TECHNICAL SPECIFICATION

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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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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- withdrawn;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

3.30
pulse repetition frequency (PRF)
the number of pulses or bursts of ultrasound emitted by the transducer per second

3.31
range gate
that part of the **Doppler ultrasound system** which selects signals received from a range of depths to generate the Doppler signal. This is achieved by selecting signals arriving during a time interval following a delay after pulse transmission

3.32
reference signal
the signal mixed with the received signal in the **Doppler demodulator** in order to generate the Doppler signal. In **non-directional Doppler ultrasound systems** or **systems** using **phase-quadrature demodulation** the **reference signal** is at the transmitted frequency. In off-set frequency **directional Doppler ultrasound systems,** the **reference signal** is at the transmitted frequency plus or minus the off-set frequency

3.33
sample volume
the region of the ultrasound beam in which moving scatterers or reflectors give rise to components of the Doppler signal from the **Doppler ultrasound system**

3.34
scan plane
plane containing ultrasonic scan lines

[3.29 of IEC 61390]

3.35
sonogram
a frequency-time display in which the relative amplitude or power of each frequency component of the detected signal from successive or overlapping time windows is displayed as adjoining vertical grey scale lines

3.36
spectral width
range of **Doppler frequencies** within the **Doppler spectrum**

3.37
spectrum
a display of amplitude or power against frequency, showing the relative amplitude or power of each frequency component contained in the detected signal (see **Doppler spectrum**)

3.38
string test object
line of scatterers moving at a constant velocity in the direction of the line, and having ultrasound scattering properties similar to that of a moving column of blood

3.39
system
Doppler ultrasound system
See 3.18

3.40
target
reflector, scatterer or collection of scatterers giving rise to a received signal

3.41
target depth
distance from the probe face to the **target** along the beam

3.42
triplex scanner
ultrasound instrument which combines real-time **B-mode** imaging and colour-flow imaging with a pulsed **Doppler ultrasound system**

4 Symbols

c = average speed of sound in a medium

L = distance from the transducer face to the centre of the **sample volume**

L_{max} = maximum depth of penetration of the pulsed **Doppler ultrasound system**

f_0 = **acoustic working frequency**

f_{vm} = frequency of sinusoidal variation in mean frequency of simulated Doppler signal used in maximum, mean, mode and median frequency estimation accuracy test

5 Overall tests of complete systems

5.1 General considerations

5.1.1 Types of pulsed Doppler ultrasound systems

A pulsed **Doppler ultrasound system** may be **directional**, **non-directional** or **direction-resolving**. **Directional** (or directional sensing) refers to a type of pulsed **Doppler ultrasound system** which indicates whether reflectors or scatterers are approaching or receding from the ultrasonic transducer. **Non-directional Doppler ultrasound systems** do not indicate the direction of movement. **Direction-resolving** (or direction-separating) **Doppler ultrasound systems** provide for **Doppler outputs** to appear at different **output channels** depending on the direction of reflector or scatterer movement. The **system** may use a **phase-quadrature demodulation** or offset reference frequency demodulation in order to derive Doppler signals retaining flow direction information. Annex A gives descriptions and diagrams of these different types of pulsed **Doppler ultrasound systems.**

The **system** may be a stand-alone instrument or part of a **B-mode** and/or flow imaging **system**. The stand-alone instrument may make use of a single transducer for transmission and reception or separate transducers for these functions, in which case the instrument may be switched to operate in the continuous wave mode. When incorporated with a **B-mode** real-time imaging instrument, a separate transducer may be used for pulsed Doppler operation or the same transducer used for pulse echo imaging and pulsed Doppler work.

The **system** may be part of a **duplex** or a **triplex scanner**. **Duplex scanners** allow display of the nominal Doppler beam axis direction used for Doppler measurements to be displayed on the **B-mode** image along with indications of the depth and length of the **sample volume**. Provision is made for the operator to line up an electronic marker parallel to the axis of the displayed blood vessel in order that the instrument may calculate the angle between the ultrasound beam and the direction of the vessel. This allows the conversion of **Doppler frequencies** to blood velocities on the assumption of flow in the axial direction. **Triplex scanners**, in addition to the functions of the **duplex scanners**, display images of moving blood, colour-coded according to blood velocity, superimposed on the **B-mode** image.

The **system** may or may not be equipped with automatic adaptation of operating parameters to the depth of the **sample volume** and the nature of the tissue between the transducer and **sample volume**. Examples of parameters which are adapted in this way are **pulse repetition frequency (PRF)**, focal depth, transducer aperture and transmission signal spectrum.

The **system** may incorporate a method of spectral analysis of the Doppler signal, displaying the time-varying frequency spectrum of the Doppler signal. This frequency analysis may be based on the Fast Fourier Transform (FFT) or other methods of spectral analysis. The **system** may as an alternative display the time-varying maximum, mean, mode or median **Doppler frequency** derived from the spectral analyser, or more directly, by time-domain processing.

The **system** may incorporate interactive or automated measurement and/or calculation systems to process further the data from the spectrum analysis and/or **Doppler frequency** waveform – calculating, for example, indices of waveform shape and **spectral width**.

The **system** may incorporate means for the operator to listen to the Doppler signal using a loudspeaker or headphones.

The **system** may be a multi-channel instrument having a number of **sample volumes** and associated Doppler signal channels.

5.1.2 Worst-case conditions

A test method may be applied to determine a particular performance parameter of a **system**. Often a number of quantities can have a bearing on overall performance, each of which requires the application of a distinct test method. Some of these quantities need to be maximized and others need to be minimized in order to obtain best overall performance. Considering overall performance, table 1 gives the worst-case conditions for key quantities appropriate to pulsed **Doppler ultrasound systems** and the corresponding subclause numbers which describe a suitable test method. As an example, if the penetration as mentioned in 5.2.4 is minimized, this will lead to worst-case overall performance; conversely, maximizing penetration will lead to maximized performance.

