AS/NZS 4966:2002
IEC TS 61895:1999

Australian/New Zealand Standard™

Ultrasonics—Pulsed Doppler diagnostic systems—Test procedures to determine performance

Standards Australia

STANDARDS NEW ZEALAND

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 28 June 2001 and on behalf of the Council of Standards New Zealand on 5 October 2001. It was published on 4 January 2002.

The following interests are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Aged Care
Medical Industry Association of Australia
Ministry of Economic Development, New Zealand
Royal Australasian College of Radiologists

Additional interests participating in the preparation of this Standard:

CSIRO National Measurement Laboratory
CSIRO Telecommunications and Industrial Physics
National Radiation Laboratory, New Zealand
N.S.W. Department of Public Works and Services
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Australian/New Zealand Standard™

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment.

This Standard is identical with and has been reproduced from IEC TS 61895:1999, *Ultrasonics—Pulsed Doppler diagnostic systems—Test procedures to determine performance*.

As this publication has been reproduced from an international Standard, the following modifications apply:

(a) Its number does not appear on each page and its identity is shown on the cover and title page.

(b) The words 'this Australian/New Zealand Standard' should replace the words 'this technical specification' wherever they appear.

(c) Substitute a full point (.) for a comma (,) where it appears as a decimal marker.

Some pages of the original, which relate to IEC administrative matters, are omitted from this edition.

The term 'normative' has been used in this Standard to define the application of the annex or appendix to which it applies. A 'normative' annex or appendix is an integral part of the Standard.

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

Reference to International Standard		*Australian/New Zealand Standard*	
IEC		AS/NZS	
61206	Ultrasonics–Continuous-wave Doppler systems—Test procedures	4188	Ultrasonics—Continuous-wave Doppler systems—Test procedures

Any International Standards not listed do not have an Australian/New Zealand equivalent.

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INTRODUCTION

Pulsed ultrasonic Doppler flowmeters and velocimeters are widely used in clinical practice, usually in combination with real-time **B-mode** imaging and colour-flow imaging instruments. The device periodically transmits pulses of ultrasound from an ultrasound transducer and measures the Doppler shift in the frequency of ultrasound reflected and scattered from moving tissues. This Doppler shift is proportional to the component of reflector or scatterer velocity along the ultrasound beam. By looking for Doppler shifts in the received signal at specific times after transmission (range-gating), the device can be used to determine the variation of tissue velocity with distance along the ultrasound beam. The device is sensitive to movement only within a region of the beam called the sample volume. The position of the sample volume along the beam may be adjusted by altering the delay between transmission and range-gating. Multi-channel devices have a number of sample volumes operating simultaneously.

The pulsed ultrasonic device is most commonly used to investigate blood flow when the ultrasound is scattered from red blood cells.

This technical specification describes a range of tests which may be used to measure performance and the test objects required. In many cases, the test method and test object have been described in IEC 61206 and in these cases reference is simply made to this document. Other tests and test objects are described in [1] and [2]. The test methods may be considered as falling into one of the following three categories. The first is routine quality control tests that can be carried out by a clinician or technologist to ensure that the system is working adequately or has adequate sensitivity. The second is more elaborate test methods, conducted less frequently, when, for example, the system is suspected of malfunctioning. The third represents tests that would be carried out by a manufacturer on complete systems in order to guarantee compliance with specification.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Ultrasonics—Pulsed Doppler diagnostic systems—Test procedures to determine performance

1 Scope

This technical specification describes

– test methods for measuring the performance of pulsed **Doppler ultrasound systems**;

– **Doppler test objects** for carrying out these tests;

and applies to

– tests made on an overall pulsed **Doppler ultrasound system**, a system which is not disassembled or disconnected;

– tests made on pulsed **Doppler ultrasound systems** whether they are stand alone or as part of another ultrasound instrument.

Electrical safety, acoustic output and electromagnetic compatibility (EMC) are not covered in this technical specification.

The workload to perform all described tests is, in general, prohibitive. It is intended that a subset of the described tests is adopted for regular use. However, experience to give guidance for selection has still to be gathered and will be the subject of ongoing work.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this technical specification. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this technical specification are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0.5 MHz to 15 MHz*

IEC 61206:1993, *Ultrasonics – Continuous-wave Doppler systems – Test procedures*

IEC 61390:1996, *Ultrasonics – Real-time pulse-echo systems – Test procedures to determine performance specifications*

3 Definitions

For the purposes of this technical report, the following definitions apply.

3.1
6 dB spectral width
width of a frequency spectrum between the frequencies at which the spectral power is 6 dB less than the maximum power