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TECHNICAL SPECIFICATION

colour inside

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

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FOREWORD

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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- withdrawn,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
- amended.

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

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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.