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TECHNICAL SPECIFICATION

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

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ULTRASONICS – PULSE-ECHO SCANNERS –

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

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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- withdrawn,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
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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. 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.

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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

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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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-802 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
addressable patch
smallest addressable group of transducer elements

3.2
echo from weakly reflecting, background scatterers
echoes from many small targets in which the scattered field is much less intense than the incident field

3.3
maximum depth of penetration
maximum range at which the ratio of the mean, digitized, B-mode-image data corresponding to images displaying **echoes from weakly reflecting, background scatterers** to the mean, digitized, B-mode-image data corresponding to images displaying only electronic noise equals 1,4, when the **echoes from weakly reflecting, background scatterers** are generated in a phantom with properties meeting the specifications of IEC 61391-2.

Note 1 to entry: The **maximum depth of penetration** is expressed in metres (m) and conventionally in centimetres (cm).

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3.4
maximum relative depth of penetration
maximum range at which the ratio of the mean, digitized, B-mode-image data corresponding to images displaying **echoes from weakly reflecting, background scatterers** to the mean, digitized, B-mode-image data corresponding to images displaying only electronic noise equals 1,4, when the **echoes from weakly reflecting, background scatterers** are generated in a phantom with properties meeting specifications more relaxed than those of IEC 61391-2

Note 1 to entry: The adjective “relative” is used because the phantom specifications defined in this document are so loose that measurements of the “maximum range” with different phantoms cannot be compared. The measurements are only for tests of stability, i.e. comparisons between measurements on the same phantom over time.

Note 2 to entry: For available phantoms and specifications see [16] and for a potential alternative measure of depth of penetration see [17]

Note 3 to entry: The **maximum relative depth of penetration** is expressed in metres (m) and conventionally in centimetres (cm).

3.5
median absolute deviation
MAD
median of the absolute value of the deviations from the median of a data set

Note 1 to entry: The MAD is similar to the standard deviation but, as the median of linear deviations rather than squared deviations, it is more resilient to outliers [18].

3.6
performance evaluation
tests performed to assess specific absolute performance of the object tested

Note 1 to entry: Typical times for ultrasound system performance evaluation are at pre-purchase evaluation, new and repaired system acceptance testing [19],[20],[21],[22],[1] at time of performance difficulties, and end of useful life evaluations. They are recommended for performance in Level 3 QC tests, though that is not required.

3.7
phantom
device designed to mimic some aspects of the human body for the purposes of testing or training

3.8
specific attenuation coefficient
attenuation coefficient divided by the frequency

Note 1 to entry: The **specific attenuation coefficient**, expressed in decibels per centimetre per megahertz (dB $cm^{-1}MHz^{-1}$), makes the explicit assumption of linear dependence of the attenuation coefficient on frequency.

3.9
quality control
QC
regularly performed procedures to assure consistent performance

Note 1 to entry: A more descriptive term is quality maintenance; quality assurance is also used.

3.10
equivalent sensitivity
sensitivity that is statistically the same or has smaller variance and bias

4 General recommendation

The manufacturer’s specification should allow comparison with the results obtained from the tests described in this document.

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5 Environmental conditions

All measurements should be performed within the following ranges of ambient conditions:

– temperature, 23 °C ± 16 °C for uniformity tests; 23 °C ± 3 °C for other measurements;
– relative humidity, 10 % to 95 %; 45 % to 75 % for relative depth of penetration;
– atmospheric pressure, 66 kPa to 106 kPa; 86 kPa to 106 kPa for relative depth of penetration.

Properties of ultrasound phantoms, such as speed of sound, backscatter coefficient and attenuation coefficient, are known to vary with temperature. The specifications published by the phantom manufacturer should be consulted to determine whether the expected acoustic properties are maintained under the above environmental conditions. If not, the environmental conditions over which expected and reproducible results can be obtained from the phantom or test object should be adopted for tests.

6 Quality control levels

6.1 General

These levels are based on the time required for performance and the interval between tests. Small facilities with a single ultrasound system might not be expected to perform Level 3 tests except for distance-measurement variance and bias or when problems are suspected that are not rapidly addressed by a service call. These levels are similar to those recommended by the European Federation of Societies in Ultrasound in Medicine and Biology [1].

6.2 Level 1 tests

Level 1 tests are short-duration (approximately 5 min) checks, to be performed monthly by the ultrasound system users, which require no special equipment, only record keeping. They are simple to perform and record with limited practice. Alternative methods of proven and at least **equivalent sensitivity**, as well as interpretability to end users, may be employed. See Table 1.

Table 1 – Outline of Level 1 tests

Test	Evaluation	Possible subsequent actions
Inspection for: Damage to transducer face or housing Damage to cable Stable wheel mounts Clean air filters	Visual	Level 2 tests or maintenance (immediately or at interval specified by the manufacturer)
Image uniformity	Visual with clean transducer face held in air	Level 2 tests or maintenance
Monitor function	Visual	Level 3 tests, adjustments or maintenance
Hard copy and image storage function	Visual	Adjustments or maintenance
Performance in clinical use	Ask users whether any changes in or insufficiencies in the system performance have been observed. Record and investigate any observations mentioned by users or interpreters	Level 2 or 3 tests, adjustments or maintenance

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