Ultrasonics — Continuous-wave Doppler systems — Test procedures

The European Standard EN 61206:1995 has the status of a British Standard $\,$



Committees responsible for this British Standard

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British Dental Association
British Institute of Radiology
British Medical Ultrasound Society
British Society for Rheumatology
Department of Health
Department of Trade and Industry (National Physical Laboratory)

Institute of Laryngology and Otology
Institute of Physical Sciences in Medicine

Institution of Electrical Engineers

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National foreword

This British Standard has been prepared by Technical Committee EPL/87 and is the English language version of EN 61206:1995 *Ultrasonics, Continuous-wave Doppler systems* — *Test procedures*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with Technical Report IEC 1206:1993, published by the International Electrotechnical Commission (IEC).

The United Kingdom voted against this document being harmonized as an EN, as the IEC Technical Report Type 2 was not intended to be regarded as an International Standard, but only as a prospective standard for provisional application, for guidance on how standards in this field should be used to meet an identified need. The IEC Technical Report is due for further review three years after publication, with the options of either extension for a further three years or conversion to an International Standard, or withdrawal. The EN will correspondingly be automatically reviewed after a period of five years or earlier depending on the outcome of the IEC review.

Cross-references

Publication referred to	Corresponding British Standard
EN 61102:1993	BS EN 61102:1994 Specification for measurement and
(IEC 1102:1991)	characterisation of ultrasonic fields using hydrophones
	in the frequency range 0.5 MHz to 15 MHz

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 22, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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EN 61206

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English version

Ultrasonics Continuous-wave Doppler systems Test procedures

(IEC 1206:1993)

Ultrasons Ensembles à effet Doppler à ondes entretenues Méthodes d'essai (CEI 1206:1993) Ultraschall Dauerschall Doppler System Prüfverfahren (IEC 1206:1993)

This European Standard was approved by CENELEC on 1994-12-06. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization Comité Européen de Normalisation Electrotechnique Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

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Introduction

Continuous-wave ultrasonic Doppler flowmeters, velocimeters, or foetal heart detectors are widely used in clinical practice. This type of medical ultrasonic equipment measures the Doppler-shift frequency which is the change in frequency of an ultrasound scattered wave caused by relative motion between a scatterer and the ultrasonic transducer. This frequency is proportional to the observed velocity, which is the component of the velocity of a scatterer that is directed towards or away from the transducer.

This technical report describes a range of test methods that may be applied to determine various performance parameters for continuous-wave Doppler ultrasound systems. They may also be applied to pulsed Doppler systems although additional tests would also be required. The test methods are based on the use of a number of specialised devices such as string, band, disk, piston and flow Doppler test objects. These 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 a technologist to ensure that the system is working adequately or has adequate sensitivity. The second is more elaborate test methods, conducted less frequently, such as when the system is suspected of not working properly. The third represents tests that would be done by a manufacturer on complete systems, as the basis of type specification of performance.

Section 1. General

1.1 Scope

This technical report describes:

- test methods for measuring the performance of continuous-wave ultrasonic Doppler flowmeters, velocimeters, or foetal heart detectors;
- special Doppler test objects for determining various performance properties of Doppler ultrasound systems.

This technical report applies to:

- tests made on an overall Doppler ultrasound system; a system which is not disassembled or disconnected;
- tests made on continuous-wave Doppler ultrasound systems. The same tests can be applied to Doppler ultrasound systems which measure position as well as velocity, such as pulsed and frequency-modulated Doppler systems, although additional tests may then be required.

Electrical safety and acoustic output are not covered in this technical report

1.2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this technical report. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this technical report are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 1102:1991, Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz.

1.3 Definitions

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

1.3.1

direction sensing; directional

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

1.3.2

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 upon the direction of scatterer motion relative to the transducer

1.3.3

doppler frequency; doppler-shift frequency

change in frequency of an ultrasound scattered wave caused by relative motion between the scatterer and the transducer. It is the difference frequency between the transmitted and the received wave

1.3.4

doppler output; direct output; doppler frequency output

voltage at the **Doppler frequency** or **at Doppler frequencies** which activates the **output device**

1.3.5

doppler output connector

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

NOTE Not all **Doppler ultrasound systems** have a physical connector at which the **Doppler output** is available.

1.3.6

doppler spectrum

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

1.3.7

doppler test object

artificial structures used in testing **Doppler ultrasound systems**. They produce ultrasonic reflections that are similar to those produced by the structures on which the **Doppler ultrasound systems** are to be used

NOTE $\,$ Doppler test objects are often referred to as phantoms.

1.3.8

doppler ultrasound system; 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

1.3.9

non-directional

descriptor of a type of **Doppler ultrasound** system which is not direction sensing

1.3.10

observed velocity

component of the velocity of a scatterer that is directed towards or away from the transducers

1.3.11

operating frequency

the ultrasonic or electrical frequency of operation of an ultrasonic transducer forming part of a **Doppler ultrasound system**

1.3.12

output channel

part of a **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.

1.3.13

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

1.4 Symbols

- c is the average speed of sound in a medium.
- v is the average speed of the fluid in a flowDoppler test object.
- Φ is the angle between the sound beam and the axis of the tube, string, band or disc in flow, string, band or disc **Doppler test objects** respectively.
- λ is the ultrasonic wavelength.

Section 2. Overall tests of complete systems

2.1 General considerations

2.1.1 Types of Doppler ultrasound systems

A major factor that affects performance testing of a

Doppler ultrasound system (system) is whether it can be described as directional, non-directional, or as direction resolving. Directional or direction sensing refers to a type of system which indicates whether scatterers are approaching or receding from the ultrasonic transducer. Non-directional systems do not indicate direction of scatterer motion. Direction resolving, or direction separating systems provide for Doppler output to appear at different output channels depending upon the direction of scatterer motion. Annex A gives descriptions and examples of these different types of systems.

2.1.2 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 one of which requires the application of a distinct test method. Some of these quantities need to be maximised and others need to be minimised in order to obtain the best overall performance. Considering overall performance, Table 1 gives the worst case conditions for key quantities appropriate to peripheral vascular systems and the corresponding clause number which describes a suitable test method. Table 1 may need modification to be appropriate for other uses. As an example, if the noise as measured in **2.2.4** is maximised this will lead to worst case overall performance; conversely, minimising noise will lead to maximised performance. The situation for spatial response (see clause 2.4), is discussed in the rationale (see Annex B).

