SLOVENSKI STANDARD
SIST EN 61266:2002

01-september-2002

Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting (IEC 61266:1994)

Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting

Ultraschall - Handgehaltene Doppler-Herzschlagdetektoren für Föten - Leistungsanforderungen sowie Meß- und Angabeverfahren

Ultrasons - Détecteurs des battements de coeur foetal à effet Doppler avec sonde à main - Prescriptions de performance et méthodes de mesure et de signalement

Ta slovenski standard je istoveten z: **EN 61266:1995**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.040.55	Diagnostiļ na oprema	Diagnostic equipment
17.140.50	Elektroakustika	Electroacoustics

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 61266

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Descriptors: Ultrasound, Doppler detector, foetus, performance, measurement

English version

Ultrasonics
Hand-held probe Doppler foetal heartbeat detectors
Performance requirements and methods of measurement and reporting
(IEC 1266:1994)

Ultrasons
Détecteurs des battements de coeur foetal à effet Doppler avec sonde à main
Prescriptions de performance et méthodes de mesure et de signalement
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This European Standard was approved by CENELEC on 1995-02-15. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 87(CO)34, future edition 1 of IEC 1266, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61266 on 1995-02-15.

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) 1996-02-15
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-02-15

For products which have complied with the relevant national standard before 1996-02-15, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2001-02-15.

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes A, B, C, D and E are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 1266:1994 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July A11 A12	1990 1994 1993 1993
IEC 854	1986	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment	-	-
IEC 866	1987	Characteristics and calibration of hydrophones for operation in the frequency range 0,5 MHz to 15 MHz	-	-
IEC 1101	1991	The absolute calibration of hydrophones using the planar scanning technique in the frequency range 0,5 MHz to 15 MHz	EN 61101	1993
IEC 1102	1991	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	EN 61102	1993
IEC 1157	1992	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment	EN 61157	1994
IEC 1161	1992	Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz	EN 61161	1994

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Ultrasons – Détecteurs des battements de coeur foetal à effet Doppler avec sonde à main – Prescriptions de performance et méthodes de mesure et de signalement

Ultrasonics – Hand-held probe Doppler foetal heartbeat detectors – Performance requirements and methods of measurement and reporting

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – HAND-HELD PROBE DOPPLER FOETAL HEARTBEAT DETECTORS – PERFORMANCE REQUIREMENTS AND METHODS OF MEASUREMENT AND REPORTING

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. 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. The 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 the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

International Standard IEC 1266 has been prepared by IEC technical committee 87: Ultrasonics.

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

DIS	Report on voting
87(CO)34	87/71/RVD

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

All annexes are for information only.

In this standard the following print types are used:

- Requirements proper: in roman type.
- *Test specifications: in italic type.*
- Notes: in smaller roman type.
- Words in **bold** in the text are defined in clause 3.

INTRODUCTION

Hand-held ultrasonic Doppler foetal heartbeat detectors are widely used for monitoring foetal heartbeat during pregnancy. They normally operate at frequencies of circa 2 MHz, and consist of an ultrasonic transducer acoustically coupled to the maternal abdomen and associated electronics. A beam of ultrasound is directed by the operator to impinge on the foetal heart and a small fraction of the incident ultrasound is reflected from the moving surfaces of the heart. This ultrasound is subject to a frequency shift as a result of the Doppler effect. It is then detected by a receiving transducer. Signal processing separates the low-frequency signals associated with the foetal heartbeat from the high-frequency ultrasonic oscillations and amplifies them for audio detection.

This International Standard, IEC 1266, specifies methods of evaluating the performance of ultrasonic foetal heartbeat detectors and, in particular, specifies a method of determining the sensitivity of the system to the detection of a moving target.

Foetal Doppler monitoring devices use a flat probe strapped to the patient and work on a principle similar to that of hand-held foetal heartbeat detectors but are not covered by this standard. The reason is that monitoring devices require a wide angle of view which is often realised by using a multi-element transducer. This makes the method of operation of foetal Doppler monitors much more complex than that of hand-held foetal heartbeat detectors which use a narrow beam. Methods of assessment of performance would also be more complex.

ULTRASONICS – HAND-HELD PROBE DOPPLER FOETAL HEARTBEAT DETECTORS – PERFORMANCE REQUIREMENTS AND METHODS OF MEASUREMENT AND REPORTING

1 Scope

This International Standard IEC 1266 establishes:

- methods of measurement of performance of a complete ultrasonic hand-held Doppler foetal heartbeat detector (hereinafter referred to as "**equipment**");
- requirements for the performance of **equipment**;
- requirements for the reporting of the performance of existing **equipment**;
- requirements for the declaration by manufacturers in accompanying literature of aspects of the performance of **equipment**.

This International Standard is applicable to ultrasonic Doppler foetal heartbeat detectors which generate a single ultrasound beam and consist of a hand-held probe which is applied to the maternal abdomen to obtain information on foetal heart activity by means of the Doppler method using continuous wave (c.w.) or quasi-continuous wave ultrasound. This standard, however, currently does not cover the continuous monitoring devices which generate more than one ultrasound beam and are usually of the type utilising a similar principle of operation but using a flat probe strapped to the patient.

This International Standard is not an equipment design standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 854: 1986, *Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment*

IEC 866: 1987, *Characteristics and calibration of hydrophones for operation in the frequency range 0,5 MHz to 15 MHz*

IEC 1101: 1991, *The absolute calibration of hydrophones using the planar scanning technique in the frequency range 0,5 MHz to 15 MHz*

IEC 1102: 1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range of 0,5 MHz to 15 MHz*

IEC 1157: 1992, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*

IEC 1161: 1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz*

3 Definitions

For the purposes of this International Standard, the following definitions apply:

3.1 **acoustic coupling medium:** Material placed between the **probe** and the body surface in order to maintain acoustic transmission.

3.2 **acoustic working frequency**: Frequency of an acoustic signal based on the observation of the output of a hydrophone placed in an acoustic field.

For the purposes of this International standard, the signal is analysed using the zero-crossing frequency technique, see IEC 854.
[3.4.1 of IEC 1102].

3.3 **continuous wave ultrasound:** Ultrasonic oscillations which are either continuous or quasi-continuous lasting for many tens of cycles.

3.4 **Doppler frequency:** Change in frequency of an ultrasound scattered wave caused by relative motion between the scatterer and the **probe**. It is the difference frequency between the transmitted and the received wave.

3.5 **effective area of the ultrasonic transducer active element:** –6 dB beam area at a distance of 5 mm from the face of the **probe**.
[3.6 of IEC 1102].

Unit: millimetre squared, mm^2

3.6 **Doppler signal:** Signal at the **Doppler frequency**.

3.7 **equipment:** Ultrasonic Doppler foetal heartbeat detector.

3.8 **nominal acoustic working frequency:** Value of the **acoustic working frequency** quoted by the designer or manufacturer.

3.9 **output power:** Time-average ultrasonic power radiated by an ultrasonic transducer into an approximately free field under specified conditions in a specified medium, preferably in water.
[3.5 of IEC 1161].

Symbol: *P*
Unit: watt, W