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

Ultrasons – Systèmes de diagnostic à effet Doppler pulsés – Procédures d'essai pour déterminer la performance

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ULTRASONICS – PULSED DOPPLER DIAGNOSTIC SYSTEMS – TEST PROCEDURES TO DETERMINE PERFORMANCE

FOREWORD

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- the required support cannot be obtained for the publication of an International Standard, despite repeated efforts, or
- the subject is still under technical development or where, for any other reason, there is the future but no immediate possibility of an agreement on an International Standard.

Technical specifications are subject to review within three years of publication to decide whether they can be transformed into International Standards.

IEC 61895, which is a technical specification, has been prepared by IEC technical committee 87: Ultrasonics.

The text of this technical specification is based on the following documents:

Enquiry draft	Report on voting
87/151/CDV	87/168/RVC

Full information on the voting for the approval of this technical specification 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 3.

Annex A forms an integral part of this technical specification.

The committee has decided that this publication remains valid until 2005. At this date, in accordance with the committee's decision, the publication will be

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- withdrawn;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

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

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.

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*