Worst case is the minimum value of:		Worst case is the maximum value of:		
Quantities	Subclause	Quantities	Subclause	
Working distance	2.2.3	Noise level	2.2.4	
High-frequency response	2.3.1	Low-frequency response	2.3.1	
Fixed target effect on sensitivity	2.3.3.2	Distortion	2.3.3.1	
Channel separation	2.6.1	Simulator flow error	2.6.2	

Table 1 — Worst case quantities, and corresponding subclause numbers

2.2 Initial conditions

These clauses describe conditions common to all of the tests given in clauses **2.3** to **2.7**, as well as a procedure for locating the appropriate **Doppler-shift 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 electronics will define a different **system**. For tests to be meaningful, all instrument controls, particularly the volume or gain controls, should be recorded during the test.

2.2.1 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 the 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 done as specified in the instruction 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.

2.2.2 Test frequency, general conditions

An initial nominal test **Doppler frequency** as specified by the manufacturer, or 1,0 kHz if none is specified, should be obtained by operating the system and transducer with one of the **Doppler** test objects specified in clause 3.1. The sound beam is directed at the appropriate moving portion of the Doppler test object, whose speed of operation should be adjusted to produce the nominal test Doppler frequency in the Doppler **frequency output** of the **system**. The transducer should be affixed in a clamp capable of translating the transducer along, and at right angles to, the axis of maximum sensitivity of the system under test. Alternatively, the **Doppler test object** can be moved to cause the same relative displacements. In both cases, the mounting should allow the angle of the sound beam emitted by the transducer to be changed relative to the moving portion of the Doppler test object, while allowing the separation of the transducer and the **Doppler test object** to be changed. The separation adjustment should be independent of the angular adjustments so that the true axial response along the sound beam can be measured.

Where appropriate, and unless otherwise stated, the **Doppler-shift frequency** and the **Doppler output** should be observed and measured on each of the outputs provided for the **system** being tested, with each of the transducers with which it is expected to work. It is recommended that the readings be taken at the **Doppler output connector** if one is available. The single-channel output **systems** usually can be tested by observing their output indication relative to any calibration scales or marks on the **system**.

In the tests that use **Doppler test objects**, as illustrated above, the use of a tissue-equivalent absorber is recommended and described in this technical report. This is done to be sure that the signal levels in the **system** are close to those that will be encountered in practice. It is possible to make these tests in a water bath without absorber and to make corrections for the effects of absorption. In this case, to obtain valid results the gain controls should be set at positions that prevent malfunction, or "overloading" of the system from the large echo signals. Overloading in the input circuits can still occur, however, depending on the design. Since this procedure may introduce errors in the case of large aperture, or array transducers, it is not recommended.

2.2.3 Working distance

The small vessel **Doppler test object** or string **Doppler test object** (see **3.1.1**) is convenient for this test. The tissue-equivalent absorber may be removed only for working distances less than 1 cm. The lateral position of the transducer assembly is adjusted with respect to the moving portion of the small vessel Doppler test object while observing the signal level of the **Doppler output** on the selected **Doppler output connector**. The position which maximises the magnitude of the **Doppler output** is located. This process is repeated over a range of separations between the transducer and the moving portion of the **Doppler test object**. The effective spacing between the face of the transducer assembly (measured on the centre line axis of the assembly) and the intersection of the centre line axis of the transducer assembly and the moving portion of the **Doppler test object** is the working distance.

If the **system** includes an automatic gain control circuit, the **Doppler output** may be relatively constant over a large range of distances. The working distance should be taken as the approximate centre of this flat region.

2.2.4 Zero-signal noise level

For future reference, the level of the noise components which are found at the **Doppler output connector** when the moving portion (string) of the **Doppler test object** is stopped should be measured using a true-r.m.s. responding power meter, or visually on each **output device**. The observer should be sure that stray reflections within the **Doppler test object** do not influence this test (see **3.1.7**). The passband of the power meter should extend over the full frequency range measured for the response of the particular **Doppler output** being tested (see **2.3.1**).

2.3 Doppler frequency response

Frequency response tests may be made by using a **Doppler test object** appropriate for the intended clinical use of the **system** positioned at the standard working distance.

Response and accuracy are preferably tested with the small vessel or string **Doppler test object** since these produce a single **Doppler frequency** which is readily measured, even visually on spectrum analyzers. **System** control settings or ranges intended for arterial occlusive diagnosis should be used for tests with this **Doppler test object**. **System** configurations designed for venous diagnosis may be tested using the large vessel or band **Doppler test object**. The disk **Doppler test object** should be reserved for the distortion test specified in **2.3.3.1**.

2.3.1 Frequency response range

The speed of the moving member (or fluid) in the **Doppler test object** is changed to produce a range of **Doppler frequencies**. The time-average **Doppler output** is measured as a function of **Doppler frequency** or speed of movement, using an r.m.s. or average responding voltmeter and a frequency counter, or other speed-indicating device. If the **Doppler output** has one maximum value, the low-frequency response frequency and the high-frequency response frequency are found from those frequencies at which the output voltage is 0,707 times its maximum value, although other limits may be used if so declared. This same procedure should apply in the case of multiple-peaked response curves where the minimum values between the maxima are not less than 0,707 times the voltage at the greatest maximum.

If the response curve is multiple-peaked (as it generally will be when using loudspeaker output tests) then the smallest value found between the peaks should be taken as defining the minimum detectable signal level. A horizontal line on the graph at this signal level will then intersect 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.

2.3.2 Doppler frequency accuracy

The **Doppler shift frequency** (or any indication that is calibrated in units of frequency) is plotted as a function of the velocity of the moving member of the **Doppler test object**. The speed of the moving member should be varied from zero to a speed which produces the high-frequency response values found in the previous test (see **2.3.1**).

This test should be repeated at different locations between the minimum and maximum spatial ranges (see 2.4.1).

For each location, a plot of true frequency versus the indicated output **Doppler shift frequency** and a least squares fitted straight line through the origin are prepared. From the test results at different distances, the maximum deviation of the output **Doppler shift frequency** from the straight line fit should be reported as the frequency accuracy, and given as a percentage of the maximum output **Doppler shift frequency** found.

