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Ultrasonics – Real-time pulse-echo systems – Test procedures to determine performance specifications

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ULTRASONICS – REAL-TIME PULSE-ECHO SYSTEMS –

Test procedures to determine performance specifications

FOREWORD

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IEC TR 61390 has been prepared by IEC technical committee 87: Ultrasonics. It is a Technical Report.

This second edition cancels and replaces the first edition published in 1996. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) Several additional phantom designs are included in the main body of the document;
b) Several additional transducer types are included in the Scope;
c) Methods of analysis are presented in new Annex B.

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

Draft	Report on voting
87/771/DTR	87/796A/RVDTR

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Report is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

NOTE Words in **bold** in the text are defined in Clause 3.

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

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- withdrawn,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

IMPORTANT – The "colour inside" logo on the cover page of this document 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 at tissue boundaries. Furthermore, the number of ultrasonic pulse-echo scanners using plane-wave imaging technology is increasing.

Alternatively, a scanner can transmit a wide-field wave-front or several transmit-beams and record from the whole transducer array the echoes backscattered from tissue boundaries [1] [2][1]. The latter is followed by software beamforming, picking several parts of the wide beam or in this way selecting one of the simultaneously transmitted beams to obtain adequate resolution. Plane-wave techniques cannot compete with physical, transmit beam-forming for maximum depth of imaging at a given **bandwidth**, maximum resolution and minimum acoustic exposure.

Ultrasonic scanners are widely used in medical practice to produce images of many soft-tissue organs throughout the human body. A variety of transducer types is employed to operate in a transmit/receive mode for generating/receiving the ultrasonic signals.

This document describes test procedures that should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use this document to prepare their own specifications, while users should use this document to check manufacturers' specifications. The measurements can be carried out without interfering with the normal working conditions of the machine. The structures of the **test objects, test equipment** and measuring systems have not been specified in detail; rather, suitable types of overall and internal structures are described, together with typical **test objects**, in Annex A. The specific structure of a **test object** and **test equipment** should be reported, together with the results obtained using them. Similar commercial versions of these **test objects** are available.

The performance parameters selected and the corresponding methods of measurement have been chosen to provide a basis for comparison with the manufacturers' specifications and between similar types of apparatus of different makes, intended for the same kind of diagnostic application. The manufacturers' specifications should allow comparison with the results obtained from the tests described in this document. Specific values of parameters and the tolerances on them have not been recommended, since these are constantly changing. 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.

The procedures recommended in this document are in accordance with IEC 60601-1:2005. Where a diagnostic system accommodates more than one option in respect of a particular system component, for example the 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.

Data relating to measuring methods, principles and equipment that are common to two or more sections of this report are given in Annex A. Specific test procedures are given in Annex B.

The measurement of acoustic output power levels and the assessment of electrical safety are dealt with in other IEC standards; they are therefore specifically excluded from this document.

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[1] Numbers in square brackets refer to the Bibliography.

ULTRASONICS – REAL-TIME PULSE-ECHO SYSTEMS –

Test procedures to determine performance specifications

1 Scope

This document describes representative methods of measuring the performance of complete real-time medical ultrasonic imaging equipment in the frequency range 0,5 MHz to 23 MHz.

NOTE The frequency range given represents, in general, the widely used range in hospitals at the date of publication; special medical applications use higher frequencies for imaging but mainly in research or pre-clinical imaging.

This document is relevant for real-time ultrasonic scanners based on the pulse-echo principle, for the types listed below:

- mechanical sector scanner;
- electronic phased array sector scanner;
- electronic linear array scanner;
- electronic curved array sector scanner;
- water-bath scanner based on any of the above four scanning mechanisms;
- plane-wave/fast imaging scanners;
- combination of several of the above methods (e.g. a linear array phased at the edge to produce a sector there to enlarge the field of view.

The methods described are based on evaluation of:

- sonograms obtained by scanning of tissue mimicking objects (phantoms);
- sonograms obtained by scanning of artificial, low- or highly reflective **target**s in suitable environments;
- parameters of the **ultrasound** field transmitted by the measured scanner.

This document does not relate to methods for measuring electrical parameters of the scanner’s electronic systems.

2 Normative references

There are no normative references in this document.