SLOVENSKI STANDARD

SIST EN 61689:2002

prva izdaja
september 2002

Ultrasonics - Physioterapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz

ICS 11.040.60; 17.140.50

Referenčna številka
SIST EN 61689:2002(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61689

November 1996

ICS 11.040.60

Supersedes HD 87 S1:1977

Descriptors: Ultrasound, physiotherapy systems, performance, measurements

English version

Ultrasonics - Physiotherapy systems Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz (IEC 1689:1996)

Ultrasons - Systèmes de physiothérapie
Prescriptions de performance et méthodes de mesure dans la gamme de fréquences de 0,5 MHz à 5 MHz
(CEI 1689:1996)

Ultraschall - Physiotherapiesysteme
Anforderungen an das Betriebsverhalten und Meßverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz
(IEC 1689:1996)

This European Standard was approved by CENELEC on 1996-10-01. 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, 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

Foreword

The text of document 87/91/FDIS, future edition 1 of IEC 1689, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61689 on 1996-10-01.

This European Standard supersedes HD 87 S1:1977.

This European Standard should be read in conjunction with HD 395.2.5 S1:1986 (IEC 601-2-5).

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) 1997-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-07-01

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

Endorsement notice

The text of the International Standard IEC 1689:1996 was approved by CENELEC as a European Standard without any modification.

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.

Publication	Year	Title	EN/HD	Year
IEC 50(801)	1984	International Electrotechnical Vocabulary (IEV) Chapter 801: Acoustics and electro-acoustics	-	-
IEC 469-1	1987	Pulse techniques and apparatus Part 1: Pulse terms and definitions	-	-
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July + A13	1990 1994 1996
		NOTE: Amendments A11 and A12 are superseded by EN 60601-1/A2:1995.		
IEC 601-2-5	1984	Part 2: Particular requirements for the safety of ultrasonic therapy equipment	HD 395.2.5 S1	1986
IEC 854	1986	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment	-	-
IEC 866	1987	Characteristics and calibration of hydrophones for operation in the frequency range 0,5 MHz to 15 MHz	-	-
IEC 1101	1991	The absolute calibration of hydrophones using the planar scanning technique in the frequency range 0,5 MHz to 15 MHz	EN 61101	1993
IEC 1102	1991	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	EN 61102	1993
IEC 1161	1992	Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz	EN 61161	1994

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
1689

Première édition
First edition
1996-08

Ultrasons – Systèmes de physiothérapie – Prescriptions de performance et méthodes de mesure dans la gamme de fréquences de 0,5 MHz à 5 MHz

Ultrasonics – Physiotherapy systems – Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz

Bureau central de la Commission Electrotechnique Internationale 3, rue de Varembé Genève Suisse

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE XA

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PHYSIOTHERAPY SYSTEMS –

Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz

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 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. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 1689 has been prepared by IEC technical committee 87: Ultrasonics.

It cancels and replaces IEC 150, published in 1963, and constitutes a technical revision. This standard should be read in conjunction with IEC 601-2-5 which, as indicated in its preface, will itself be revised in order to be compatible with this standard.

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

FDIS	Report on voting
87/91/FDIS	87/103/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.

Annexes A and B form an integral part of this standard.

Annexes C to M are for information only.

In this standard, the following print types are used:

- requirements: in roman type;
- *test specifications: in italic type;*
- notes: in small roman type;
- words **in bold** in the text are defined in clause 3.

INTRODUCTION

Ultrasound at low megahertz frequencies is widely used in medicine for the purposes of physiotherapy. Such equipment consists of a generator of high-frequency electrical energy and usually a hand-held **treatment head**, often referred to as an applicator. The **treatment head** consists of a transducer, usually a disk of piezoelectric material, for converting the electrical energy to ultrasound and is often designed for contact with the human body.

ULTRASONICS – PHYSIOTHERAPY SYSTEMS –

Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz

1 Scope

This International Standard is applicable to **ultrasonic equipment** designed for physiotherapy consisting of an **ultrasonic transducer** generating continuous or quasi-**continuous wave** ultrasonic energy in the frequency range 0,5 MHz to 5 MHz.

This standard only relates to **ultrasonic physiotherapy equipment** employing a single plane circular transducer per **treatment head**, producing static beams perpendicular to the face of the **treatment head** in accordance with present practice.

This standard specifies:

- methods of measurement and characterization of the output performance of **ultrasonic physiotherapy equipment** based on reference testing methods;
- characteristics to be declared by manufacturers of **ultrasonic physiotherapy equipment** based on reference testing methods;
- requirements for performance and safety of the ultrasonic field generated by **ultrasonic physiotherapy equipment**;
- methods of measurement and characterization of the output performance of **ultrasonic physiotherapy equipment** based on routine testing methods;
- acceptance criteria for aspects of performance of **ultrasonic physiotherapy equipment** based on routine testing methods.

