle of the profile for one transducer (TD) mode C9-4 and the specified serial number (S/N)		32
Figure C.1 – AAPM TG18-UN10 (left) and TG18-UN80 (right) patterns for luminance uniformity, colour uniformity, and angular response evaluations [35]		33
Figure C.2 – Example data entry form for visual display evaluation: left for Figure C.1; right for Figure C.3.....		34
Figure C.3 – TG18-CT low-contrast test pattern for the evaluation of the luminance response of display systems [35].....		34
Table 1 – Outline of Level 1 tests		10
Table 2 – Outline of Level 3 tests additional to those in Table 1		11
Table B.1 – Output of analysis		31

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PULSE-ECHO SCANNERS –

Simple methods for periodic testing to verify stability of an imaging system's elementary performance

FOREWORD

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- the required support cannot be obtained for the publication of an International Standard, despite repeated efforts, or
- the subject is still under technical development or where, for any other reason, there is the future but no immediate possibility of an agreement on an International Standard.

Technical Specifications are subject to review within three years of publication to decide whether they can be transformed into International Standards.

IEC TS 62736, which is a Technical Specification, has been prepared by IEC technical committee 87: Ultrasonics.

The text of this Technical Specification is based on the following documents:

Enquiry draft	Report on voting
87/576/DTS	87/592A/RVC

Full information on the voting for the approval of this Technical Specification 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. Symbols and formulae are in *Times New Roman italic*.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- transformed into an International Standard,
- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

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 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. As ultrasound systems are usually employed under rigorous time restrictions and in diverse environments to help make decisions often critical to patients' well being, it is important that the systems perform consistently at the level provided and accepted in initial tests, e.g. those of IEC 61391-1 and IEC 61391-2. This document provides methods to verify the stability of an imaging system's elementary performance.

This document is deemed necessary because substandard ultrasound system performance is often accepted, or remains undetected in the absence of unequivocal and documented tests. The most common of the failures, in all but the oldest systems nearing retirement, are subperformance of a transducer-array element or lens or of a cable or electronic channel. Sensitive image uniformity tests for these transducer- and channel failures are presented in this document for use monthly (Level 1), biannually (Level 2) and biennially (Level 3). With approximately 14 % transducer-failure rate and 10 % system-failure rate per year on first testing [1],[2],[3],[4],[5],[6],[7],[8],[9],[10],[11],[12], there are, very approximately, 100 000 systems worldwide routinely performing suboptimal diagnostic exams for part of the year.

This common occurrence of suboptimal diagnostic examinations has created an urgent need to standardize quality-control (QC) and performance-evaluation procedures to promote improved efficacy of diagnostic examinations through widespread use of effective QC procedures and to dispel myths as to their utility. Proposers believe, however, that existing national standards and guides [13],[14] specify too many tests and inappropriate tests for detecting and discriminating the common flaws in diagnostic ultrasound systems during routine QC. These practices include tests, such as spatial resolution, which are low-yield and belong in performance-evaluation procedures, rather than QC.

Modern flat-panel display technology is more stable than, and generally far superior to, earlier CRT displays. However, LCD displays can still exhibit luminance drift, as well as problems such as defective pixels. It is still necessary to evaluate them periodically.

ULTRASONICS – PULSE-ECHO SCANNERS –

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1 Scope

This document specifies requirements and methods for periodic testing of the quality of diagnostic medical ultrasound systems with linear array, curved linear array, single element, annular array, phased array, matrix linear array transducers and two-dimensional arrays. Image interpretation and measurement workstations are included. Usually, "periodic testing" is referred to here as "quality control". This document represents a minimum set of such tests intended for frequent users of medical ultrasound systems, for quality control professionals in their organization, or those hired from other quality-control and/or service-provider organizations. System-manufacturing and repair companies might well employ other or additional tests. The tests are defined in three levels, with the simplest and most cost-effective performed most frequently, similarly to [1]. More complete tests for acceptance testing and for assessment at times of particular importance or concern are specified in IEC 61391-1, IEC 61391-2 and IEC TS 62791 [15]. These more complete tests are categorized as performance evaluation, rather than quality control or frequent periodic testing.

This document also defines terms and specifies methods for measuring (for quality maintenance or quality control) the **maximum relative depth of penetration** of real-time ultrasound B-MODE scanners, though this penetration measure is listed as less frequently applied.

Frequent distance-measurement accuracy tests are recommended only for certain classes of position encoding that are not now known to be highly stable and without bias.

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.

Transducers not readily amenable to transducer-element testing by the simple image-uniformity procedures specified (for example, phased array and 2D-array transducers) are tested only partially by maximum relative depth of penetration. System manufacturers are encouraged to provide pulsing patterns of the transducer elements to allow testing of individual elements or small-enough groups of elements to enable users to detect significant element failure or to provide access to another implemented and explained element-test program. Dedicated Doppler systems are excluded from coverage here as specialized equipment is required to test them. This test equipment can be specific to the intended application of the Doppler system.

All scanners considered include basic pulse-echo techniques. The failures to be detected by the recommended pulse-echo tests also will affect the operation of other modes, such as colour-flow, harmonic-, elasticity- and compound imaging. The test methodology is applicable for transducers operating in the 1 MHz to 17 MHz frequency range and could be made applicable up to 40 MHz, if the depth of penetration were allowed to be relative, rather than

absolute, and phantom stability were verified [15]. Image-uniformity QC is applicable to transducers operating in the 1 MHz to 40 MHz frequency range as the requirements for phantoms are not stringent.

NOTE Phantom manufacturers are encouraged to extend the frequency range to which phantoms are specified to enable relative depth-of-penetration tests of systems operating at fundamental and harmonic frequencies above 17 MHz.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60050-802, *International Electrotechnical Vocabulary – Part 802: Ultrasonics* (available at <http://www.electropedia.org>)

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

IEC 61391-2, *Ultrasonics – Pulse-echo scanners – Part 2: Measurement of maximum depth of penetration and local dynamic range*

Withdrawn