IEC 60601-2-37

Edition 2.0 2007-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

Appareils électromédicaux –
Partie 2-37: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de diagnostic et de surveillance médicaux à ultrasons

IEC 60601-2-37:2007

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-37 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2001 and its Amendment 1 (2004) and Amendment 2 (2005). This edition combines the previous edition and its amendments into a form compatible with the parent IEC 60601-1:2005.

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

Enquiry draft	Report on voting
62B/624/CDV	62B/657/RVC

Full information on the voting for the approval of this particular 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 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

In this particular standard, safety requirements additional to those in the general standard are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA.

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.

The approach and philosophy used in drafting this particular standard for safety of ULTRASONIC DIAGNOSTIC EQUIPMENT are consistent with those in standards of the IEC 60601-2-xx 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 ULTRASONIC DIAGNOSTIC EQUIPMENT, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the PATIENT.

MEDICAL ELECTRICAL EQUIPMENT –

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

The clauses and subclauses of the general standard apply except as follows:

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

201.1.1 *Scope

Addition:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217, hereinafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of this standard.

NOTE See also subclause 4.2 of this standard.

This particular standard does not cover ultrasonic therapeutic equipment. Equipment used for the imaging or diagnosis of body structures by ultrasound in conjunction with other medical procedures is covered.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.6 in this particular standard addresses the content of Clause 6 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies except as follows:

Addition:

IEC 62359, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

201.3 Terminology and definitions

For the purposes of this document, the terms and definitions given in the general standard and in IEC 62359, as well as the following additions apply:

NOTE 1 An index of defined terms is given after the Bibliography.

NOTE 2 A list of symbols used in this particular standard is found in Table 201.101.

201.3.201
BONE THERMAL INDEX
THERMAL INDEX for applications, such as foetal (second and third trimester) or neonatal cephalic (through the fontanelle) applications, in which the ultrasound beam passes through soft tissue and there is bone close to a focal region

Symbol: *TIB*

Unit: None

NOTE See IEC 62359 for methods of determining the BONE THERMAL INDEX.

201.3.202
COMBINED-OPERATING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that combines more than one DISCRETE-OPERATING MODE

201.3.203
CRANIAL-BONE THERMAL INDEX
THERMAL INDEX for applications, such as paediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body

Symbol: *TIC*

Unit: None

NOTE See IEC 62359 for methods of determining the CRANIAL-BONE THERMAL INDEX

201.3.204
DEFAULT SETTING
specific state of control the ULTRASONIC DIAGNOSTIC EQUIPMENT will enter upon power-up, new PATIENT select, or change from non-foetal to foetal applications

201.3.205
DISCRETE-OPERATING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT in which the purpose of the excitation of the ULTRASONIC TRANSDUCER or ULTRASONIC TRANSDUCER element group is to utilise only one diagnostic methodology

201.3.206
FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT
means by which the ULTRASONIC DIAGNOSTIC EQUIPMENT manages the acoustic output independent of direct OPERATOR control

201.3.207
INVASIVE TRANSDUCER ASSEMBLY
a transducer which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body

201.3.208
MECHANICAL INDEX
the displayed parameter representing potential cavitation bioeffects

Symbol: *MI*

Unit: None

NOTE See IEC 62359 for methods of determining the MECHANICAL INDEX.

201.3.209
MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT
ULTRASONIC DIAGNOSTIC EQUIPMENT that is intended for more than one clinical application

201.3.210
NON-SCANNING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that involves a sequence of ultrasonic pulses that give rise to ultrasonic scan lines that follow the same acoustic path

201.3.211
PRUDENT USE STATEMENT
affirmation of the principle advising avoidance of high exposure levels and long exposure times while acquiring only information which is clinically required

201.3.212
SCANNING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that involves a sequence of ultrasonic pulses that give rise to scan lines that do not follow the same acoustic path

201.3.213
SOFT TISSUE THERMAL INDEX
THERMAL INDEX related to soft tissues

Symbol: *TIS*

Unit: None

NOTE 1 See IEC 62359 for methods of determination of the SOFT-TISSUE THERMAL INDEX.

