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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Amendment No. 1
to
AS/NZS 4374:1996
Ultrasonics—Hand-held probe Doppler foetal heartbeat
detectors—Performance requirements and methods of measurement
and reporting

CORRECTION

The 1996 edition of AS/NZS 4374 is amended as follows; the amendment should be inserted in the appropriate place.

SUMMARY: This Amendment applies to the front cover and title page.

Published on 5 January 1997.

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Front cover and title page

Delete 'heatbeat' from title and substitute 'heartbeat'.

AS/NZS 4374:1996
IEC 1266:1994

Australian/New Zealand Standard[®]

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

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AS/NZS 4374:1996

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/17, Ultrasonic Medical Equipment. It was approved on behalf of the Council of Standards Australia on 5 February 1996 and on behalf of the Council of Standards New Zealand on 14 February 1996. It was published on 5 May 1996.

The following interests are represented on Committee HT/17:

Australasian Society for Ultrasound in Medicine
Australian Physiotherapy Association
CSIRO, Division of Applied Physics
CSIRO, Division of Radiophysics
Department of Public Works and Services, N.S.W.
Ministry of Commerce, New Zealand
National Radiation Laboratory, New Zealand

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AS/NZS 4374:1996

Australian/New Zealand Standard[®]

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

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PREFACE

This Standard was prepared by the Joint Standards Australian/Standards New Zealand Committee HT/17 on Ultrasonic Medical Equipment as a Joint Australian/New Zealand Standard.

This Standard is identical to and has been reproduced from IEC 1266:1994, *Ultrasonics—Hand held probe Doppler foetal heartbeat detectors—Performance requirements and methods of measurement and reporting*.

As this Standard is reproduced from an international Standard, the following applies:

- (a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (b) In the source text 'this International Standard' should read 'this Australian/New Zealand Standard'.
- (c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

<i>Reference to International Standard</i>		<i>Australian/New Zealand Standard</i>	
IEC		AS	
601-1	Medical electrical equipment Part 1: General requirements for safety	3200 (NZS 6150)	Approval and test specification—Medical electrical equipment
		3200.1	Part 1: General requirements for safety
854	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment	—	
866	Characteristics and calibration of hydrophones for operation in the frequency range 0.5 MHz to 15 MHz	—	
1101	The absolute calibration of hydrophones using the planear scanning technique in the frequency range 0.5 MHz to 15 MHz	—	
1102	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range of 0.5 MHz to 15 MHz	—	
1157	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment	AS/NZS 4194	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
1161	Ultrasonic power measurement in liquids in the frequency range 0.5 MHz to 25 MHz	—	

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NOTES

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AUSTRALIAN/NEW ZEALAND STANDARD

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.**