Table 1 – Worst case for various quantities, and corresponding subclause numbers

Worst case is minimum value of		Worst case is maximum value of	
Quantities	**Subclauses**	**Quantities**	**Subclauses**
Penetration depth	5.2.4	**Dead zone**	5.9
Clutter rejection index	5.4.3.1	High-frequency response error	5.4.1
Flow direction separation	5.11	Low-frequency response error	5.4.1
		Harmonic distortion	5.4.3.2
		Intermodulation distortion	5.4.3.3
		Sample volume registration error	5.6
		Intrinsic broadening	5.8
		Beam position and orientation error	5.7
		Velocity estimation error	5.12
		Volume flow estimation error	5.13
		Maximum, mean, mode and median frequency estimation errors	5.14

5.1.3 Doppler beam axes

For the purposes of determining the orientation of the ultrasound probe, three orthogonal axes should be defined. One of these is the **nominal Doppler beam direction axis** and the other two are the first and second lateral Doppler beam axes. The first lateral axis is perpendicular to the sound beam axis and is in the plane of the scan. The second lateral axis is also perpendicular to the sound beam axis but is perpendicular to the plane of the scan. In a self-contained pulsed **Doppler ultrasound system,** these axes should be defined with respect to a mark or feature on the probe body. In a **duplex** or **triplex scanner**, the first lateral Doppler beam axis should be within the **scan plane** (see annex A).

5.1.4 Probe/target distance variation and measurement

The probe of the **Doppler ultrasound system** should be attached to a calibrated positioning mechanism capable of movement in three orthogonal directions. The directions of movement should be parallel to the **nominal Doppler beam direction axis** and parallel to the **nominal first** and **second lateral Doppler beam axes**. Alternatively, the probe of the **Doppler ultrasound system** may be held in a fixed position and the **target** moved parallel to these axes.

5.2 Initial conditions

These subclauses describe conditions common to all of the tests given in 5.2.4 and 5.3 to 5.15, as well as a procedure to determine the appropriate **Doppler frequency** and distance ranges to be used for these measurements.

Where a particular type of **system** may be comprised of various combinations of components, it is intended that each combination should be regarded as a separate **system** for testing purposes. For example, a **system** may have various transducer options. In this case, each transducer and output recording or presentation device connected to the basic **system** will define a different **system**. For the test to be meaningful, all instrument control settings should be recorded during the test. For those tests where the operator is required to make an assessment of performance from a grey scale or colour video display, the video monitor settings and ambient lighting conditions should be such that the lowest displayed intensity level above background is clearly distinguishable from the background.

5.2.1 Power supply

To ensure that the stated specifications hold over the range of power supply voltage, tests should be undertaken for the different power line voltages and worst-case test result values reported. The power line voltages are to be used at their nominal values and at 10 % above and below the nominal voltage. For power line operated **systems,** the worst-case values are those obtained after a specified warm-up time.

Portable, battery-operated **systems** weighing less than one kilogram should be tested with no warm-up and only over the time span sufficient to perform each test to simulate typical use. Heavier battery-powered **systems** should be tested under the same conditions as the power line operated **systems**.

For all battery-operated **systems** the results should be the worst case found over the span of battery voltages from the fully charged condition to a nominal end-of-life voltage. Any **system** tuning or adjustment should be carried out as specified in the instructions supplied to the user. It should be stated whether the nominal life-span of the battery occurs under continuous or intermittent conditions of use. This allows the manufacturer to select the intended normal battery life for either intermittent or continuous use. Manufacturers may report best-case results (for example, with fully charged batteries) in addition to worst-case results, provided that they report the **system** condition under which the results were obtained.

5.2.2 Target movement direction

If the pulsed **Doppler ultrasound system** is part of a **duplex** or **triplex scanner** then the **target** movement should be within the **scan plane** of the imaging system, unless otherwise stated. If the pulsed **Doppler ultrasound system** is stand-alone, then the **target**'s movement should be within the plane defined by the **nominal Doppler beam direction axis** and the **nominal first lateral Doppler beam axis,** unless otherwise stated.

5.2.3 Propagation medium

Most of the tests listed below can be performed in an appropriate non-attenuative medium whose acoustic velocity is 1 540 ms^{-1}, such as a 9,0 % glycerol solution by volume. If an electronic injection system is used, this may be coupled to the transducer under test using a solid medium such as perspex which has a higher acoustic velocity of 2 700 to 2 800 ms^{-1}. Attenuation using a suitable absorbor is required for the measurement of penetration depth. This should have an acoustic velocity of 1 540 ms^{-1}. The attenuation may be tissue equivalent (0,45 dB cm^{-1} MHz^{-1} to 0,55 dB cm^{-1} MHz^{-1}), as commonly used in a flow phantom, or it may be higher, as it may be necessary to perform sensitivity measurements using an attenuative polyurethane wedge in conjunction with a string test object.

5.2.4 Penetration depth

The maximum depth of penetration along the ultrasound beam (L_{max}) is measured using a **Doppler test object** with an attenuating tissue-mimicking medium between the probe and **target**. The **target depth** is increased until the Doppler signal power is equal to the noise power – that is, when the power of the **Doppler output** with a moving **target** (signal plus noise) is double that with a stationary **target** (noise only). In this case the signal-to-noise ratio (SNR) is zero decibels.

If the maximum depth in the **Doppler test object** is insufficient to reduce the signal power to give a SNR of zero decibels, the transmitter power should be reduced to enable the above condition to be achieved. In this case, the transmitter output setting should be noted.

The attenuation coefficient of the tissue mimicking medium should be within the range 0,45 dB cm^{-1} MHz^{-1} to 0,55 dB cm^{-1} MHz^{-1}, as commonly used in a flow phantom, or it may be higher (for example 0,70 dB cm^{-1} MHz^{-1} to 0,80 dB cm^{-1} MHz^{-1}) and should be reported along with the results of this test.

