TECHNICAL SPECIFICATION

IEC TS 61895

First edition
1999-10

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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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- withdrawn;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*

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

3.2
20 dB spectral width
width of a frequency spectrum between the frequencies at which the spectral power is 20 dB less than the maximum power

3.3
acoustic working frequency
centre frequency
zero-crossing acoustic-working frequency of the transmitted pulse spectrum

[3.4 of IEC 61102, modified]

3.4
aliasing
false indication of signal frequency as a result of sampling at too low a frequency

NOTE **Aliasing** occurs when the **Doppler frequency** exceeds the **Nyquist limit frequency** of the **Doppler ultrasound system**. In a **non-directional system**, the indicated frequency of the Doppler signal is the true **Doppler frequency** mirrored in the **Nyquist limit frequency**. In a **directional system,** the indicated frequency of the Doppler signal is the true **Doppler frequency** mirrored in the **Nyquist limit frequency** and changed in sign. In **systems** using a baseline shift, the term **Doppler frequency** should be replaced by **Doppler frequency plus baseline frequency shift** in the above explanation**.**

3.5
baseline frequency shift
frequency by which the Doppler signal is shifted before analysis in order to alleviate the effects of aliasing

3.6
B-mode (brightness-modulated display)
image generated by a pulse-echo ultrasound scanner in which the echoes from reflectors and scatterers in the tissues swept by a pulsed ultrasound beam are represented by a brightness-modulated two-dimensional display

3.7
clutter
unwanted components of the Doppler signal as it appears after the **Doppler demodulator**

NOTE **Clutter** arises from stationary or slowly moving reflectors and is usually removed by high-pass filters (wall-thump filters) within the **Doppler ultrasound system.**

3.8
dead zone
region close to the transducer in which the **system** is insensitive to tissue movement

3.9
directional
direction sensing
descriptor of a type of **Doppler ultrasound system** which indicates whether scatterers or reflectors are approaching or receding from the ultrasonic transducer

[1.3.1 of IEC 61206]

3.10
direction resolving
direction separating
descriptor of a type of **Doppler ultrasound system** in which the **Doppler output** appears at different output terminals, **output channels** or **output devices** depending on the direction of scatterer or reflector motion relative to the transducer

[1.3.2 of IEC 61206, modified]

3.11
Doppler angle
acute angle between the axis of the ultrasound beam during Doppler measurements and the direction of movement of the scatterer or reflector

3.12
Doppler demodulator
that part of the **Doppler ultrasound system** at which the Doppler signal is derived through mixing of the received signal and a **reference signal**

3.13
Doppler frequency
Doppler-shift frequency
change in frequency of an ultrasound scattered or reflected wave caused by relative motion between the scatterer or reflector and the transducer. It is the difference in frequency between the transmitted and the received wave
[1.3.3 of IEC 61206, modified]

3.14
Doppler output connector
electrical connector or that part of the **Doppler ultrasound system** at which the **Doppler output** is available for connection to external **output devices**

[1.3.5 of IEC 61206]

3.15
Doppler output
signal at the Doppler frequency or at Doppler frequencies which activates the output device

[1.3.4 of IEC 61206, modified]

3.16
Doppler spectrum
set of Doppler frequencies produced by a **Doppler ultrasound system**

[1.3.6 of IEC 61206]

3.17
Doppler test object
artificial structure used in testing **Doppler ultrasound systems**

3.18
Doppler ultrasound system
equipment designed to transmit and receive ultrasound and to generate a **Doppler output** from the difference in frequency between the transmitted and received waves

[1.3.8 of IEC 61206]

3.19
duplex scanner
ultrasound instrument which combines real-time **B-mode** imaging with a **Doppler ultrasound system**

3.20
nominal Doppler beam direction axis
assumed axis of the ultrasonic beam from the transducer used for Doppler measurements. This axis will often be the axis of rotational symmetry of the Doppler probe for a single-element transducer

3.21
nominal first lateral Doppler beam axis
coordinate axis perpendicular to the **nominal Doppler beam direction axis** and with a position indicated on the probe body for a single-beam direction probe or contained within the scan plane for the probe of a **duplex** or **triplex scanner** (see figure A.2)

3.22
nominal second lateral Doppler beam axis
coordinate axis perpendicular to both the **nominal Doppler beam direction axis** and the **nominal first lateral Doppler beam axis.** This axis is perpendicular to the scan plane for a the probe of a **duplex** or **triplex scanner** (see figure A.2)

NOTE The nominal first lateral Doppler beam axis, the nominal second Doppler beam axis and the nominal Doppler beam direction axis form a right-handed Cartesian co-ordinate set as shown in figure A.2.

3.23
nominal sample volume length
length of the sample volume indicated by the system. This normally will be a numerical display or a distance between markers on a screen indicating the extent of the sample volume along the nominal Doppler beam direction axis

3.24
non-directional
descriptor of a type of Doppler ultrasound system which is not **directional**

[1.3.9 of IEC 61206]

3.25
Nyquist limit frequency
half the **pulse repetition frequency.** In systems not using a baseline shift, it equals the frequency under which **aliasing** does not occur

3.26
observed velocity
component of the velocity of a scatterer or reflector along the axis of the ultrasound beam. This is directed towards or away from the transducers

3.27
output channel
part of the **Doppler ultrasound system** which functionally represents a particular aspect of the **Doppler output**

NOTE **A Doppler ultrasound system** may have two **output channels**, each representing a flow in a particular direction.

[1.3.12 of IEC 61206]

3.28
output device
any device included in a **Doppler ultrasound system** or capable of being connected to it that makes the **Doppler output** accessible to the human senses

[1.3.13 of IEC 61206]

3.29
phase-quadrature demodulation
a method of derivation of Doppler signals incorporating flow direction information, in which two **Doppler demodulators** are used with **reference signals** 90° out of phase – leading to in-phase and quadrature Doppler signals 90° out of phase. The direction of the phase shift between the in-phase and quadrature parts of the Doppler signal component at a particular frequency indicates the direction of movement of the **target** giving rise to that component