SLOVENSKI

PREDSTANDARD

SIST EN 60601-2-37:2002/oprA2:2005

april 2005

Medicinska električna oprema – 2-37.del: Posebne varnostne zahteve za ultrazvočno medicinsko diagnostično in nadzorovalno opremo

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

ICS 11.040.55; 17.140.50

Referenčna številka
SIST EN 60601-2-37:2002/oprA2:2005(en)

62B/557/CDV

COMMITTEE DRAFT FOR VOTE (CDV)
PROJET DE COMITÉ POUR VOTE (CDV)

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Secretary: Norbert Bischof Secrétaire:		
Also of interest to the following committees Intéresse également les comités suivants TC 87	Supersedes document Remplace le document 62B/519/CD and 62B/545/CC	

Functions concerned
Fonctions concernées

☒ Safety / Sécurité ☐ EMC / CEM ☐ Environment / Environnement ☐ Quality assurance / Assurance qualité

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Titre :

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

Introductory note

The Maintenance Team IEC/62B/MT34 has prepared this 2nd amendment of IEC 60601-2-37. It is intended to introduce the bilingual version with the FDIS.
In subclause 35.4, line 60 the text "and results from clinical evaluations" has been crossed out. There was a discussion in the group whether or not this piece of text was necessary and clear. Convenor and Secretary are in favour of a cancellation. The term "clinical evaluations" is not clear within the standards referenced while ISO14971 puts clear requirements.
National committees are requested to comment whether or not the text part crossed out should be included in the standard.

ATTENTION	ATTENTION
CDV soumis en parallèle au vote (CEI) et à l'enquête (CENELEC)	**Parallel IEC CDV/CENELEC Enquiry**

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

This amendment to 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

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.

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 THAT HAVE BEEN DEFINED IN CLAUSE 2 AND IEC 60601-1: IN SMALL CAPITALS.

The committee has decided that the contents of this publication may remain unchanged until December 2006. At or before 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.

The numbering of sections, clauses, and subclauses of this Amendment corresponds to that of the Particular Standard. The changes to the text of the Particular Standard are specified by the use of the following words:

"Replace in the Particular Standard": means that the clause or subclause of the Particular Standard is replaced completely by the text of this Amendment.

"Add to the Particular Standard": means that the text of this Amendment is additional to the requirements of the Particular Standard.

"Change the Particular Standard": means that the clause or subclause of the Particular Standard is changed as indicated by the text of this Amendment.

1.3.101 Related international standards

Add to the Particular Standard:

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

6.8.2 INSTRUCTIONS FOR USE

aa) INSTRUCTIONS FOR USE shall contain the following:

Add to the Particular Standard:

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.

35 Acoustical energy (including ultrasonic)

Add to the Particular Standard:

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

NOTE: for guidance on the relevance of the safety 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.

68 **Annex BB**
69 (informative)

70 **Guidance and rationale for particular subclauses**

71

72 **Concerning 35 Acoustical energy (including ultrasonic)**

73 ***Add to the Particular Standard:***

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

80 Compliance with subclause 35.4 may be checked by inspection of the relevant documentation
81 of the results of RISK MANAGEMENT process provided by the MANUFACTURER, including the
82 results of the clinical evaluations.