SLOVENSKI STANDARD

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Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2001)

ICS 11.040.55; 17.140.50

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EUROPEAN STANDARD **EN 60601-2-37**

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ICS 11.040.55; 17.140.50

English version

Medical electrical equipment
Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
(IEC 60601-2-37:2001)

Appareils électromédicaux
Partie 2-37: Règles particulières de sécurité pour les appareils de diagnostic et de surveillance médicaux à ultrasons
(CEI 60601-2-37:2001)

Medizinische elektrische Geräte
Teil 2-37: Besondere Festlegungen für die Sicherheit von Ultraschall-Geräten für die medizinische Diagnose und Überwachung
(IEC 60601-2-37:2001)

This European Standard was approved by CENELEC on 2001-09-25. 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

Ref. No. EN 60601-2-37:2001 E

Foreword

The text of document 62B/428/FDIS, future edition 1 of IEC 60601-2-37, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-37 on 2001-09-25.

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) 2002-07-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2004-10-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes AA and DD are normative and annexes BB, CC, EE, FF, GG and HH are informative.

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: smaller roman type;
– *test specifications and headings of subclauses: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS STANDARD OR IN OTHER IEC STANDARDS REFERENCED IN ANNEX AA: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-37:2001 was approved by CENELEC as a European Standard without any modification.

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INTERNATIONAL STANDARD

IEC 60601-2-37

First edition
2001-07

Medical electrical equipment –

Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

Appareils électromédicaux –

Partie 2-37:
Règles particulières de sécurité pour les appareils de diagnostic et de surveillance médicaux à ultrasons

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Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-37: Particular requirements for the safety of ultrasonic diagnostic and monitoring equipment

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 60601-2-37 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/428/FDIS	62B/440/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 AA and DD form an integral part of this Particular Standard.

Annexes BB, CC, EE, FF, GG and HH are for information only.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type
– notes, explanations, advice, introductions, general statements, exceptions, and references: in smaller type
– *test specifications: in italic type*
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IEC 60601-1: IN SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2002. At this date, the publication will be

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

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

In this Particular Standard, safety requirements additional to those in the General Standard are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

Guidance and a rationale for the requirements of this Particular Standard are given below.

Knowledge of the reasons for these requirements will not only facilitate the proper application of this Particular Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology.

General guidance and rationale

The approach and philosophy used in drafting this particular standard for safety of ULTRASONIC DIAGNOSTIC EQUIPMENT are consistent with those in current standards in the IEC 60601-2 series that apply to other diagnostic modalities, such as X-ray equipment and magnetic resonance systems.

In each case, the safety standard is intended to require increasing sophistication of output display indicators and/or controls with increasing energy levels in the interrogating field of diagnosis. Thus, for all such diagnostic modalities, it is the responsibility of the OPERATOR to understand the risk of the output of the equipment, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the PATIENT.

The reference given in the bibliography, UD-3 Rev.1, 1998: *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment* will be replaced by an IEC standard when available.

It should be noted that although UD-3 Rev.1, 1998 was developed as a national standard, it has since been referenced by about 24 countries world wide and by all internationally operating manufacturers and test houses; regulative authorities also follow the standard as it has become a *de facto* international standard. The material taken from UD-3 Rev.1, 1998 forms only a part of this Particular Standard and is used to generate the present International Standard which will be replaced by a revised edition within one year.

The standards currently under development, IEC 61973 and IEC 61681-1, will be considered at the time of revision of this standard.

NOTE The ALARA principle, referred to in UD-3 Rev.1, 1998, is currently under discussion. This may be reflected in the next edition of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

SECTION ONE: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies particular safety requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 2.1.145.

This standard does not cover ultrasonic therapeutic equipment; however, equipment used for the imaging of body structures by ultrasound in conjunction with therapeutic modalities is covered.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of ULTRASONIC DIAGNOSTIC EQUIPMENT and those aspects thereof which are directly related to safety.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as the "General Standard", consisting of

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety* and its Amendments 1 (1991) and 2 (1995)

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1-4: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems* and its Amendment 1 (1999)

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa)*, *bb)*, etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk (*). These rationales can be found in an informative annex BB. Annex BB should be used in determining the relevance of the requirements addressed, but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or of a Collateral Standard takes precedence over the corresponding general requirement(s).

1.3.101 Related international standards

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*

IEC 61157:1992, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*

IEC 61161:1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz*
Amendment 1 (1998)

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.1.101
ACOUSTIC ATTENUATION COEFFICIENT
coefficient intended to account for ultrasonic attenuation of tissue between the source and a specified point

Symbol: α

Unit: decibels per centimetre per megahertz, dB cm^{-1} MHz^{-1}

2.1.102
ACOUSTIC WORKING FREQUENCY
arithmetic mean of the most widely separated frequencies f_1 and f_2 at which the amplitude of the pressure spectrum of the acoustic signal is 3 dB lower than the peak amplitude [3.4.2 of IEC 61102, modified]

Symbol: f_{awf}

Unit: megahertz, MHz

2.1.103
ATTENUATED OUTPUT POWER
value of the acoustic OUTPUT POWER after attenuation and at a specified distance from the transducer, and given by

$$P_\alpha = P\,10^{(-\alpha z\, f_{awf}/10)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

P_α is the ATTENUATED OUTPUT POWER in milliwatts;

P is the OUTPUT POWER in milliwatts measured in water.