2.3.3 Large-signal performance

Large signals, particularly those at different frequencies, can cause errors in the indication of communication system receivers that are similar to ultrasound Doppler receivers. The tests in this section look for the magnitude of these effects for interfering signals that are about the maximum level that would be encountered in practice.

2.3.3.1 Distortion and linearity

The largest possible signal from moving blood should be simulated by using the disk **Doppler test object** (see **3.1.3**) at the standard working distance with no tissue equivalent absorbing material between the transducer and the disk. The axis of the sound beam should be placed at a distance corresponding to the working distance determined using the procedure given in **2.2.3**.

The output distortion is to be measured and reported as a percentage of the fundamental **Doppler frequency output**. This output measurement is to be made with a spectrum analyzer or with filters of known gain at the fundamental **Doppler frequency** and its low order harmonics.

Doppler frequency output is the r.m.s. value of the signal level at the fundamental frequency and distortion output is the sum of the r.m.s. values of the output signal at all other significant frequencies. The upper limit of frequency for this sum is any frequency above the third harmonic that contributes an r.m.s. level greater than 10 % of the sum of all lower frequencies, excluding the fundamental.

2.3.3.2 Fixed target effect on sensitivity

The effect of strong, fixed targets on the amplitude of the **Doppler output** can be determined by using the small vessel or string **Doppler test object** (see **3.1.1**) with tissue equivalent material in place and a transducer-to-string spacing corresponding to the working distance determined in accordance with **2.2.3**. The speed of the moving string should be adjusted to give a **Doppler-shift frequency** which is the geometric mean of the high- and low-frequency response frequencies measured according to **2.3.1**.

The change in the **Doppler output** from the output device being evaluated should be reported in terms of the decibel change observed when a highly reflecting target is placed to intersect the full region of lateral response (see 2.4.2) of the Doppler probe at the working distance. The reflecting target should be placed as close as practicable to the moving string and oriented to produce the maximum fixed target echo (generally at right angles to the axis of sensitivity of the probe). Note that the area of the target and actual axis position should be determined by the procedures given in clause 2.4. This test should be repeated if the target was too small. The angular position of the fixed, highly reflecting target should be varied about the position of perpendicularity to the axis of probe symmetry while observing the **Doppler output**. The maximum change in **Doppler output** encountered while systematically moving the fixed target should be reported for this section.

The high amplitude reflector should be a 3 cm thick piece of metal or metal-resin mixture, having a reflectivity not more than 3 dB below a perfect reflector. This reflectivity may be determined by calculation if the speed of sound and the density of the reflector material are known and are combined with those of water.

2.3.3.3 Intermodulation distortion

Intermodulation distortion is determined by measuring the spurious output with two moving targets, each target producing different **Doppler frequencies**. This spurious output will occur at frequencies equal to the sum and the difference of the different **Doppler frequencies**.

A **Doppler test object** is required with two moving members, either strings, bands, or flows. The speed of the member producing the "desired" output is to be held constant at a value that produces the nominal test frequency in the Doppler output. The second moving member should produce a signal level equal to that produced by a blood-vessel wall. That is, about 30 dB above the level produced by a blood equivalent disk **Doppler test object** at the working distance. The second member should operate at a speed that produces a **Doppler frequency** of 0,1 times the nominal test frequency. The total r.m.s. output level at the sum and difference frequencies should be reported as a percentage of the r.m.s. output at the "desired" Doppler frequency.

2.4 Spatial response

The relative sensitivity of the **Doppler ultrasound** system to scatterers at different points in space can be determined by these procedures. Only the amplitude of the **Doppler output** is used for these tests. A string Doppler test object is often suitable to test **systems** intended for use as peripheral vascular flowmeters. These **Doppler test objects** produce a narrow-band **Doppler output** which is easier to measure than the wideband **Doppler** output that results from using a flow Doppler test object. A string Doppler test object should be used which simulates the scattering strength from a vessel of specified size, and this size should be reported as part of the spatial response results. A similar specification for vessel size for a flow **Doppler test object** is usually necessary to account for losses in the wall of the tubing, or for the reflectivity of the fluid used.

The moving piston **Doppler test object** is suitable for testing those **systems** that may be used for foetal heart detection. For testing high resolution cardiac **systems**, a 1 mm diameter moving piston, or a ball target of similar size can be used.

Where this section refers to moving the transducer, it is to be understood that the relative positions of transducer and the moving member of the **Doppler test object** are to be changed.

2.4.1 Axial response

This test specifies the depth range in tissue over which a small signal is detectable.

Initially, the transducer is set at the working distance determined in accordance with 2.2.3 using the string **Doppler test object** and at the nominal **Doppler frequency** specified by the manufacturer, or 1,0 kHz if none is specified by the manufacturer. The axial response should to be determined by changing the spacing between the Doppler transducer and the moving string, maintaining the position of the attenuating tissue equivalent material fixed.

The axial response is determined by plotting the time average signal level of the **Doppler output** as a function of the spacing. The minimum and maximum ranges are specified as the ranges at which the **Doppler output** is 3 dB above the noise level as found in **2.2.4**, for the voltage output. The axial response range for any frequency-to-voltage converter should be determined for the number of decibels above the noise level specified by the manufacturer as necessary for the specified accuracy.

2.4.2 Lateral response

This test specifies the lateral distance in tissue over which scatterers giving rise to a given signal can be localised. It is also a test of the ability to separate signals from two adjacent vessels. The test should be made by moving the transducer perpendicular to the axis of maximum sensitivity in those directions in which the lateral response function is expected to be wide, and also in the directions where it should be narrow. If a point-by-point plot of lateral sensitivity is made using a small ball target both the lateral response distances and the area of response can be stated.

The lateral response is measured by returning the probe and the moving portion of the **Doppler test object** to those initially used in the test specified in **2.4.1**. Starting at the working distance, the transducer is moved in a direction perpendicular to the transducer sensitivity axis and a plot of the **Doppler output** is made as a function of this displacement. The lateral resolution or beam width is the distance between the points at which the lateral response function is greater than the -3 dB level. If subsidiary peaks are found whose amplitude is less than 3 dB below the primary peak, then the total range which encompasses all such peaks is the lateral response.

2.5 Operating frequency

Operating frequency or the range over which the **operating frequency** is adjustable, may be determined either acoustically or electrically.

