

Ultrasonics — Continuous-wave Doppler systems — Test procedures

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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 (IEC 1102:1991)	BS EN 61102:1994 <i>Specification for measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0.5 MHz to 15 MHz</i>

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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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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)

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

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Foreword

The text of the International Standard IEC 1206:1995, prepared by IEC TC 87, Ultrasonics, was submitted to the formal vote and was approved by CENELEC as EN 61206 on 1994-12-06 without any modification.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1995-12-15
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1995-12-15

Annexes designated “normative” are part of the body of the standard. Annexes designated “informative” are given for information only. In this standard, Annex ZA is normative and Annex A, Annex B and Annex C are informative. Annex ZA has been added by CENELEC.

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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 flow **Doppler 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).

Table 1 — Worst case quantities, and corresponding subclause numbers

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

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**.