

FINAL VERSION

VERSION FINALE

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

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
INTRODUCTION TO AMENDMENT 1	6
201.1 Scope, object and related standards.....	7
201.2 Normative references	8
201.3 Terms and definitions	9
201.4 General requirements	14
201.5 General requirements for testing ME EQUIPMENT	5
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	15
201.7 ME EQUIPMENT identification, marking and documents.....	16
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	20
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	21
201.10 Protection against unwanted and excessive radiation HAZARDS.....	21
201.11 Protection against excessive temperatures and other HAZARDS	21
201.12 Accuracy of controls and instruments and protection against hazardous outputs	25
201.13 Hazardous situations and fault conditions.....	27
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	27
201.15 Construction of ME EQUIPMENT.....	27
201.16 ME SYSTEMS	28
201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	28
202.6 ELECTROMAGNETIC COMPATIBILITY.....	28
Annex AA (informative) Guidance and rationale for particular subclauses	31
Annex BB (informative) Guidance on classification according to CISPR 11	37
Annex CC (informative) Guidance to the MANUFACTURER on the interpretation of <i>Tl</i> and <i>Ml</i> to be used to inform the OPERATOR.....	38
Annex DD (informative) Example set-up to measure surface temperature of externally applied TRANSDUCER ASSEMBLIES	41
Annex EE (informative) Acoustic output table intended for 3rd parties	44
Bibliography.....	47
Index of defined terms	50
Figure DD.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers	43
Table 201.101 – List of symbols.....	14
Table 201.102 – Distributed essential performance requirements	15
Table 201.103 – Acoustic output reporting table	19
Table 201.104 – Overview of the tests noted under 201.11.1.3	25
Table CC.1 – Relative importance of maintaining low exposure indices in various scanning situations	40

Table DD.1 – Acoustic and thermal properties of tissues & materials	41
Table DD.2 – Weight % pure components	42

Currently in preview, click buy full version

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.
- 2) The formal decisions or agreements of 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 IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use, and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, accept to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

DISCLAIMER

This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-37 bears the edition number 2.1. It consists of the second edition (2007-08) [documents 62B/624/CDV and 62B/657/RVC] and its amendment 1 (2015-06) [documents 62B/978/FDIS and 62B/988/RVD]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

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 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 REFERRED TO BY 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. 7.1.1, 7.1.2 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 the base publication and its amendment will remain unchanged until the stability 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.

INTRODUCTION TO AMENDMENT 1

The second edition of IEC 60601-2-37 was published in 2007. Since that publication, the parent standard, IEC 60601-1:2005, entered maintenance, under which an amendment (IEC 60601-1:2005/AMD1:2012) and a consolidated edition 3.1 (IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012) were published. This amendment to IEC 60601-2-37:2007 addresses three issues:

- 1) technical changes proposed by National Committees as a result of 4 years of practical usage,
- 2) technical and editorial changes resulting from the amended general standard IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and its collateral standards IEC 60601-1-xx, and
- 3) technical changes as a result of maintenance to normative references.

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

Replacement:

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.

201.1.3 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.