NOTE For continuous-wave **Doppler ultrasound systems**, the frequency of the ultrasonic wave generated by the transducer and measured at or near the face of the transducer using a hydrophone is usually identical to the frequency of the electrical excitation of the transducer.

2.5.1 Acoustical measurement

The ultrasound **operating frequency** may be measured in a tank by the use of a wideband hydrophone (see IEC 1102) connected to an amplifier and radio-frequency spectrum analyzer, or frequency counter.

2.5.2 Electrical measurement

The electrical **operating frequency** may be measured by winding turns of wire around the Doppler probe, amplifying the received signal from the coil, and reading the frequency on a spectrum analyzer or counter as in **2.5.1**.

2.6 Flow direction separation

The tests in this section apply only to direction-sensing or direction-resolving systems. These systems are to be tested under the procedures of the previous clauses using the equivalent single-channel tests on the two separate flow direction outputs. A complete test requires specification of both outputs: "forward" and "reverse" outputs (see Figure A.2). The least-favourable case values, as specified in Table 1, should be reported as a single set.

Separation tests are to be done at the working distance measured according to **2.2.3**, with the transducer mounted on an appropriate **Doppler test object** with the tissue equivalent absorber and stray reflection absorbers in place. For these tests the direction of motion of the moving part may be reversed by any means that leaves the relative positions of the parts unchanged.

Tests made using the **Doppler test objects** that contain tissue equivalent attenuating material, as described here, are intended to be representative of the results found during normal operation. Very different results may be found for signals that overload the **system**, such as may be encountered when attenuating material is not used. Such tests can be conducted and reported if the signal level to which the test pertains is also given.

2.6.1 Channel separation

The separation value is obtained by measuring the voltage from the channel corresponding to the string direction, as well as from the opposite channel. For example, if the string is moving away from the transducer, then the voltage at the "away" output terminal is to be measured and regarded as the desired voltage; that at the "toward" output terminal representing errors within the **system** is the undesired output voltage. Separation is to be quoted in decibels as twenty times the logarithm of the ratio of the desired output to the undesired output voltage. Separation is measured for each direction of string motion throughout the range of string speeds which correspond to the frequencies between the low-frequency response and the high-frequency response found in 2.3.1. The minimum value of the separation ratio for either channel at any frequency should be reported as the separation.

Since the output amplitude presently cannot be measured accurately for spectrum display outputs, a hard copy print of the display corresponding to the minimum value of the separation ratio should be made. It will show both desired and undesired responses. The latter is often referred to as the "ghost" or "mirror" image.

2.6.2 Simultaneous flow

The output indication of **direction sensing systems** that are not **direction resolving** should be zero if measuring equal flows in opposite directions. This is a test of the symmetry of the **Doppler output** response about zero frequency. For these **systems**, the accuracy test of **2.3.2** is not sufficient to indicate the response to simultaneous flows in two directions because of the possible effect of the phase errors in cross-connecting the channels.

The **Doppler frequency output** indication of **direction resolving systems**, when observing a flow in one direction, should not be influenced when flow in the other direction occurs. This test method should also be sensitive to this effect.

A **Doppler test object** is required that has the two moving members travelling in different directions but close together. They must both be within the sensitive region of the transducer field, at least to give equal amplitude **Doppler outputs** when operated separately. Otherwise, the balance would depend on critical details of positioning.

The **Doppler frequency** output indication of the **directional sensing systems** should be zero. The actual value, expressed as a percentage down from the output obtained when only one of the moving members is stopped, is the unbalance. The maximum value found for the speeds of the moving member of the **Doppler test object** that produce **Doppler frequencies** within the range found using the procedure given in **2.3.1** should be recorded.

A **Doppler frequency output** for **direction resolving systems** is observed first with only the appropriate member moving, and then with both members moving at the same speed. The change in indicated **Doppler frequency** should be reported as a percentage of the indication with one member moving. The maximum percentage value found for moving member speeds that produce frequencies within the range found in **2.3.1** should be recorded.

2.7 Response to Doppler spectrum

Derived outputs which obtain information from the **Doppler spectrum** resulting from different velocities of blood flow within a given blood-vessel are to be tested using the flow **Doppler test object** (or volume-flow generator) described in **3.1.6**. This **Doppler test object** provides a flow stream inside a tube which is to be mounted as is the string or band in the **Doppler test objects** described in **3.1.1** and **3.1.2**. The tests are to be made at the working distance.

2.7.1 Volume-flow circuits

Systems intended for relative and absolute volume-flow measurements should be tested by using as a standard the volume-flow determined by "stopwatch and bucket" collection or from a flowmeter so calibrated. The test will use the flow **Doppler test object** described in **3.1.6**.

The range of blood-vessel inner diameters for which the **system** is designed should be stated and tests made with test sections of tubing in the water tank which cover this same range.

The tests should cover the range of angles between the **system** sensitivity axis and the centre line of the vessel from 30° to 60°, and a range of **Doppler frequencies** covering the range found in the tests specified in **2.3.1**. Results may be reported as the maximum deviation between the measured output and a straight line fitted to the data by the least squares method.

2.7.2 Maximum-frequency followers

Circuits which derive the maximum frequency of the **Doppler spectrum** should be tested using the flow **Doppler test object** and a liquid with viscosity equal to that of blood. The maximum **Doppler frequency** indication produced by the **system** under test is to be compared with the maximum **Doppler frequency** which would be generated theoretically from a parabolic flow profile. In parabolic flow, the peak-flow velocity is equal to twice the average flow velocity observed in the **Doppler test object**. Average-flow velocity is obtained by dividing the volume-flow rate by the area of the test tubing. Theoretical maximum **Doppler frequency** is derived from the formula:

maximum **Doppler frequency** = $(4v/\lambda) \cos \Phi$

where

- λ is the wavelength of the ultrasound in the fluid material within the tubing;
- $\boldsymbol{\Phi}$ is the angle between the sound beam and the tubing section;
- υ is the average speed of the fluid.

Section 3. Special doppler test objects

3.1 Doppler test objects

The special **Doppler test objects** described in **3.1.1** to **3.1.6** are specified in terms of some of their performance characteristics at present, with tentative constructions suggested. It is expected that future standards will specify the construction of these devices in more detail.