It should be noted that penetration depends on the target, and comparisons between **systems** are valid only if similar targets are used.

5.2.5 Working depth

Except where otherwise stated, measurements should be made at a distance between the probe face and the **target** (along the beam) of $L_{max}/2$, where L_{max} is the maximum depth of penetration (see 5.2.4).

5.2.6 Focusing

When testing **systems** with an operator-set (non-automatic) variable focus in **duplex** or **triplex scanners**, the nominal focus should be adjusted to the depth of the centre of the **sample volume,** or as close as the **system** focus and **sample volume** depth settings allow.

5.2.7 Working Doppler angle

Except where stated otherwise, the angle between the **nominal Doppler beam direction axis** and the direction of **target** movement in the **Doppler test object** should be 0°, 30°, 45°, or 60°. It should be noted that it may not be possible to achieve all these angles in all test objects (for example 0° in most flow test objects).

In a stand-alone pulsed **Doppler ultrasound system** with a transducer mounted in such a way that the beam axis is designed to be coincident with the probe axis, the probe axis should be taken as the **nominal Doppler beam direction axis**. In other isolated **systems,** the **nominal Doppler beam direction axis** should be described by the manufacturer.

In **duplex** and **triplex scanners**, the working Doppler angle is that measured between the Doppler beam and the direction of **target** movement as indicated on the image screen. If the Doppler beam orientation is variable, this angle should be set to 60°.

5.2.8 Wall-thump filter cut-off frequency

Except where otherwise stated, in **systems** with variable wall-thump filter cut-off frequencies this frequency should be set to $4 \times 10^{-5}\ f_0$ or the nearest value allowed by the **system** for peripheral vascular applications, where f_0 is the **acoustic-working frequency.** This corresponds approximately to 3 cms^{-1} for a **Doppler angle** of zero. For other systems other filter cut-off frequencies may be more appropriate. For example, for fetal applications this frequency should be set to $2 \times 10^{-5}\ f_0$ or the nearest value allowed by the **system,** and for adult cardiology applications, this frequency should be set to $6 \times 10^{-5}\ f_0$ or the nearest value allowed by the **system.**

5.2.9 Transmitter output power

Except where otherwise stated, in **systems** where the transmitted output power is variable, this power should be set at maximum.

5.2.10 Working pulse repetition frequency (PRF)

Except where otherwise stated, the PRF should be set to $0{,}4c/L_{max}$ or the nearest lower frequency allowed by the **system**.

5.2.11 Doppler (receiver) gain

Except where otherwise stated, in **systems** with a real-time spectrum analyser as an **output device**, the Doppler gain should be set in such a way that, with the transmitter power at minimum and the **target** stationary, the noise is just not visible on the display. Alternatively, in **systems** with no spectral analyser, the Doppler gain should be set to give a small but measurable noise signal on the **Doppler output.**

5.2.12 Test frequency

The test frequency is the **Doppler frequency** to be used in performing the tests. For the electronic injection test device, this is the frequency of the injected audio signal. For other test devices, this is the mean **Doppler frequency**. Except where otherwise stated, a test frequency of $5 \times 10^{-4}\ f_0$ or a frequency specified by the manufacturer should be used.

5.2.13 Working sample volume length

Except where otherwise stated, in **systems** where the **sample volume** length is variable, the **nominal sample volume length** should be set to $25 \times 10^6/f_0$ mm, or the nearest greater length allowed by the **system**, or if a greater length is not available, the nearest length, where f_0 is the **acoustic working frequency** in hertz.

5.2.14 Doppler signal power measurement

Doppler signal power can be measured at a **Doppler output connector**. The Doppler signal power may be measured by any device having an accuracy of better than 5 % at the signal level under consideration. It should be quoted as mean square signal volts, root-mean-square (r.m.s.) volts or in decibels relative to 1,0 volts r.m.s. A true reading r.m.s. meter is suitable. Note that only relative values are required in all the tests.

5.3 Zero signal noise level

With the test object producing a Doppler signal at the test frequency, the receiver level and transmitted power output are set to display the Doppler signal on the **sonogram** such that the full grey scale range of the display is utilized. The motion of the target is stopped, or in the case of the electronic injection device, the injected signal is switched off. The signal level at the **Doppler output** is noted as the zero signal noise level.

5.4 Doppler frequency response

The **Doppler frequency** response and accuracy are preferably tested with a test object giving rise to a narrow **Doppler spectrum**. An electronic **Doppler test object** with a single-frequency Doppler shift or a string **Doppler test object** may be used.

5.4.1 Frequency response range

The baseline of the frequency display should be set to zero. Frequency response is measured for the frequency range from 0 Hz to the upper Nyquist limit. The shift frequency of the electronic **Doppler test object** or the speed of the moving **target** in a string or flow **Doppler test object** is varied over this range. The time-average **Doppler output** signal level is measured as a function of **Doppler frequency** using an r.m.s. voltmeter or power meter and a means of mean frequency measurement. If the **Doppler output** signal level has one peak value, the low-frequency response frequency and the high-frequency response frequency are found from those frequencies at which the output voltage is 3 dB less than its peak level, although other limits may be used if so declared. The same procedure should apply in the case of multiply peaked response curves, where the lowest value between the peaks is above the –3 dB level relative to the largest peak described above.

If the response curve is multiply peaked and the lowest value between the peaks is below the –3 dB level relative to the largest peak described above, then the smallest value found between the peaks should be taken as the minimal detectable signal level. A horizontal line graph at this signal will then intercept the frequency response curve at this minimum and two other points. These two other points are the low- and high-frequency response values and should be quoted as the result of the test, qualified by a statement of the level of this minimum relative to the highest value.

