INTERNATIONAL STANDARD

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AMENDMENT 2
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Amendment 2

Medical electrical equipment –

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

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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- withdrawn;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.

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Annex BB – Guidance and rationale for particular subclauses

Concerning 35 Acoustical energy (including ultrasonic)

Add the following paragraphs:

While this Particular Standard places no upper limits on permitted levels of acoustic output, all EQUIPMENT is limited for technical reasons, compliance with local regulatory requirements, or reasons resulting from the MANUFACTURER'S RISK MANAGEMENT. On the one hand the MANUFACTURERS should continuously track the scientific discussions on safety of ultrasonic fields for diagnostic ultrasound, on the other hand the USERS should know about the – possibly application-dependent – limits of their EQUIPMENT as selected by the MANUFACTURER.

Compliance with subclause 35.4 may be checked by inspection of the relevant documentation of the results of the RISK MANAGEMENT process provided by the MANUFACTURER, including relevant information such as clinical experience.