3.1.1 String Doppler test object

The string **Doppler test object**, shown in Figure 1, has a moving cylindrical member whose small surface roughness acts as the source of moving "scatterers". Such a Doppler target generates a single **Doppler frequency** rather than the spectral characteristic of a flowing liquid or vibrating ball, and also is a small and practical target for reproducibly simulating very small blood-vessels. See [1]¹⁾.

This type of **Doppler test object** may consist of a string passing over three or four pulleys driven by a motor, preferably reversing, with an attached tachometer. String velocity is calculated from the known motor speed and pulley diameter, or equivalent means.

The string is mounted in the sound beam according to the arrangement shown in the lower half of Figure 1.

 $^{^{1)}\,\}mathrm{The}$ figures in square brackets refer to the bibliography in Annex C.

The sketch at the bottom of Figure 1 is of the plane defined by the active part of the moving string and by the axis of the sound beam. The transducer is moved along the diagonal member of a block of tissue equivalent **Doppler test object** material. This material should have an attenuation coefficient equivalent to the average attenuation coefficient for human soft tissue, 0,5 to 1 dB cm⁻¹ MHz⁻¹. The attenuation should be checked at intervals recommended by the manufacturer using the following procedure:

Set up a test tank filled with water such that the block of material to be tested can be inserted between ultrasonic transmitting and receiving transducers acoustically coupled through the water. The receiving transducer may be a hydrophone. The output of the receiving transducer is connected to a signal measurement system such as an oscilloscope. The transmitting transducer is driven by repetitive tone bursts at the frequency of interest.

Add the block under test and note the change in level of the electrical signal output of the receiving transducer. This change (in dB) is the attenuation of the block. Linear operation of the measurement system is assumed. This may be verified by inserting an additional identical block and checking that the change in output is within 0,3 dB of that above.

The insertion loss or attenuation, B_a in dB, of the block of tissue equivalent material is determined from the output signal level change as given by:

$$B_{\rm a} = 20 \log_{10} \left[\frac{V_{\rm out}(0)}{V_{\rm out}(1)} \right]$$

where

 $V_{\rm out}(0)$ is the output signal level without the block;

 $V_{\mathrm{out}}(1)$ is the output signal level with the block.

The sound beam, after passing through the material and striking the string, should be strongly absorbed to prevent echoes from the walls. Provision should also be made for removing the tissue equivalent material and for substituting a strong reflector for performing the fixed-target rejection test specified in 2.3.3.2.

The space or distance between the string and the tissue equivalent material may be enlarged by use of a second block of tissue equivalent material as shown in the lower half of Figure 1. The second material, if it occupies half the space between the wedge and the string, should have an attenuation coefficient equal to twice that of the first material. A spacing of 1 cm with a 0,5 cm thick block of the second material is suggested. In this case, the range can be calculated from the equation given in Figure 1, where the quantities are defined in the figure. A value of angle Φ equal to 30° or less, is recommended as giving an adequate Doppler-shift **frequency** without selectively attenuating one edge of the sound beam relative to the other, and also allowing adequate space for the fixed-target reflector.

A problem with string **Doppler test objects** is vibration of the string, probably in the plane of the pulleys. Vibration can introduce lower harmonics and spectral spreading, thereby degrading its quality as a single frequency **Doppler test object**. This problem might be cured by providing more than one guide pulley, isolating motor vibrations, increasing the viscosity of the tank liquid, or changing the free-running length of the string. The material for the string is still open for investigation. Suggested materials include surgical silk, packing cord, monofilament nylon or other fishing line, silastic tubing, small-diameter rubber drive belts for portable tape recorders, or large "O" rings. A principal problem is obtaining a string without a knot that produces a large transient signal. A very long string can be used with data taken while the knot is out of the sound beam.

To use a string **Doppler test object** to simulate small blood vessels, the scattering strength should be chosen to be the same as a small blood vessel. The size of blood vessel chosen should be stated on the label of the **Doppler test object**.

3.1.2 Band Doppler test object

This **Doppler test object** is identical to the moving string **Doppler test object** except that a band of finite width is used instead of a string. It is designed to produce a single **Doppler-shift frequency**, but from a scattering surface which is as wide as the widest commonly encountered arteries or veins. A width of 1,5 cm is suggested. The general arrangement of the band **Doppler test object** in a three pulley drive situation is the same as the string **Doppler test object** as shown in Figure 1. The requirements for the transducer mounting and adjustments are the same as given for the string **Doppler test object**. The amplitude of band vibrations, however, should be very much less than that for the string.

3.1.3 Disk Doppler test object

A **Doppler test object** consisting of an appropriate blood-equivalent scattering material is shown in Figure 2. The purpose of the disk **Doppler test** object is to simulate a vessel which is wider than the transmitter sound beam and thus to produce the maximum strength of Doppler-shifted backscattering. The material for the disk should have the same reflection strength in the 1 MHz to 10 MHz region as does a 3 cm thick slab of whole human blood. The transducer could be positioned relative to this **Doppler test object** as shown in Figure 2, with the same mounting considerations as outlined in 3.1.1 for the string Doppler test object. The entire incident sound beam should intersect the disk and not extend beyond the disk edge. To maintain a narrow spectrum, the total width of the sound beam should be less than about 10 % of the radial distance measured between the axis of rotation of the disk and the centre of the sound beam.

3.1.4 Piston Doppler test object

The piston **Doppler test object** is designed to duplicate the back-and-forth motions of surfaces such as those of blood-vessels or of the pulsating heart, and is shown schematically in Figure 2 [2]. The reflection strength and range of motion of the piston material should be chosen to approximate that of the structure of interest. The displacement of the piston of the **Doppler test object** is calculated from the dimensions of the driving system or by direct measurement of displacement. The pulsations can be at the rate of 1 s⁻¹ to 2 s⁻¹ and need not be accurately sinusoidal.

3.1.5 Small ball test object

Another type of **Doppler test object** which utilises an oscillating target is the small ball **Doppler test object**. This consists of a strongly reflecting small ball with a diameter of typically 1 mm which is made to vibrate with small amplitude (1 µm) by a loudspeaker. The echo-signals returned by the vibrating sphere will be modulated in phase with respect to the reference signal of the **Doppler** ultrasound system. This phase modulation will be detected as a **Doppler frequency** which equals the frequency of the loudspeaker. The detected Doppler output will be at a maximum when the signal received from the sphere is 90° out of phase with respect to the internal reference signal of the Doppler ultrasound system. By moving the sphere in such a way that the condition of 90° out of phase is met a number of times, the sensitive volume of the **Doppler ultrasound system** can be deduced from the envelope of these maxima (see [3]).