In all of the above cases the minimum and maximum frequency limits should be compared with those indicated by the **system** or quoted in the **system** specification and the errors reported. Note that the minimum frequency is the wall-thump cut-off frequency.

The procedure should be repeated for the negative frequency range, from 0 Hz to the lower Nyquist limit.

5.4.2 Deviation from flat response

For the frequency range from zero to the upper Nyquist frequency, half the range of the signal level (in decibels), from the level at the maximum and minimum frequency limits to the maximum level measured, should be quoted as the maximum deviation from a flat response.

The procedure should be repeated for the negative frequency range, from 0 Hz to the lower Nyquist limit.

5.4.3 Large signal performance

Large spurious signals can cause errors in ultrasound Doppler receivers which behave similarly to communication system receivers. The tests in this section look for the magnitude of these effects for interfering signals that are of the order of the maximum levels that will be encountered in practice.

5.4.3.1 Fixed target effect on sensitivity (clutter rejection)

The effect of highly reflecting fixed **targets** on the amplitude of the **Doppler output** can be determined by using the small vessel or string **Doppler test object**. The change in the **Doppler output** should be reported in terms of the change (in decibels) observed when a highly reflecting **target** is placed within the **sample volume** in the far side of the string or small vessel from the transducer. The reflecting **target** should be placed as close as practicable to the moving string or vessel and oriented to produce the maximum fixed **target** echo. A spherical **target** large enough to produce a strong echo without overload is suggested in order to reduce alignment problems. The **Doppler output** should be observed while moving the fixed **target** laterally and axially within the **sample volume** and the maximum change in **Doppler output** reported.

Alternatively, the electronic **Doppler test object** may be used to determine the instrument's **clutter** rejection. The electronic **Doppler test object** is operated such that it generates a test frequency at such an amplitude that the **Doppler output** is at least 20 dB greater than the noise level but significantly below saturation. The **Doppler test object** is then operated in such a way that it generates simultaneously a stationary (zero Doppler shift) frequency signal and the amplitude of the signal is increased until the **Doppler output** changes by 3 dB. Here, it is assumed that the signal at the zero **Doppler frequency** does not contribute directly to the Doppler ouput power. The ratio of the stationary to test **Doppler frequency** signal amplitudes generated by the electronic **Doppler test object** is recorded as the **clutter** rejection index.

5.4.3.2 Harmonic distortion

This may be measured as detailed in 2.3.3.1 of IEC 61206. Alternatively, an electronic **Doppler test object** may be used to measure harmonic distortion. Using a spectrum analyser connected to the Doppler output connector, the sum of the powers of the harmonics of the test frequency is measured and expressed as a percentage of the signal power at the test frequency. This is the percentage harmonic distortion. The distortion is measured and reported at Doppler signal output levels at the test frequency of 10 dB above the noise level and at additional 10 dB increments until the distortion exceeds 10 %.

5.4.3.3 Intermodulation distortion

This may be measured as detailed in 2.3.3.3 of IEC 61206. Alternatively, an electronic **Doppler test object** may be used to measure harmonic distortion. The electronic **Doppler test object** is operated such that it generates a low-frequency signal at a frequency of 10 % of the test frequency in addition to a signal at the test frequency. The low-frequency signal level should be maintained at 30 dB above the test frequency signal. Using a spectrum analyser connected to the Doppler output connector, the sum of the powers of the signals at the test frequency plus and minus the low frequency is measured and expressed as a percentage of the signal power at the test frequency. This is the percentage intermodulation distortion. The distortion is measured and reported at Doppler signal output levels at the test frequency of 10 dB above the noise level and at additional 10 dB increments until the distortion exceeds 10 %.

5.5 Spatial response

The relative sensitivity of the **Doppler ultrasound system** to scatterers at different points in space can be determined by these procedures. The measurements are made at the nominal first lateral Doppler beam axis orientation unless otherwise stated.

5.5.1 Sample volume response

The following tests can be used to measure the sensitivity variation within the **sample volume** and its lateral widths and axial length. These distances are those between points at which the instrument response to a moving **target** falls to a specified fraction of the maximum response.

The test should be carried out at the working **sample volume** length setting at depths of 0,2 kL_{max} where k = 1, 2, 3, 4, or as specified by the manufacturer.

It should be noted that measurements made with different **targets** are likely to give rise to different values for the dimensions of the **sample volume** since the sensitivity variation depends on **target** acoustic response. The measurements using one type of **target** may, nevertheless, be used for comparative purposes.

In particular, the Doppler signal power when using an **ideal string test object** would be proportional to the line integral of the sensitivity variation (signal power from a moving single monopole scatterer versus position) along the string path. Non-ideal behaviour in real-string **Doppler test objects** resulting from finite scatterer dimensions, string thickness and periodicity in string structure, for example, has yet to be fully investigated [2].

As a consequence of the complex nature of the scatter from small-sphere **targets** [3], and in particular its variation with frequency, the small-ball **Doppler test object** is not recommended for use in pulsed **Doppler ultrasound systems** or **systems** with narrow beam widths until its performance limits have been evaluated.

NOTE When measuring low Doppler signal power when the background noise is not negligible (for example, near L_{MAX}), then the measured noise power should be subtracted from the signal-plus-noise power measured at the Doppler signal connector in order to estimate the Doppler signal power.

5.5.1.1 Sample volume axial response

With the Doppler beam direction axis set at the working **Doppler angle** with respect to the string, the probe is moved axially and laterally while monitoring the Doppler signal power until this is a maximum. The probe is then moved parallel to the **nominal Doppler beam direction axis** and the distance between the points at which the Doppler signal power falls to –6 dB of the maximum and the distance between the points at which the power falls to –20 dB of the maximum are noted and reported as the 6 dB and 20 dB axial **sample volume** lengths at 60°. These measurements are repeated at **Doppler angles** of 45° and 75° and the measurements extrapolated to find the **sample volume** length at 90°. This length should be compared with the **nominal sample volume length** indicated by the pulsed **Doppler ultrasound system**.

