

# INTERNATIONAL STANDARD

# IEC 60601-2-37

**Edition 1.1**

2004-10

Edition 1:2001 consolidated with amendment 1:2004

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## **Medical electrical equipment –**

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

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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

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## MEDICAL ELECTRICAL EQUIPMENT –

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

#### FOREWORD

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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.

This consolidated version of IEC 60601-2-37 is based on the first edition (2001) [documents 62B/428/FDIS and 62B/440/RVD] and its amendment 1 (2004) [documents 62B/524/FDIS and 62B/542/RVD].

It bears the edition number 1.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

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 the base publication and its amendments 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- withdrawn,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.

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.

It should be noted that although UD-3 Rev.1, 1998<sup>1</sup> was developed as a national standard, it has since been referenced by numerous countries worldwide and by all internationally operating manufacturers and test houses; regulatory 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.

This standard contains normative measurement methodologies. These clauses may be replaced in a future revision by reference to an appropriate future measurement standard.

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

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<sup>1</sup> See reference [19] in the Bibliography.

## 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 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – 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)