

### SLOVENSKI STANDARD SIST EN 61685:2002

01-september-2002

Ultrasonics - Flow measurement systems - Flow test object (IEC 61685:2001)

Ultrasonics - Flow measurement systems - Flow test object

Ultraschall - Durchflussmesssysteme - Durchfluss-Doppler-Prüfobjekt

Ultrasons - Systèmes de mesure de débit - Montage pour essai de débit

Ta slovenski standard je istoveten z: EN 61685:2001

SIST EN 61685:2002

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**EUROPEAN STANDARD** 

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**EUROPÄISCHE NORM** 

October 2001

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**English version** 

### Ultrasonics -Flow measurement systems -Flow test object

(IEC 61685:2001)

Ultrasons -Systèmes de mesure de débit -Montage pour essai de débit (CEI 61685:2001) Ultraschall -Durchflussmesssysteme -Durchfluss-Doppler-Prüfobjekt (IEC 61685:2001)

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This European Standard was approved by CENELEC on 2001-09-01. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

### **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

EN 61685:2001

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#### **Foreword**

The text of document 87/202/FDIS, future edition 1 of IEC 61685, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61685 on 2001-09-01.

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) 2002-06-01

 latest date by which the national standards conflicting with the EN have to be withdrawn

(dow) 2004-09-01

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annexes B and ZA are normative and annexes A, C, D, E and F are informative.

Annex ZA has been added by CENELEC.

### iTeh STEndorsement notice VIEW

The text of the International Standard IEC 61685:2001 was approved by CENELEC as a European Standard without any modification.

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## Annex ZA (normative)

## Normative references to international publications with their corresponding 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 (including amendments).

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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	EN/HD	<u>Year</u>
IEC 61102	1991	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	EN 61102	1993
IEC 61206	1993	Ultrasonics - Continuous-wave Doppler systems - Test procedures	EN 61206	1995
IEC 61895	1999	Ultrasonics - Pulsed Doppler diagnostic systems - Test procedures to determine performance	L_W	-

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# INTERNATIONAL STANDARD

IEC 61685

First edition 2001-07

Ultrasonics – Flow measurement systems – Flow test object

Systèmes de mesure de débit – Montage pour essai de débit ai

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#### INTERNATIONAL ELECTROTECHNICAL COMMISSION

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## ULTRASONICS – FLOW MEASUREMENT SYSTEMS – FLOW TEST OBJECT

#### **FOREWORD**

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
- 6) Attention is drawn to the possibility that some of the elements of this international Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61685 has been prepared by IEC Technical Committee 87: Ultrasonics.

The text of this standard is based on the following documents:

FDIS	Report on voting
87/202/FDIS	87/208/RVD

Full information on the voting for the approval of this standard 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.

Annexes A, C, D, E and F are for information only.

Annex B forms an integral part of this standard.

The committee has decided that the contents of this publication will remain unchanged until 2006. At this date, the publication will be

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

#### INTRODUCTION

The purpose of this International Standard is to establish a **flow Doppler test object** for the acceptance testing, quality assurance testing and clinical calibration of Doppler systems, working at a frequency between 2 MHz and 10 MHz. As the response of Doppler systems depends on the signal level and on the spectral contents of the signal, it is desirable to test some aspects of a Doppler system with a test object that mimics the *in vivo* situation. A **flow Doppler test object** is particularly useful for

- testing the influence of the size and the depth of the blood vessel on the signal recorded by a Doppler system;
- testing the response of a Doppler system with a spectrum of blood velocities typical of the in vivo situation.

This **flow test object** is not intended as a phantom mimicking clinical conditions.

The basis of this International Standard is given by IEC Technical Report 61206:1993 *Ultrasonics – Continuous Wave Doppler systems – Test procedures*. In annex A the position of this standard in relation to IEC 61206 and IEC 61895 is described. This standard only declares parameters that can be measured with the test object. Measurement methods are given in IEC 61206 and IEC 61895.

This International Standard deals only with the **flow Doppler test object** in a restricted sense, i.e. the section in which the ultrasonic measurements are performed. Where the whole of the set-up is meant, the phrase 'flow rig' is used. The prescriptions of this International Standard define the ultrasonic properties and the flow pattern in the measurement section of the flow test object. For other aspects of the flow rig (i.e. generating and measuring flows) standard engineering practice has to be followed.