With the centre of the **sample volume** at the working depth, the length should be altered from its minimum to maximum value in five equal steps or those allowed by the **system,** and the 6 dB and 20 dB **sample volume** lengths at 90° reported together with the **nominal sample volume lengths** indicated by the pulsed **Doppler ultrasound system**.

5.5.1.2 Sample volume **lateral responses**

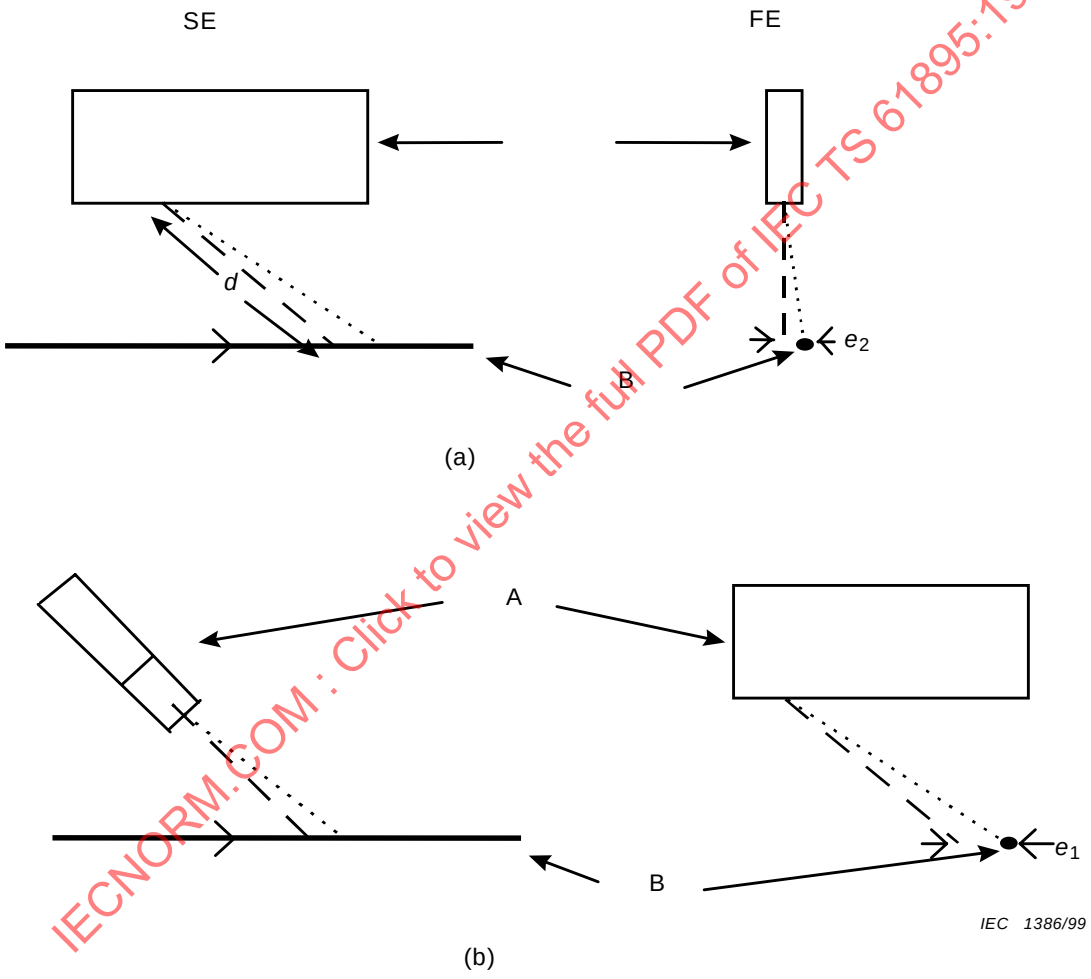
The measurements carried out in 5.5.1.1 are repeated, with the difference that the probe is moved laterally perpendicular to the string. This gives the first lateral sample volume width. The measurements are repeated with the probe rotated by 90° about the **nominal Doppler beam direction axis**, giving the second lateral sample volume width.

5.6 Sample volume position registration error

Using a string **Doppler test object,** the **sample volume** is moved along the beam until the Doppler signal power is at maximum and this power is noted. The **sample volume** is then moved to the two positions at which the Doppler signal power is 3 dB lower than the maximum. With a **duplex** or **triplex scanner** the distance along the Doppler beam between the point halfway between the centres of the **sample volumes** (as indicated on the screen) in these positions and the image of the string is reported as the registration error.

5.7 Beam position and orientation

These tests are designed to measure the deviation of beam axis position and orientation with respect to the **nominal Doppler beam direction axis**. The tests are most conveniently carried out at the same time as the sample volume lateral response tests in 5.5.1.2. During these tests, the co-ordinates of the points at which the Doppler power falls to –6 dB of the maximum are calculated and the co-ordinates of their mid point along the two lateral beam axes are noted. These mid-point co-ordinates are those of the measured beam axis. The difference between these co-ordinates and the co-ordinates of the nominal beam direction axis at the depth under consideration are the deviations of the beam position at that depth (see figure 1). It is clearly necessary for the test rig to be such that the co-ordinates of the string and the nominal Doppler beam direction are known within the co-ordinate system defined by the calibrated probe positioning system (see 5.1.4).



Key

A Probe

B String

SE Side elevation

FE Front elevation

Dashed line – nominal Doppler beam axis direction

Dotted line – true Doppler beam axis direction

NOTE This figure shows views along the line perpendicular to the plane containing string and nominal Doppler beam direction axis (and along the direction of the string respectively) for beam deviation measurements (e_2, e_1) at depth d along second (a) and first (b) lateral beam axes.