Therapeutic value and methods of use of **ultrasonic physiotherapy equipment** are not covered by the scope of this standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and 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. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 50(801): 1994, *International Electrotechnical Vocabulary (IEV) – Chapter 801: Acoustics and electroacoustics*

IEC 469-1: 1987, *Pulse techniques and apparatus – Part 1: Pulse terms and definitions*

IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 601-2-5: 1984, *Medical electrical equipment – Part 2: Particular requirements for the safety of ultrasonic therapy equipment*

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IEC 1101: 1991, *The absolute calibration of hydrophones using the planar scanning technique in the frequency range 0,5 MHz to 15 MHz*

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

IEC 1161: 1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz*

3 Definitions

For the purpose of this International Standard, the following definitions apply.

3.1 **acoustic pulse waveform:** Temporal waveform of the **instantaneous acoustic pressure** at a specified position in the acoustic field and displayed over a period sufficiently long to include all significant information in a single pulse or tone burst (see 3.2 of IEC 1102).

3.2 **acoustic repetition period:** Time interval between corresponding points of consecutive cycles for **continuous wave** ultrasound (see 3.3 of IEC 1102).

3.3 **acoustic working frequency:** Frequency of an acoustic signal based on the observation of the output of a **hydrophone** placed in an acoustic field. The signal is analysed using the zero-crossing frequency technique (see 3.4.1 of IEC 1102).

3.4 **amplitude modulated wave:** Wave in which the ratio $p_p/\sqrt{2}\,p_{rms}$ at any point in the **far field** on the **beam alignment axis** is greater than 1,05, where p_p is the **temporal-peak acoustic pressure** and p_{rms} is the **r.m.s. acoustic pressure**.

3.5 **attachment head:** Accessory intended to be attached to the **treatment head** for the purpose of modifying the ultrasonic beam characteristics (see IEC 601-2-5).

3.6 **beam alignment axis:** Straight line joining two points of spatial-peak **temporal-peak acoustic pressure** on two plane surfaces parallel to the faces of the **treatment head**. One plane is at a distance of approximately $A_{ERN}/(\pi\lambda)$ where A_{ERN} is the nominal value of the **effective radiating area** of the **treatment head** and λ is the wavelength of the ultrasound corresponding to the nominal value of the **acoustic working frequency**. The second plane surface is at a distance of either $2A_{ERN}/(\pi\lambda)$ or $A_{ERN}/(3\pi\lambda)$ whichever is the more appropriate. For the purposes of alignment, this line may be projected to the face of the **treatment head**.

NOTES

1 If the nominal value of the **effective radiating area** is unknown, then another suitable area may be used to define the **beam alignment axis** such as the area of the active element of the **ultrasonic transducer**.

2 As the **beam alignment axis** is used purely for the purposes of alignment, the definitions of specific distances may be relaxed slightly to reflect the constraints of the measurement system employed. For example, some **treatment heads** will have $A_{ERN}/(\pi\lambda)$ considerably greater than 12 cm, in which case a maximum distance of 12 cm may be used to define the first plane. General guidelines for determining the **beam alignment axis** are given in 8.2.

See 3.5 of IEC 1102 in the case of plane surfaces.

3.7 **beam cross-sectional area:** Minimum area in a specified plane perpendicular to the **beam alignment axis** for which the sum of the mean **square acoustic pressure** is 75 % of the **total mean square acoustic pressure.**

Symbol: A_{BCS}
Unit: centimetre squared, cm^2

3.8 **beam maximum intensity:** Product of the **beam non-uniformity ratio** and **rated output power** divided by the **effective radiating area.**

Unit: watt per centimetre squared, W/cm^2

3.9 **beam non-uniformity ratio:** Ratio of the square of the **maximum r.m.s. acoustic pressure** to the spatial average of the square of the **r.m.s. acoustic pressure** where the spatial average is taken over the **effective radiating area. Beam non-uniformity ratio** is given by:

$$R_{BN} = \frac{p_{max}^{\,2}\ A_{ER}}{pms_t\ a_o}$$

where

p_{max} is the **maximum r.m.s. acoustic pressure;**

A_{ER} is the **effective radiating area;**

pms_t is the **total mean square acoustic pressure;**

a_o is the unit area for the raster scan.

Symbol: R_{BN}
Unit: dimensionless.

3.10 **absolute maximum beam non-uniformity ratio: Beam non-uniformity ratio** plus the 95 % confidence overall uncertainty in the **beam non-uniformity ratio.**

3.11 **beam type:** Descriptive classification for the ultrasonic beam in one of three types: **collimated, convergent or divergent.**

3.12 **collimated:** Beam for which the **linear regression coefficient**, Q, obeys the following inequality:

$$-0{,}05\ cm^{-1} \leq Q \leq 0{,}1\ cm^{-1}$$