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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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE XB

For price, see current catalogue

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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 –

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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)