As a consequence of the complex nature of the scatter from small sphere targets, 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 (comparable to or less than 1 mm) beam widths until its performance limits have been evaluated.

3.1.6 Flow Doppler test object

The flow **Doppler test object** is designed to produce a spectrum of **Doppler frequencies** as produced by blood in a natural blood-vessel. Since the flow profile in vessels within the body is not parabolic and varies throughout the cardiac cycle, it is very difficult to simulate in a **Doppler test object**. The usual compromise is to aim to achieve a parabolic profile since it is reproducible.

The part of the flow **Doppler test object** which is used for the tests should be mounted in the water tank in the same relative position with respect to the transducer as for the other Doppler test objects. The Doppler test object, shown in Figure 3, includes a pump, reservoir and settling tank providing a gravity head for the flow system. Particulate matter and air bubbles are removed by a filter, if necessary, and flow is conducted through a straight, non-expanding flow section through the test tubing in the water bath. This section should be long enough to establish a parabolic flow profile with the recommended fluid. The fluid may be collected in a sump for recirculation by a pump. The outlet should be provided with a switchable stopcock leading to a graduated vessel. Volume-flow calibration is accomplished by collecting and measuring the volume of fluid passed by the system over a timed interval. If practicable, an electromagnetic flow probe or other flowmeter may be attached to the system to provide dynamic flow indications for later addition of pulsatile flow generators, or for more convenient use.

The pump and tubing should be carefully chosen to avoid cavitation of the liquid. Such bubble generation can occur with too high a pump speed or from the presence of any tubing section which has an increasing cross-sectional area in the direction of flow. Flow disturbances from tubing connectors should also be minimised.

3.1.6.1 Fluid

The blood-simulating fluid should consist of water or a material of approximately the acoustic impedance of blood containing particulate scatterers, the whole having the scattering strength of whole human blood. Suggested scatterers are polystyrene beads, paraffin (mineral) oil emulsion, Sephadex beads in water, or starch particles. Glycerine is added to reach the viscosity of blood. The fluid may be degassed as specified in **3.1.7**.

3.1.6.2 Test tubing

The tubing should have a known and uniform inside diameter. The walls should introduce minimal beam attenuation, and beam distortion as a result of attenuation, refraction and critical angle reflections. These effects lead to a loss of low-frequency components in the **Doppler spectrum**.

A suggested wall material is dialysis (cellophane) or similar tubing in sufficiently small diameters. A sound speed in the wall less than that in the fluid, or a construction with the fluid passing through a hole in a block of tissue equivalent material minimises or avoids refraction of the sound beam which otherwise causes loss of low frequencies in the **Doppler spectrum**.

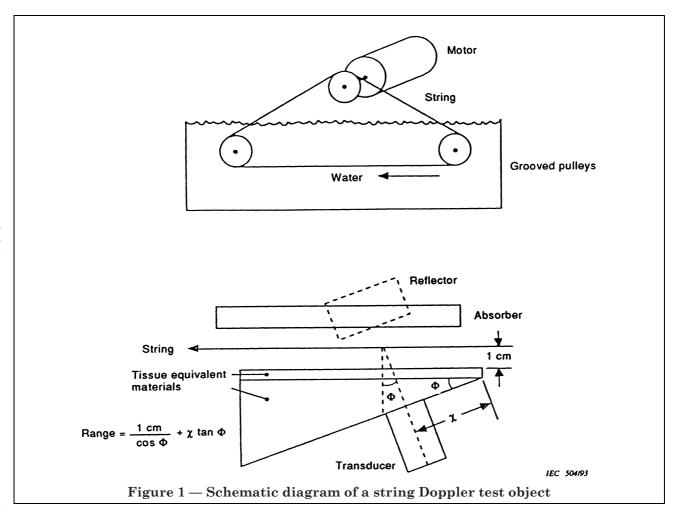
Any wall material should be tested by observing the **Doppler output** on a spectrum analyzer. The level should be constant at frequencies above the lower cut-off frequency in the **Doppler ultrasound system** used when the fluid can be guaranteed to have laminar flow and the sound beam fills the tubing.

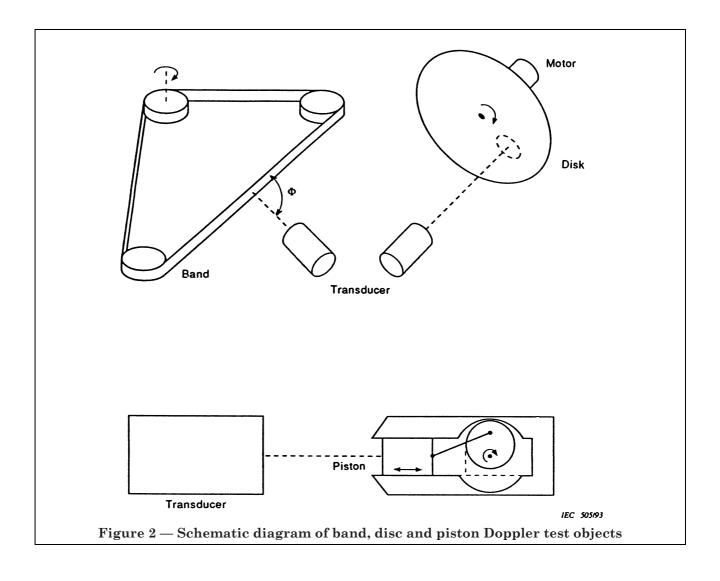
3.1.7 Water tank (or gel block)