Symbol: P_α

Unit: milliwatts, mW

2.1.104
ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE
value of the PEAK-RAREFACTIONAL ACOUSTIC PRESSURE after attenuation and at a specified point, and given by

$$p_{ra}(z) = p_r(z)\,10^{(-\alpha z\, f_{awf}/20)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest, in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

$p_r(z)$ is the PEAK-RAREFACTIONAL ACOUSTIC PRESSURE measured in water.

Symbol: p_{ra}

Unit: megapascals, MPa

2.1.105
ATTENUATED PULSE-AVERAGE INTENSITY
value of the acoustic PULSE-AVERAGE INTENSITY after attenuation and at a specified point, and given by

$$I_{pa,\alpha} = I_{pa}(z)10^{(-\alpha z f_{awf}/10)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY, at distance z in megahertz;

$I_{pa}(z)$ is the PULSE-AVERAGE INTENSITY measured in water, in milliwatts per centimetre squared.

Symbol: $I_{pa,\alpha}$

Unit: watts per centimetre squared, W cm^{-2}

2.1.106
ATTENUATED PULSE-INTENSITY INTEGRAL
value of the PULSE-INTENSITY INTEGRAL after attenuation and at a specified point, and given by

$$I_{pi,\alpha} = I_{pi}\, 10^{(-\alpha z f_{awf}/10)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

$I_{pi,\alpha}$ is the ATTENUATED PULSE-INTENSITY INTEGRAL in millijoules per centimetre squared;

I_{pi} is the PULSE-INTENSITY INTEGRAL measured in water in millijoules per centimetre squared.

Symbol: $I_{pi,\alpha}$

Unit: millijoules per centimetre squared, mJ cm^{-2}

2.1.107
ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY
value of the SPATIAL-PEAK TEMPORAL AVERAGE INTENSITY after attenuation and at a specified distance z, and given by

$$I_{zpta,\alpha}(z) = I_{zpta}(z)10^{(-\alpha z f_{awf}/10)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

$I_{zpta}(z)$ is the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY, at a specified distance z in milliwatts per centimetre squared measured in water.

Symbol: $I_{zpta,\alpha}(z)$

Unit: milliwatts per centimetre squared, mW cm^{-2}

2.1.108
ATTENUATED TEMPORAL-AVERAGE INTENSITY
value of the TEMPORAL-AVERAGE INTENSITY after attenuation and at a specified point, and given by

$$I_{ta,\alpha}(z) = I_{ta}(z)10^{(-\alpha z f_{awf}/10)}$$

where

α	is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;
z	is the distance from the source to the point of interest in centimetres;
f_{awf}	is the ACOUSTIC WORKING FREQUENCY in megahertz;
$I_{ta,\alpha}(z)$	is the ATTENUATED TEMPORAL-AVERAGE INTENSITY in milliwatts per centimetre squared;
$I_{ta}(z)$	is the TEMPORAL-AVERAGE INTENSITY measured in water in milliwatts per centimetre squared.

Symbol: $I_{ta,\alpha}(z)$

Unit: milliwatts per centimetre squared, mW cm^{-2}

2.1.109
BEAM AREA
area in a specified plane perpendicular to the BEAM-ALIGNMENT AXIS consisting of all points at which the PULSE-INTENSITY INTEGRAL is greater than a specified fraction of the maximum PULSE-INTENSITY INTEGRAL in that plane
[3.6 of IEC 61102, modified]

NOTE For measurement purposes the PULSE INTENSITY INTEGRAL can be taken as being proportional to the PULSE PRESSURE-SQUARED INTEGRAL

2.1.110
BEAM ALIGNMENT AXIS
straight line joining the points of maximum PULSE INTENSITY INTEGRAL measured at several different distances in the far field. For the purposes of alignment, this line may be projected to the face of the ULTRASONIC TRANSDUCER
[3.5 of IEC 61102, modified]

2.1.111
BONE THERMAL INDEX
THERMAL INDEX for applications, such as foetal (second and third trimester) or neonatal cephalic (through the fontanelle), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone

Symbol: *TIB*

Unit: None

NOTE See annex DD.4.2 and DD.5.2 for methods of determining the BONE THERMAL INDEX.

2.1.112
BOUNDED OUTPUT POWER
OUTPUT POWER emitted in SCANNING MODE from a region of the active area of the transducer whose width in the scan plane is limited to 1 cm

Symbol: P_1

Unit: milliwatts, mW