

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

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- British Dental Association
- British Institute of Radiology
- British Medical Ultrasound Society
- British Society for Rheumatology
- Department of Health
- Department of Trade and Industry (National Physical Laboratory)
- Institute of Laryngology and Otology
- Institute of Physical Sciences in Medicine
- Institution of Electrical Engineers

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Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Text of EN 61266	3
List of references	Inside back cover

National foreword

This British Standard has been prepared by EPL/87 and is the English language version of EN 61266:1995 *Ultrasonics — Hand-held probe Doppler foetal heartbeat detectors — Performance requirements and methods of measurement and reporting*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 1226:1994, published by the International Electrotechnical Commission (IEC).

Cross-references

Publication referred to	Corresponding British Standard
EN 60601-1:1990 (IEC 601-1:1988)	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i>
EN 61101:1993 (IEC 1101:1991)	BS EN 61101:1994 <i>Specification for absolute calibration of hydrophones using the planar scanning technique in the frequency range 0,5 MHz to 15 MHz</i>
EN 61102:1993 (IEC 1102:1991)	BS EN 61102:1994 <i>Specification for measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0.5 MHz to 15 MHz</i>
EN 61157:1994 (IEC 1157:1992)	BS EN 61157:1995 <i>Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment</i>
EN 61161:1994 (IEC 1161:1992)	BS EN 61161:1995 <i>Specification for ultrasonic power measurement in liquids in the frequency range 0.5 MHz to 25 MHz</i>
IEC 866:1987	BS 7041:1989 <i>Specification for characteristics and calibration of hydrophones for operation in the frequency range 0.5 MHz to 15 MHz</i>

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 22, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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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
(CEI 1266:1994)

Ultraschall

Handgehaltene Doppler-Herzschlag-detektoren
für Föten
Leistungsanforderungen sowie Meß- und
Angabeverfahren
(IEC 1266:1994)

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

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

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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 Annex A, Annex B, Annex C, Annex D and Annex E are informative. Annex ZA has been added by CENELEC.

Contents

	Page
Foreword	2
Introduction	3
1 Scope	3
2 Normative references	3
3 Definitions	4
4 List of symbols	5
5 Configuration	5
6 Performance	5
6.1 Acoustic working frequency	5
7 Safety	5
8 Tests	5
8.1 Acoustic working frequency	5
8.2 Output power	6
8.3 Spatial-peak temporal-peak acoustic pressure	6
8.4 Effective area of the ultrasonic transducer active element	6
8.5 Overall sensitivity	6
9 Preferred method for reporting performance of existing equipment	8
10 Specifications for labelling	9
11 Sampling	9
Annex A (informative) Choice of target and determination of target plane-wave reflection loss	12
Annex B (informative) Typical test equipment and test procedures	17
Annex C (informative) Determination of the two-way insertion loss of acoustic attenuators	19
Annex D (informative) Rationale	20
Annex E (informative) Bibliography	20
Annex ZA (normative) Normative references to international publications with their corresponding European publications	21
Figure 1 — Configuration block diagram of the equipment	9
Figure 2 — Configuration block diagram for acoustic working frequency measurement	10
Figure 3 — Block diagram illustrating the basic concepts of the overall sensitivity test method	10
Figure 4 — Sample point for determining signal level in relation to triangular excitation waveform for target	11
Figure A.1 — Target plane-wave reflection loss at a distance of 100 mm for four types of target as a function of frequency	15
Figure A.2 — Three typical configurations for the determination of the plane-wave reflection loss for a target, a) and b) use hydrophones as detectors; c) uses the transducer for both transmission and reception. All configurations show the positions of the target and detector first for determining the reflected acoustic pressure and second for determining the incident acoustic pressure	16
Figure B.1 — Typical vessel for overall sensitivity test	18
Table A.1 — Details of steel ball reflectors	13

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.

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, mm²

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

3.10

overall sensitivity

measure of the ability of an ultrasonic Doppler foetal heartbeat detector to detect, above the noise level, a **Doppler signal** from a simulated point target (less than three wavelengths wide) of known **target plane-wave reflection loss**, moving at a specified velocity and placed at a specified distance from the **probe**. The **overall sensitivity** level, S , in decibels (dB) is determined from:

$$S = A(d) + B + C$$

where

$A(d)$ is the **target plane-wave reflection loss** (dB) for the target at a distance d from the **probe**;

B is the two-way attenuation over the acoustic pathway (dB), including that of the acoustic attenuator(s), any coupling window and water path;

C is the signal-to-noise ratio (dB).