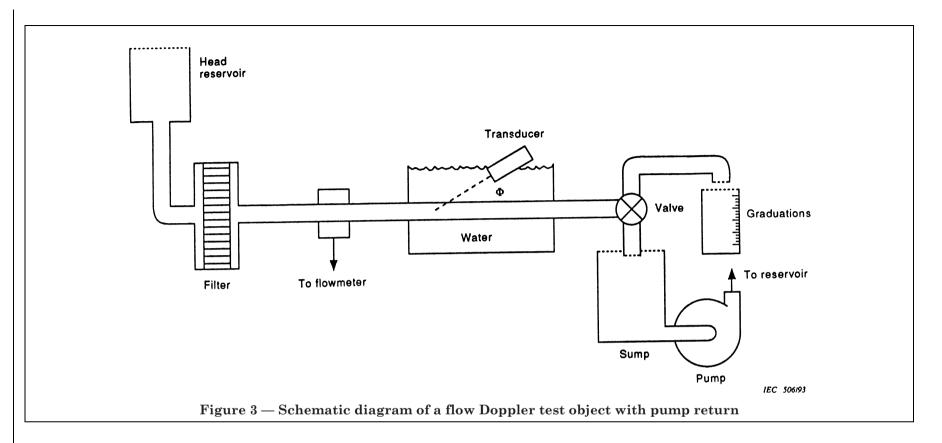
Tests using the **Doppler test objects** described in 3.1.1 to 3.1.6 should be conducted with the transducer surfaces and **Doppler test objects** in a water tank maintained at the temperature specified for the **Doppler test object**. This section will also apply to **Doppler test objects** in which the water is replaced by a block of tissue equivalent gel, with holes in place of tubing. The tank should be lined with sufficient acoustic absorbing material so that the tests are independent of position of the transducer and **Doppler test object** in the central region of the tank. A simple test for the presence of stray tank wall or surface reflections, or bubbles, is to move the sound beam the minimum amount necessary to just eliminate the **Doppler output** caused by the **Doppler test object**, while observing them on a spectrum analyzer output device. The motor drive, pumps or vibrator are to be kept running. The remainder of the **Doppler output** will be caused by motion induced by these driving devices, and will exceed the noise level determined in accordance with 2.2.4 if reflections exist. An additional test is to move the water surface or tank liner by one half-wavelength or more and observe the total output indication to see if it experiences a significant change. This test can be applied to test **Doppler test objects** embedded in a block of gel if the surfaces are exposed.

Solid block **Doppler test objects** are best explored for internal reflections with a pulse-echo diagnostic system. These reflections must be weaker than the reflection from the simulated blood-vessel for testing continuous-wave flowmeters.

Water can be degassed by raising its temperature to boiling, followed by cooling to room temperature, or by applying a vacuum while shaking the fluid. Subsequent transfer to the test tank should be made without entraining or trapping air bubbles. The procedure should be repeated weekly or when the system noise level increases.







Annex A (informative) Description of continuous-wave Doppler ultrasound systems

A.1 Single-channel system

Figure A.1 shows the arrangement of components of a single-channel **Doppler ultrasound system**. If the reference voltage for the detector (shown at the top of Figure A.1) is obtained from the transmitter, the **system** is **non-directional**. If the offset oscillator is used, then the **system** will be **directional**. In this case, the **Doppler frequency output** will have a strong component at the frequency corresponding to the difference between those of the transmitter and offset oscillator for stationary scatterer signals, and a notch filter must be used to remove this component. The **Doppler frequency output** will have a frequency differing from that of the offset oscillator only for moving scatterers. The direction of this frequency difference will depend on the direction of scatterer motion and on the offset oscillator frequency.

Several **output devices** are illustrated in Figure A.1. An audio amplifier and internal, and possibly external, speaker are used in almost all systems. Audio outputs may also be provided for headphones or as magnetic drivers of tubing which conduct the sound to the ear of the listener; for example, conventional medical stethoscopes.

A **Doppler output connector** (Figure A.1) may be provided for external connection of optional or additional signal-processing or recording circuits. The **Doppler output** will generally consist of a spectrum, that is many **Doppler frequencies** produced by scatterers moving at different speeds.

Doppler ultrasound systems used for detection of foetal heart motion and other low-velocity scatterers, which lead to Doppler shifts which are less than the frequencies of normal human hearing, may use a frequency-to-voltage converter and modulated oscillator combination to deliver to the ear an output within the frequency range of good human hearing. The previously described audio outputs are sometimes available in this type of **system**.

The frequency-to-voltage converter (Figure A.1) is used to derive a voltage proportional to relative flow velocity; this voltage can be recorded on a strip-chart recorder for reproducing the flow velocity waveform of the bloodstream.

The actual frequencies present in the spectrum of the **Doppler output** can also be presented or recorded as a function of time through use of a spectrum analyzer and fast recorder. There are many types of such analyzers, including time-interval histogram, "chirp" Z transform, digital Fourier transform, fast Fourier transform, time compression and parallel filter.

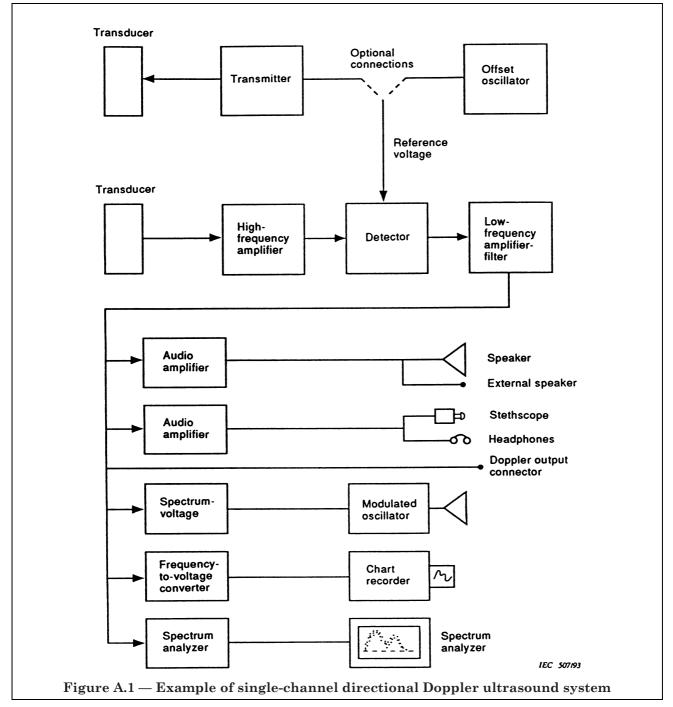
A.2 Two-channel system

Figure A.2, at the top, shows the block diagram of a two-channel Doppler receiver which achieves directional detection through the use of phasing, or single sideband, techniques. In this **system**, the returned Doppler-shifted ultrasound signal is detected in two channels whose detectors are driven by the transmitter frequency processed through a phase-shift network whose outputs are 90° apart. The two channels of difference-frequency information can be referred to as the "A" and "B" **output channels**, or alternatively, the quadrature channels. Either one of these output lines can be connected to the separate single-channel **output devices** shown in Figure A.1. Such connection is frequently done to provide a listening channel.

