SLOVENSKI STANDARD
SIST EN 61391-2:2010

01-september-2010

Ultrazvok - Impulzno-odmevni skenerji - 2. del: Meritev največje globine prodiranja in lokalno dinamično območje (IEC 61391-2:2010)

Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range (IEC 61391-2:2010)

Ultraschall - Impuls-Echo-Scanner - Teil 2: Messung der maximalen Eindringtiefe und des lokalen Dynamikbereichs (IEC 61391-2:2010)

Ultrasons - Scanners à impulsion et écho - Partie 2 : Mesure de la profondeur maximale de pénétration et de la plage dynamique locale (CEI 61391-2:2010)

Ta slovenski standard je istoveten z: **EN 61391-2:2010**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 61391-2:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61391-2

April 2010

ICS 17.140.50

English version

Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range (IEC 61391-2:2010)

Ultrasons -
Scanners à impulsion et écho -
Partie 2 : Mesure de la profondeur maximale de pénétration et de la plage dynamique locale
(CEI 61391-2:2010)

Ultraschall -
Impuls-Echo-Scanner -
Teil 2: Messung der maximalen Eindringtiefe und des lokalen Dynamikbereichs
(IEC 61391-2:2010)

This European Standard was approved by CENELEC on 2010-04-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC
European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 87/400/CDV, future edition 1 of IEC 61391-2, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61391-2 on 2010-04-01.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-01-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-04-01

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61391-2:2010 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1:2005	NOTE	Harmonized as EN 60601-1:2006 (not modified).
IEC 61161:1992	NOTE	Harmonized as EN 61161:1994 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 61391-1	2006	Ultrasonics - Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of system point spread function response	EN 61391-1	2006
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007

IEC 61391-2

Edition 1.0 2010-01

INTERNATIONAL STANDARD

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PULSE-ECHO SCANNERS –

Part 2: Measurement of maximum depth of penetration and local dynamic range

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.
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International Standard IEC 61391-2 has been prepared by IEC technical committee 87: Ultrasonics.

The text of this standard is based on the following documents:

Enquiry draft	Report on voting
87/400/CDV	87/426/RVC

Full information on the voting for the approval of this standard 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.

A list of all parts of the IEC 61391 series, published under the general title *Ultrasonics – Pulse-echo scanners,* can be found on the IEC website.

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

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

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

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.

This standard is being published in two or more parts:

- Part 1 deals with techniques for calibrating spatial measurement systems and measurement of system point spread function response;
- Part 2 deals with measurement of system sensitivity (maximum depth of penetration) and local dynamic range.

This standard describes test procedures for measuring the **maximum depth of penetration** and the **local dynamic range** of these imaging systems. Procedures should be widely acceptable and valid for a wide range of types of equipment. Manufacturers should use the standard to prepare their specifications; users should employ the standard to check performance against those specifications. The measurements can be carried out without interfering with the normal working conditions of the machine.

Typical phantoms are described in Annex A. The structures of the phantoms are not specified in detail; instead, suitable types of overall and internal structures for phantoms are described. Similar commercial versions of these test objects are available. The specific structure of a test object selected by the user should be reported with the results obtained when using it.

The performance parameters described herein and the corresponding methods of measurement have been chosen to provide a basis for comparison between similar types of apparatus of different makes but intended for the same kind of diagnostic application. The manufacturer's specifications of **maximum depth of penetration** and **local dynamic range** must allow comparison with the results obtained from the tests described in this standard. It is intended that the sets of results and values obtained from the use of the recommended methods will provide useful criteria for predicting performance with respect to these parameters for equipment operating in the 1 MHz to 15 MHz frequency range. However, availability and some specifications of test objects, such that they are similar to tissue in vivo, are still under study for the frequency range 10 MHz to15 MHz.

The procedures recommended in this standard are in accordance with IEC 60601-1 [1] and IEC 61391-1.

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 for a specific task 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.

The paradigm used for the framework of this standard is to consider the ultrasound imaging system to be composed architecturally of a front-end (generally consisting of the ultrasound transducer, amplifiers, digitizers and beamformer), a back-end (generally consisting of signal conditioning, image formation, image processing and scan conversion) and a display (generally consisting of a video monitor but also including any other output device). Under ideal conditions it would be possible for users to test performance of these components of the system independently. It is recognized, however, that some systems and lack of some laboratory resources might prevent this full range of measurements. Thus, the specifications and measurement methods described in this standard refer to image data that are provided in

a digitalized format by the ultrasound machine and that can be accessed by users. Some scanners do not provide access to digitized image data. For this group of scanners, tests can be done by utilizing frame grabbers to record images. Data can then be analyzed in a computer in the same manner as for image data provided directly by the scanner.