



BSI Standards Publication

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

National foreword

This Published Document is the UK implementation of IEC/TS 62736:2016.

The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2016.

Published by BSI Standards Limited 2016

ISBN 978 0 580 76290 1

ICS 17.140.50

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 July 2016.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------



TECHNICAL SPECIFICATION



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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 17.140.50

ISBN 978-2-8322-3529-4

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....4

INTRODUCTION.....6

1 Scope.....7

2 Normative references.....8

3 Terms and definitions8

4 General recommendation9

5 Environmental conditions10

6 Quality control levels10

 6.1 General.....10

 6.2 Level 1 tests10

 6.3 Level 2 tests11

 6.4 Level 3 tests11

7 Equipment and data required12

 7.1 General.....12

 7.2 Phantoms12

 7.2.1 Phantoms for Level 2 and/or Level 3 quality control12

 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 data14

 7.3.2 Image-archiving systems15

 7.4 Expectations of system suppliers16

8 Level 1 test methods.....16

9 Level 2 measurement methods.....17

 9.1 Mechanical inspection17

 9.2 Image uniformity for transducer element and channel integrity.....17

 9.2.1 General17

 9.2.2 Apparatus scanning procedures and system settings17

 9.2.3 Image acquisition18

 9.2.4 Analysis19

10 Level 3 measurement methods.....20

 10.1 General20

 10.2 Maximum relative depth of penetration.....20

 10.2.1 Assessment20

 10.2.2 Scanning system settings20

 10.2.3 Image acquisition21

 10.2.4 Analysis22

 10.2.5 Commentary23

 10.3 System-image display23

 10.3.1 General23

 10.3.2 Level 1 tests of the US-system and interpretation-station display23

 10.3.3 Level 2 and 3 tests.....23

 10.4 Distance measurements for mechanically scanned distances24

 10.4.1 General24

 10.4.2 Apparatus and scanning system settings25

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		6
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-UN70 (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

- 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 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.

The main task of IEC technical committees is to prepare International Standards. In exceptional circumstances, a technical committee may propose the publication of a Technical Specification when

- 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 of 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 –

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

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