Many **output devices** used with **directional Doppler ultrasound systems** require as inputs both quadrature signals shown at the top of Figure A.2. This includes most of the frequency-to-voltage conversion devices such as, for example, mean frequency circuits or maximum frequency followers. The output of these circuits is a low-frequency waveform voltage for a strip chart recorder. The polarity of this voltage waveform indicates the direction of flow. Directional spectrum analyzers, such as those using the fast Fourier transform technique, for example, are also connected at the A and B outputs, Figure A.2, since these analyzers require quadrature inputs.

Figure A.2 also shows how wideband phase shifters are used to produce directional spectrum outputs. The outputs of these circuits differ in phase by 90° from each other, if the input phase difference is zero. The spectrum of **Doppler frequency outputs** from scatterers approaching the transducer are present only in the "forward" output and those from scatterers proceeding in the opposite direction only in the "reverse" output. Each separate **directional Doppler frequency output** may be connected to an individual single channel **output device** as shown in Figure A.1.

A **non-directional** spectrum analyzer can do directional analysis by using a low frequency offset oscillator as shown at the bottom right of Figure A.2. With this circuit the zero scatterer-velocity frequency, which is the baseline of the display, is offset to the frequency of the low-frequency oscillator. Higher frequencies, which correspond to approaching scatterers, thus will appear above the new baseline, and lower frequencies will appear below to represent receding scatterers.



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Annex B (informative) Rationale

The tests described in this technical report are intended to determine important performance characteristics of **Doppler ultrasound systems**.

This technical report describes three categories of tests:

- tests appropriate to routine quality control carried out by a clinician or a technologist to ensure that the **system** is working adequately or has adequate sensitivity. Reports on these tests would present results in a form which would be significant to the ultimate medical user. For example, the distances to a specified blood-vessel over which adequate sensitivity is obtained would be expressed as centimetres of average tissue.
- tests of a more complex and elaborate nature. These tests would be conducted less frequently, such as when the **system** is suspected of not working properly. Results would be reported in a form which can be compared to the manufacturers' specifications.
- tests undertaken by a manufacturer on complete **systems** as the basis of type tests. Also, on a sampling inspection basis, undertaken to determine whether a given production run meets specifications.

The reasons for performing these tests specified in this technical report are stated briefly below.

Initially, the **system** being tested is set up in such a way as to ensure that it is operating and that the most sensitive region or regions have been located. These initial conditions are discussed in **2.2.2** and **2.2.3**. Power-supply voltage ranges that can be expected in use are outlined in **2.2.1**. A reference noise-level measurement for use in several of the other tests is outlined in **2.2.4**.

The frequency response tests specified in clause **2.3** and **2.3.1** determine the detectability of high velocity flow (through stenosis, for example) and of low-velocity flow (as in near-complete occlusion and in veins). The accuracy of the frequency indicated by **output devices** is tested as described in **2.3.2**. Since large signals are known to cause problems in communication receivers similar to these Doppler receivers, several large-signal tests are suggested in **2.3.3** that could be of interest to **system** developers.

The spatial response tests given in clause **2.4**, **2.4.1** and **2.4.2** test the ability of the device to detect structures that are close to the transducer, such as subcutaneous veins and arteries, and also more distant structures such as deep vessels in large patients. The use of separate transmitting and receiving transducers in continuous-wave **systems** usually sets definite limits to both these ranges, as do transducers focusing in pulsed **systems**.

The limits to spatial response revealed by these tests could be useful in acceptance testing of transducer probes, but the criteria depend upon the application. Generally, the region of spatial response should be large. In special applications, however, it may be desirable to limit the spatial regions from which signals are wanted, to exclude interfering signals. Tests given in **2.4.2** determine the width of the sensitive area. Narrow areas aid in separating flow from adjacent vessels, but make probe positioning more critical and searching for a vessel more time-consuming. In some applications, such as foetal monitoring, a very wide sensitive area is needed.

Clause **2.5** gives alternative ways of determining the **operating frequency**, primarily to be sure it is within specification for the attached probes.

Direction resolving systems require tests on two outputs as described in clause **2.6**. The basic tests are the same as those listed above and in clauses **2.1** to **2.5**, except that they are made on each output separately. These directional systems also require tests on the adequacy of their flow **direction resolving** or **separating** circuits in situations where the previous tests do not suffice. Errors can result from lack of phase accuracy in the oscillators or signal handling circuits shown in Figure A.2. These additional tests are discussed in **2.6.1** for spectrum analysis or display **output devices** when these are part of the system. Frequency-to-voltage converter circuits, Figure A.2, require testing with simultaneous flows in opposite directions (see **2.6.2**). This situation is common since arteries and veins are often side by side. Local turbulence may cause simultaneous bidirectional Doppler signals even in cases of no net flow.

The distribution of scatterer velocities in blood vessels leads to the generation of a group of frequencies, the **Doppler spectrum**. Accurate processing of the spectrum is important in determining volume flow and in some spectrum parameter measurements. Tests for accuracy are described in **2.7.1** and **2.7.2**. The measurement of maximum frequency is considered alone by **2.7.2**, but other spectral amplitude and frequency width measures could also be determined by similar means.

Section 3 outlines the construction and application of several types of **Doppler test objects** which may be needed. Some of these are expected to be more suitable for some tests than others. These **Doppler test objects** are intended to be the subject of separate standards that would specify their construction or performance in detail.

Annex C (informative) Bibliography

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- [2] Reuter R., Trier H. G., Lepper R. D., Ansprechempfindlichkeit und Schallfeldgeometrie von Ultraschall-Doppler-Geräten, Ultraschalldiagnostik in der Medizin, Drei-Länder-Treffen Davos (1979).
- [3] Hoeks A. P. G., Ruissen C. J., Hick P., Reneman R. S., *Methods to evaluate the sample volume of pulsed Doppler systems*, Ultrasound in Med. and Biol. 10, 427–435 (1984).

Annex ZA (normative)

Other international publications quoted in this standard with the references of the relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

NOTE When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC Publication	Date	Title	EN/HD	Date
1102	1991	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	EN 61102	1993

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List of references

See national foreword.

BS EN 61206:1995 IEC 1206:1993

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