Figure 1 – Probe/string geometry for beam position and orientation test

5.8 Intrinsic broadening

In this test, the Doppler signal is passed to a spectrum analyser capable of displaying spectra acquired for signals of several seconds duration and allowing measurement of the **6 dB spectral width**. The accuracy of measurement is dependent on the frequency and amplitude resolution of the spectrum analyser, the width of the spectrum being measured and the product of signal duration and frequency resolution. The spectrum analyser, its settings and the signal duration should be such that the **6 dB spectral width** can be measured to an accuracy of 10 %.

The test should be carried out at the working **sample volume** length setting at depths of $0{,}2kL_{max}$ where k = 1, 2, 3, 4, or as specified by the manufacturer.

This test may be carried out using a string test object as follows. With the Doppler beam direction axis set at the working **Doppler angle** with respect to the string, and the string speed set such that the mean frequency of the Doppler signal spectrum is the Doppler test frequency, the probe is moved axially and laterally while monitoring the Doppler signal power until this is a maximum. The **6 dB spectral width** of the measured Doppler signal spectrum is expressed as a percentage of the test frequency. This figure is reported as the percentage intrinsic spectral broadening.

5.9 Dead zone

Using a string **Doppler test object**, the **target depth** is decreased until the Doppler signal power reduces to –20 dB of the maximum power recorded in 5.4.1. The **target depth** is then reported as the **dead zone** thickness.

5.10 Acoustic working frequency

This should be measured by the zero-crossing frequency or spectrum analysis methods as detailed in 3.4 of IEC 61102.

5.11 Flow direction separation

This should be measured as detailed in 2.6 of IEC 61206.

5.12 Velocity estimation accuracy

These tests are to be carried out on a **system** having a velocity estimation facility.

Using a string **Doppler test object** under the standard working conditions, the velocity estimated by the **Doppler ultrasound system** is compared with the true string speed. The error is reported for string speeds from –2 m/s to +2 m/s in steps of 0,04 m/s, or speeds corresponding to ±0,8 of the frequency at which **aliasing** occurs, whichever leads to the smallest **Doppler frequency** magnitude.

Using a fixed string speed giving a mean Doppler shift equal to the test frequency at a **Doppler angle** of 60°, the velocity measurement error is measured and reported for **Doppler angles** at extremes for the particular **system** under test and for a number of intermediate angles.

5.13 Volume flow estimation accuracy

This test should be carried out on systems having a flow estimation facility. The test should be carried out as detailed in 2.7 of IEC 61206. A suitable flow test object is described in [10].

5.14 Maximum, mean, mode and median frequency estimation accuracy

The ability of the Doppler system to estimate correctly various spectral parameters, such as maximum Doppler frequency, mean frequency, etc., from the detected ultrasound signal depends on a number of machine-dependent factors, such as the algorithms used for Doppler detection and spectral analysis, and also on the shape and width of the Doppler spectrum. The accuracy of estimation of spectral parameters will be dependent on their rate of change. The tests below aim to assess the estimation accuracy of various spectral parameters, and the dependence of accuracy on the rate of change of these parameters. These tests are only concerned with the effect of machine processing on accuracy, and are not concerned with physical effects, such as geometric spectral broadening.

These tests require the generation of a Doppler signal with a time-varying spectrum of controllable and known frequency content. The only test object which meets these criteria is an electronic one.

Firstly, the test object should be used with a simulated Doppler signal having a constant spectral shape and constant mean frequency. At least three spectra should be used: a narrow symmetrical spectrum having a **20 dB spectral width** in the range 0,1 to 0,2 times the spectral mean frequency, a wide symmetrical spectrum having a **20 dB spectral width** in the range 0,4 to 0,6 times the spectral mean frequency, and a wide asymmetrical spectrum having a **20 dB spectral width** in the range 0,4 to 0,6 times the spectral mean frequency and a mode frequency greater than the mean frequency by at least 0,2 times the spectral mean frequency. For each spectrum, tests should be carried out using three positive and three negative mean frequencies. In each case, the three frequencies should be such that

- the minimum frequency in the spectrum is equal to the wall-thump filter 3 dB cut-off frequency;
- the maximum frequency in the spectrum is equal to the upper 3 dB cut-off of the system frequency response (see 5.4.1);
- they are mid-way between these two frequencies.

Secondly, the system should be tested using simulated Doppler signals with sinusoidal mean-frequency variation. The amplitude of the mean-frequency variation should be such that the peak frequency generated is equal to the upper 3 dB cut-off of the system frequency response. For each spectrum shape, the frequency f_{vm} of the sinusoidal mean-frequency variation should be varied from 1,0 Hz to 50 Hz in at least six steps and the error in the calculated maximum, mean, mode and median frequencies noted. Typical spectra and minimum/mean/maximum frequency variations are shown in figures 2 and 3. The error for each f_{vm} /spectrum combination should be quoted as the average bias and standard deviation over a cycle calculated from a sufficiently large number of cycles such that the estimation error for these two quantities is less than 10 %. The above tests should be carried out at signal-to-noise ratios of 0 dB, 10 dB, 20 dB and 40 dB.