NOTE 2 For the purposes of this document, "soft tissue" includes all body tissues and fluids but excludes skeletal tissues.

201.3.214
THERMAL INDEX

ratio of attenuated acoustic power at a specified point to the attenuated acoustic power required to raise the temperature at that point in a specific tissue model by 1 °C.

Symbol: *TI*

Unit: None

NOTE See IEC 62359 for methods of determining the THERMAL INDEX

201.3.215
TRANSDUCER ASSEMBLY
the transducer housing (probe), any associated electronic circuitry, the active ultrasonic transducer module, and any liquids contained in the housing and the integral cable that connects the transducer probe to an ultrasound console

201.3.216
TRANSMIT PATTERN
combination of a specific set of transducer beam-forming characteristics (determined by the transmit aperture size, apodisation shape, and relative timing/phase delay pattern across the aperture, resulting in a specific focal length and direction), and an electrical drive waveform of a specific fixed shape but variable amplitude

201.3.217
ULTRASONIC DIAGNOSTIC EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT that is intended for ultrasonic medical examination

201.3.218
ULTRASONIC TRANSDUCER
device capable of converting electrical energy to mechanical energy and/or mechanical energy to electrical energy, both within the ultrasonic frequency range

Table 201.101 – List of symbols

Symbol	Term	Reference
A_{aprt}	= -12dB OUTPUT BEAM AREA	IEC 62359, 3.25
d_{eq}	= EQUIVALENT BEAM DIAMETER	IEC 62359, 3.22
f_{awf}	= ACOUSTIC WORKING FREQUENCY	IEC 62359, 3.2
$I_{pa,\alpha}$	= ATTENUATED PULSE-AVERAGE INTENSITY	IEC 62359, 3.5
I_{pi}	= PULSE-INTENSITY INTEGRAL	IEC 62359, 3.32
$I_{pi,\alpha}$	= ATTENUATED PULSE-INTENSITY INTEGRAL	IEC 62359, 3.6
I_{spta}	= SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY	IEC 62359, 3.38
$I_{ta,\ \alpha}(z)$	= ATTENUATED TEMPORAL-AVERAGE INTENSITY	IEC 62359, 3.8
MI	= MECHANICAL INDEX	IEC 62359, 3.23
P	= OUTPUT POWER	IEC 62359, 3.27
P_{α}	= ATTENUATED OUTPUT POWER	IEC 62359, 3.3
$P_{r,\alpha}$	= ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359, 3.4
P_r	= PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359, 3.28
prr	= PULSE REPETITION RATE	IEC 62359, 3.34
TI	= THERMAL INDEX	IEC 62359, 3.41
TIB	= BONE THERMAL INDEX	IEC 62359, 3.11
TIC	= CRANIAL-BONE THERMAL INDEX	IEC 62359, 3.15
TIS	= SOFT-TISSUE THERMAL INDEX	IEC 62359, 3.37
t_d	= PULSE DURATION	IEC 62359, 3.31
X, Y	= -12dB OUTPUT BEAM DIMENSIONS	IEC 62359, 3.26
z_b	= DEPTH FOR BONE THERMAL INDEX	IEC 62359, 3.17
z_{bp}	= BREAK-POINT DEPTH	IEC 62359, 3.13
z_s	= DEPTH FOR SOFT-TISSUE THERMAL INDEX	IEC 62359, 3.18

201.4 General requirements

Clause 4 of the general standard applies except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Table 201.102 lists the potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT and the subclauses in which the requirements are found.

Table 201.102 – Distributed essential performance requirements

Requirement	Subclause
Free from noise on a waveform or artefacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.	202.6.2.1.10
Free from the display of incorrect numerical values associated with the diagnosis to be performed [a].	202.6.2.1.10
Free from the display of incorrect safety-related indications.[a]	201.12.4.2 202.6.2.1.10
Free from the production of unintended or excessive ultrasound output.	201.10.101 202.6.2.1.10
Free from the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature.	202.6.2.1.10
Free from the production of unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.	202.6.2.1.10
[a] "incorrect" in the sense that the displayed value differs from what is calculated (having been altered during data transfer), or the calculation itself is not correct.	