Symbol: S

Unit: decibel, dB

3.11

probe

an assembly, including the ultrasonic transducer element(s), which is dedicated to the transmission and reception of ultrasound energy. It may also include other components as necessary

3.12

receiver unit

part of the **equipment** which processes the ultrasonic signals from the **probe** to produce at least a **Doppler signal** in the audible frequency range

3.13

signal output part

part of the **equipment** not being an applied part, intended to deliver output signal voltages or currents to other equipment, for example, for display, recording or data processing. [2.1.19 of IEC 601-1]

NOTE For an ultrasonic Doppler foetal heartbeat detector, the **signal output part** is usually a terminal or connector at the output of the **receiver unit** which allows connection of an earphone, headphone, speaker or other audio equipment.

3.14

spatial-peak temporal-peak acoustic pressure

larger of the maximum positive or modulus of the maximum negative instantaneous acoustic pressure in an acoustic field. [3.26, 3.27 and 3.50 of IEC 1102]

Unit: pascal, Pa

3.15

target plane-wave reflection loss

ratio (dB) of the acoustic pressure at a specified distance from a target, in the ultrasonic field 180° back-reflected from the target, to the acoustic pressure in the plane wave incident coaxially with the target axis of symmetry and at the position of the target if the target were removed

target plane-wave reflection loss is expressed as a positive number

Symbol: A

Unit: decibel, dB

3.16

transmitter unit

part of the **equipment** which generates a high-frequency continuous wave or quasi-continuous wave electrical signal for energising the **probe**

4 List of symbols

a	= radius of a ball or rod target
$A(d)$	= target plane-wave reflection loss (dB) at a distance d
B	= two-way attenuation (dB) over a total acoustic path
B_a	= two-way insertion loss (dB) of an acoustic attenuator
B_w	= two-way insertion loss (dB) of a coupling window
C	= signal-to-noise ratio (dB)
c	= speed of sound in a medium
d	= distance between a target and the face of an ultrasonic transducer or probe
f	= ultrasonic frequency
k	= $(= 2\pi/\lambda)$ circular wavenumber
P	= output power of an ultrasonic transducer
P_a	= audio output power
S	= overall sensitivity of an ultrasonic Doppler foetal heartbeat detector
t	= thickness of an acoustic window
U_r	= hydrophone or ultrasonic transducer peak-to-peak signal at the position of a target
U_t	= hydrophone or ultrasonic transducer peak-to-peak signal at a specified distance from a target
V_s	= r.m.s. Doppler signal
V_n	= r.m.s. noise
Z	= Electrical impedance

α = Amplitude attenuation coefficient of plane waves in a medium

λ = Ultrasonic wavelength

5 Configuration

The **equipment** normally comprises the following modules (which may or may not be incorporated within the same housing), as shown in Figure 1:

- **probe**;
- **transmitter unit**;
- **receiver unit**;
- **signal output part**.

6 Performance

6.1 Acoustic working frequency

The **acoustic working frequency** shall not deviate more than $\pm 15\%$ from the **nominal acoustic working frequency** value stated by the manufacturer in accordance with clause 10.

Compliance is checked by measurement in accordance with the test method given in 8.1.

7 Safety

The **equipment** shall comply with IEC 601-1 and any in the IEC 601-2-X series dealing with foetal heartbeat detectors.

8 Tests

All measurements shall be undertaken using degassed water at a temperature of $22\text{ °C} \pm 5\text{ °C}$.

8.1 Acoustic working frequency

The **acoustic working frequency** of the **equipment** shall be determined using the acoustic coupling method shown in Figure 2. The hydrophone shall comply with IEC 866 as a class-B hydrophone. The active element of the hydrophone shall be positioned in the centre, and at least 5 cm from the side and bottom walls, of the water vessel. Acoustic absorbers shall be used to line the vessel in order to reduce stray reflections. The hydrophone shall be aligned for maximum signal. If the **equipment** operates in true continuous wave mode then a frequency counter may be used for the determination of the **acoustic working frequency**. In this case, the amplifier may be omitted if the frequency counter has sufficient sensitivity. The frequency counter used for this purpose shall have a flat frequency response range greater than 140 % of the **nominal acoustic working frequency** of the **equipment**.