

# INTERNATIONAL STANDARD

# IEC 60601-2-37

2001

AMENDMENT 2  
2005-11

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Amendment 2

**Medical electrical equipment –**

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

<https://standards.iteh.ai/catalog/standards/iec/8ac7e21c-b92c-4fbc-8a6f-7562ad0d203e/iec-60601-2-37-2001/AMD2:2005>

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Commission Electrotechnique Internationale  
International Electrotechnical Commission  
Международная Электротехническая Комиссия

PRICE CODE

**C**

*For price, see current catalogue*

## FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/591/FDIS	62B/598/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

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- withdrawn;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.

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### 1.3.101 Related international standards

*Add, to the existing list, the following new standard.*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*  
Amendment 1 (2003)

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### 6.8.2 INSTRUCTIONS FOR USE

aa) *Add, on page 20, to the existing list of items, the following new item:*

- 14) declaration of output limits as selected according to Clause 35.4. For MULTI-PURPOSE ULTRASONIC EQUIPMENT the output limits shall be declared for each application.

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## 35 Acoustical energy (including ultrasonic)

*Add the following subclause:*

**35.4.** Acoustic output shall be limited based on RISK ASSESSMENT and RISK MANAGEMENT following ISO 14971 using the safety-related parameters defined in this standard and other relevant information such as clinical experience.

NOTE For guidance on the relevance of the safety-related parameters defined in this standard, see Annex HH.

When applicable, the MANUFACTURER shall address the risks associated with ultrasound acoustic output in the RISK MANAGEMENT process.