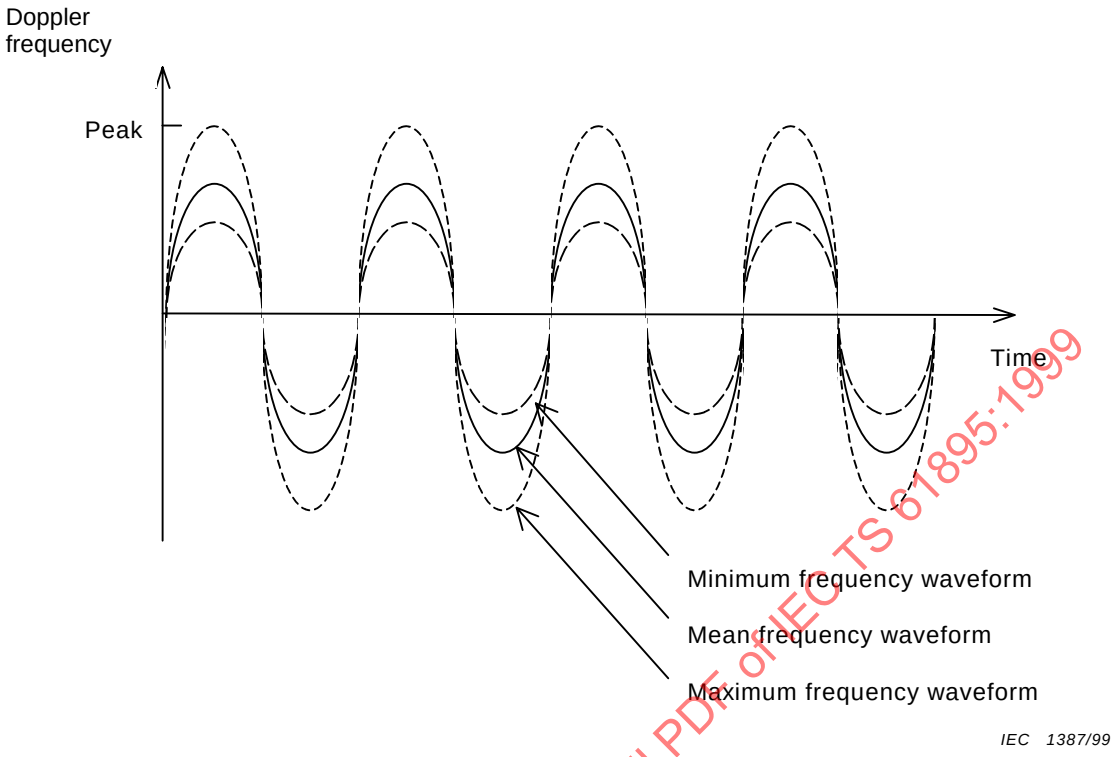
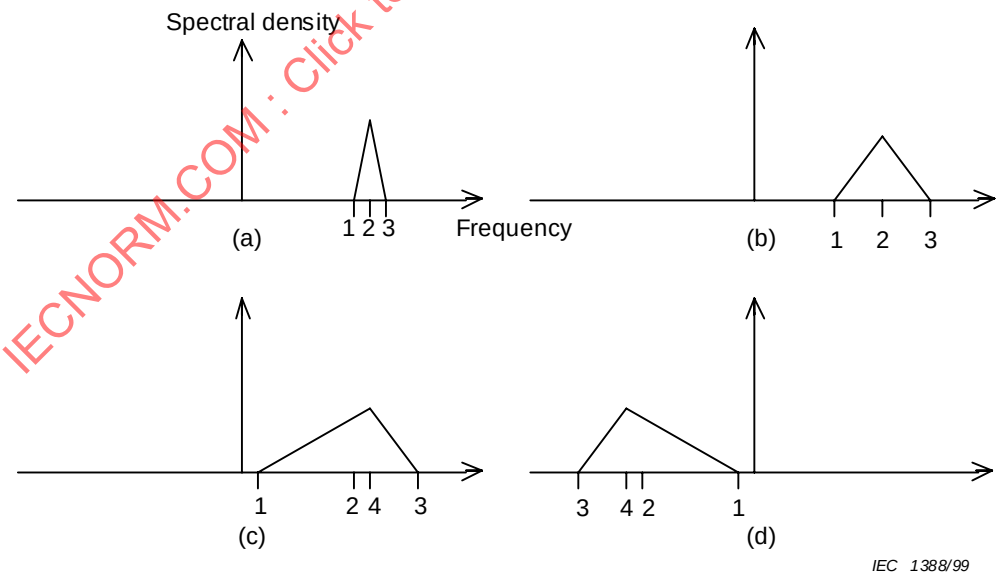


Figure 2 – Sinusoidal variation of minimum, mean and maximum simulated Doppler signal frequencies



NOTE This figure shows a narrow positive symmetrical spectrum (a), a wide positive symmetrical spectrum (b), a wide positive asymmetrical spectrum (c) and a wide negative asymmetrical spectrum (d). Frequencies indicated are minimum (1), mean (2), maximum (3) and mode (4). The mode and mean frequencies are equal for the symmetrical spectra.

Figure 3 – Simulated Doppler spectra with a constant mean frequency or at an instant when using a sinusoidal mean-frequency variation

5.15 Velocity waveform indices estimation accuracy

Doppler ultrasound systems often incorporate algorithms to compute indices of velocity waveform shape such as pulsatility index, resistance index and A/B ratio [4]. These may be computed from the maximum frequency envelope of the displayed spectrum automatically or from a trace of the envelope performed by the operator. The results are dependent not only on the algorithms used but also on the effect of the sample volume and spectral analysis method, since these may give rise to maximum frequency waveform shapes which are different from the shape of the velocity waveforms. Ideally, estimation accuracy of the velocity waveform indices should be assessed by the use of a pulsatile flow test object with an accurately known time-varying velocity field and having a negligible distorting effect on the sample volume of the system. In the absence of such a test object, the algorithms used to calculate the indices may be tested, in isolation, by the use of an electronic test object delivering simulated Doppler signals of known time-varying spectra. Since the number and type of indices calculated by Doppler ultrasound systems are very variable and there is no consensus on the required accuracy, it is sufficient that tests are performed to test the estimation accuracy declared by the manufacturer.