NOTE In some circumstances the need for the repetition of an ultrasound examination should be evaluated as a potential hazard, for example, intra-corporeal investigation and stress testing for cardiopathic PATIENTS.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.9 IP classification

Addition:

If the specified IPX classification is applicable for only part of the TRANSDUCER ASSEMBLY, the marking of the IPX code on the TRANSDUCER ASSEMBLY is not required.

201.7.2.13 *Physiological effects (safety signs and warning statements)

Addition:

A description of the means used to limit the surface heating of INVASIVE TRANSDUCER ASSEMBLIES to no more than 43 °C in the event of a SINGLE FAULT CONDITION shall be provided in accordance with the requirements of Clause 12.

201.7.2.101 *Acoustic output

For ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 201.12.4.2 and which allows the OPERATOR to directly vary the output levels, the effect of

adjusting the control which varies the output level shall be clear. The marking shall be of the nature of an active display.

A display of THERMAL INDEX and MECHANICAL INDEX shall be provided in accordance with the requirements of Clause 201.12, together with the declaration of accuracy described in 201.7.9 and Clause 201.12.

A display relevant to ultrasound output levels (Clause 201.12) shall be clearly visible from the OPERATOR'S position, with the full name(s) or abbreviation(s) of the index (indices) displayed.

201.7.9.2.2 *Warning and safety notices

Addition:

For ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to Clause 201.12, information shall be provided to the OPERATOR on how to interpret the displayed ultrasonic exposure parameters, THERMAL INDEX (*TI*) and MECHANICAL INDEX (*MI*) according to the guidance given in Annex CC.

The procedures necessary for safe operation shall be provided, drawing attention to the safety hazards that may occur as a result of an inadequate electrical installation when the APPLIED PART of the ULTRASONIC DIAGNOSTIC EQUIPMENT is a TYPE B APPLIED PART.

Instruction on the safe use of TRANSDUCER ASSEMBLIES shall be provided, and, in particular, instructions to ensure that the ULTRASONIC DIAGNOSTIC EQUIPMENT is of the correct type for its intended application; for TRANSDUCER ASSEMBLIES intended for intra-corporeal use, a warning in the instructions not to activate the TRANSDUCER ASSEMBLY outside the PATIENT'S body if the TRANSDUCER ASSEMBLY, when so activated, would not comply with electromagnetic compliance requirements and may cause harmful interference with other equipment in the environment. The identification of interference with other equipment and mitigation techniques shall be included in the ACCOMPANYING DOCUMENTS if the MANUFACTURER claims a reduction in test levels.

A notice shall be provided if the ULTRASONIC DIAGNOSTIC EQUIPMENT or parts thereof are provided with protective means against burns to the PATIENT when used with high frequency (HF) surgical equipment. If no such means are incorporated, notice shall be given in the ACCOMPANYING DOCUMENTS and advice shall be given regarding the location and use of the TRANSDUCER ASSEMBLY to reduce the hazard of burns in the event of a defect in the HF surgical neutral electrode connection.

A PRUDENT USE STATEMENT shall be provided for ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 201.12.4.2.

Descriptions shall be provided of any display or means relevant to ultrasound output by which the OPERATOR may modify the operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT. These descriptions shall be in a separate section.

A description of any display or means by which the OPERATOR may modify the operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT relevant to surface temperature for INVASIVE TRANSDUCER ASSEMBLIES intended for trans-oesophageal use shall be provided.

A description of those parts of the TRANSDUCER ASSEMBLY that are permitted to be immersed in water or other liquids either for NORMAL USE or performance assessment purposes shall be provided.

A recommendation calling the OPERATOR'S attention to the need for regular testing and periodic maintenance including inspection of the TRANSDUCER ASSEMBLY for cracks that allow the ingress of conductive fluid shall be provided.