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The flow conditions are simplified as much as possible? a steady-flow-through a straight tube with a circular cross-section. Generalisation of the flow conditions to other geometries and time dependent flows is required in order to test some instrument functions. This generalisation is not undertaken in this International Standard.

In annex D, an example **flow Doppler test object** is described which complies with the requirements of this International Standard. Compliance with this International Standard can also be fulfilled by measuring the properties of the materials to be used, and complying with the values given in this International Standard.

In literature [1], [2] the nomenclature about the primary measurand of Doppler systems is confused. 'Doppler frequency' and 'velocity' occur on equal footing. In 'velocity' often a correction for **Doppler angle** has been included. To avoid this ambiguity, in this International Standard the term 'Doppler frequency' is preferred. In case a Doppler system is declared to measure velocity, it is intended that measured values are converted to Doppler frequency, using **acoustic working frequency** and, if applicable, **Doppler angle**.

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## ULTRASONICS – FLOW MEASUREMENT SYSTEMS – FLOW TEST OBJECT

#### 1 Scope

This International Standard specifies parameters for a **flow Doppler test object** representing a blood vessel of known diameter at a certain depth in human tissue, carrying a steady flow.

This International Standard establishes a **flow Doppler test object** which can be used to assess various aspects of the performance of Doppler diagnostic equipment.

#### 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 61206:1993, Ultrasonics - Continuous wave Doppler systems - Test procedures

IEC 61102:1991, Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0.5/MHz to 15 MHz log/standards/sist/7d333d5f-50e5-4e96-9f94-55699cb4401e/sist-en-61685-2002

IEC 61895:1999, Ultrasonics – Pulsed Doppler diagnostic systems – Test procedures to determine performance

#### 3 Definitions

For the purposes of this International Standard, the following definitions apply:

#### 3.1

#### -3 dB Doppler frequency

frequency at which the power per unit frequency in the Doppler spectrum is half (-3 dB) of the maximum value

#### 3.2

#### -3 dB sample volume

volume of a region in space for which the Doppler system gives a response to a point Doppler target that is above -3 dB from the maximal response, taking account of the effects of both transmission and reception

Unit: cubic millimetre, mm<sup>3</sup>

#### 3.3

#### -3 dB sample volume length

largest dimension of the -3 dB sample volume in the direction of the beam alignment axis (see 3.5 of IEC 61102)

Unit: millimetre, mm

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#### 3.4

#### -3 dB sample volume width

largest value of the dimension of the **-3 dB sample volume** along an axis which is perpendicular to the beam alignment axis. In case the Doppler system has a scan plane, the axes are taken in the scan plane and perpendicular to the scan plane

Unit: millimetre, mm

#### 3.5

#### acoustic-working frequency

frequency of an acoustic signal based on the output observed by a hydrophone placed in an acoustic field: it is the arithmetic mean of the two frequencies at which the amplitude of the acoustic pressure spectrum is 3 dB below the peak amplitude

[conforms to 3.4.2 of IEC 61102]

Unit: hertz, Hz

#### 3.6

#### aliasing

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

NOTE The threshold for aliasing depends on pulse repetition frequency and a possible base line shift.

#### 3.7

#### average frequency of the Doppler spectrum

parameter estimated by clinical Doppler systems for the short-time average in a Doppler spectrum, ignoring the contributions from noise

NOTE The average frequency of the Doppler spectrum is generally determined for a small time interval, typically 2 ms to 20 ms).

Unit: hertz, Hz

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#### axial response range

depth range in tissue over which a signal from a specific target plus noise is at least 3 dB above the noise level

[see 2.4.1 of IEC 61206]

Unit: millimetre, mm

#### 3.9

#### blood-mimicking fluid (BMF)

fluid which simulates blood acoustically and is moved at a known flow rate through the **flow Doppler test object** 

#### 3.10

#### channel separation

ratio of the signal level in the signal channel corresponding to the movement in the test object (the desired output voltage) and the signal level in the opposite channel (the undesired output voltage)

NOTE **Channel separation** is to be quoted in decibels as twenty times the logarithm of the desired output to the undesired output voltage.

[see 2.6.1 of IEC 61206]

Unit: decibel, dB