When using a pulsatile flow-test object, tests should be carried out using waveforms of known index values covering the declared range for the system under test. The centre of the test object vessel should be at the working depth, and the angle between the vessel axis and the nominal Doppler beam direction axis should be at the working Doppler angle. The error between the measured index and the known index of the pulsatile flow should be declared for each waveform tested. The test should be carried out at signal-to-noise ratios of 0 dB, 10 dB, 20 dB and 40 dB, and the ratio may be adjusted by the use of the system's transmitted output power control. The test should be carried out with both a narrow spectrum achieved by the use of a vessel of diameter greater than five times the greater of the 6 dB width or length of the sample volume, and a wide spectrum achieved by the use of a vessel of diameter less than the smaller of the 6 dB width or length of the sample volume.

When using an electronic test object, Doppler signals of known maximum frequency waveforms should be generated and the system should be tested with narrow and wide spectra. The spectra used for the frequency estimation tests in 5.14 would be suitable. Since there is also no consensus on what constitutes "maximum" frequency (a typical Doppler spectrum gradually reduces to zero as a consequence of intrinsic spectral broadening and window broadening, for example, and the true maximum is not used), the definition of the maximum frequency of the simulated Doppler signal spectrum (for example, the frequency below which the spectrum contains 95 % of the total Doppler signal power) should be declared along with the results of these tests. The range of velocity indices and signal-to-noise ratios should be as for the tests using the pulsatile flow test object.

In order to test the response of the system to the varying amplitude velocity waveforms obtained in practice as result of breathing or other involuntary patient movement, the electronic test object should be capable of generating simulated Doppler signals for which the velocity waveform amplitude reduces from its maximum value randomly and smoothly to a minimum value of half the maximum amplitude so that this change from an amplitude maximum to a minimum takes place over a minimum time of two and a maximum time of 10 cardiac cycles. The deviation of each index calculated by the system from the index of the maximum amplitude waveform should be declared.

The above tests should be carried out with cardiac periods of 400 ms, 800 ms and 1 600 ms or at three periods spanning the declared range of the system.

6 Doppler test objects

6.1 Test objects

Test objects suitable for pulsed **Doppler ultrasound systems** are described briefly in Section 3 of IEC 61206 and in [10]. In addition, an electronic **Doppler test object** is described briefly here.

Flow, string, belt and electronic test objects together with their strengths and limitations are described in [2].

It should be noted that the moving belt test object consisting of a distributed target in the form of a motor driven belt of scattering material in a fluid bath [5] is suitable for some of the Doppler frequency response (5.4.1, 5.4.2, 5.4.3.2) tests, the intrinsic broadening test (5.8) and the velocity estimation accuracy test (5.12).

It is important that those characteristics of the test object used which are known or are likely to have an effect on the test results should be reported along with the test results.

6.2 Electronic test object

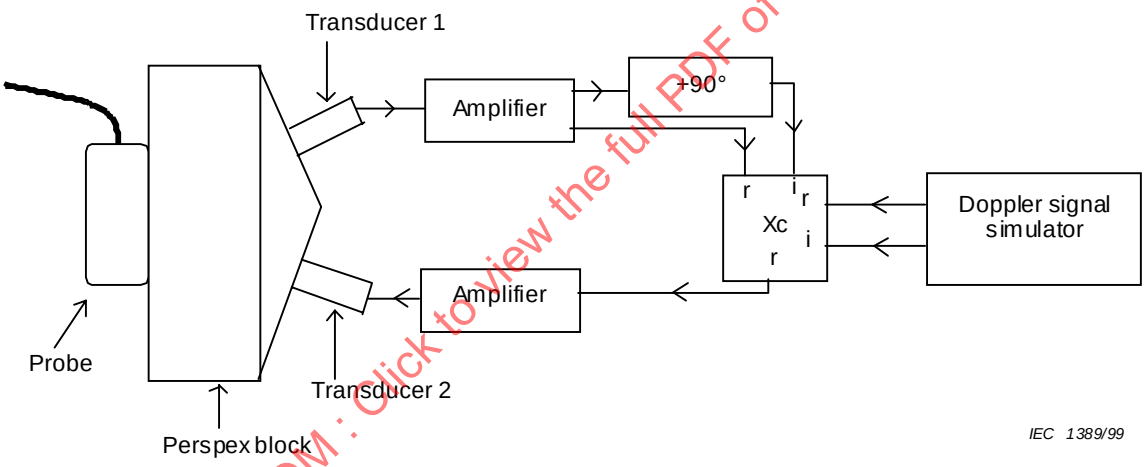


Figure 4a – Electronic test object

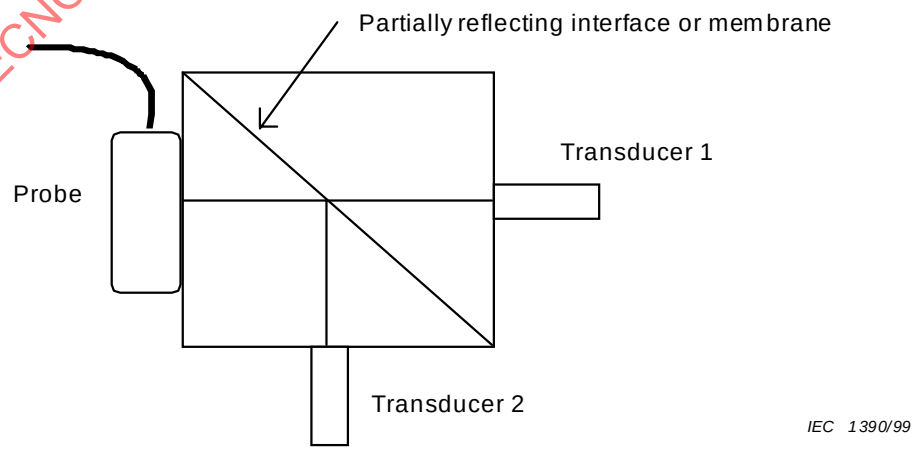


Figure 4b – Alternative coupling arrangement between probe and test object transducers