SLOVENSKI STANDARD

SIST EN 60601-2-13:2006/A1:2008

01-februar-2008

Medicinska elektriļ na oprema - 2-13. del: Posebne varnostne zahteve in bistvene lastnosti sistemov za anestezijo (IEC 60601-2-13:2003/A1:2006)

Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems (IEC 60601-2-13:2003/A1:2006)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit von Anästhesiesystemen (IEC 60601-2-13:2003/A1:2006)

Appareils électromédicaux - Partie 2-13: Regles particulieres de sécurité et performance essentielle pour les systemes d'anesthésie (IEC 60601-2-13:2003/A1:2006)

Ta slovenski standard je istoveten z: **EN 60601-2-13:2006/A1:2007**

ICS:

11.040.10

SIST EN 60601-2-13:2006/A1:2008 **en,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-13/A1

March 2007

ICS 11.040.10

English version

Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems

(IEC 60601-2-13:2003/A1:2006)

Appareils électromédicaux -
Partie 2-13: Règles particulières
de sécurité et performance essentielle
pour les systèmes d'anesthésie
(CEI 60601-2-13:2003/A1:2006)

Medizinische elektrische Geräte -
Teil 2-13: Besondere Festlegungen
für die Sicherheit
von Anästhesiesystemen
(IEC 60601-2-13:2003/A1:2006)

This amendment A1 modifies the European Standard EN 60601-2-13:2006; it was approved by CENELEC on 2007-03-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of amendment 1:2006 to the International Standard IEC 60601-2-13:2003, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the Unique Acceptance Procedure and was approved by CENELEC as amendment A1 to EN 60601-2-13:2006 on 2007-03-01 without any modification.

The following dates were fixed:

– latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2008-03-01
– latest date by which the national standards conflicting with the amendment have to be withdrawn	(dow)	2010-03-01

Endorsement notice

The text of amendment 1:2006 to the International Standard IEC 60601-2-13:2003 was approved by CENELEC as an amendment to the European Standard without any modification.

INTERNATIONAL STANDARD

IEC 60601-2-13

2003

AMENDMENT 1
2006-05

Amendment 1

Medical electrical equipment –

Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems

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FOREWORD

This amendment has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

CDV	Report on voting
62D/516/CDV	62D/537A/RVC

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the amendment has been approved by 18 P-members out of 18 having cast a vote.

The committee has decided that the contents of this amendment and the base 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.

SECTION ONE – GENERAL

Page 13

6.8.2 Instructions for use

Add, on page 16, the following new text:

ddd)

The instructions for use shall contain a statement to the effect that any anaesthetic gas scavenging transfer and receiving system used with the anaesthetic system shall comply with ISO 8835-3.

Unless the anaesthetic gas scavenging transfer and receiving system is integral to the anaesthetic gas delivery system, the manufacturer/supplier of the anaesthetic gas delivery system shall provide information on how to connect an anaesthetic gas scavenging transfer and receiving system.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

Page 22

51.101.7

Modify the final sentence in parentheses to read as follows:

See items aa) and ddd) of 6.8.2.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS

ENVIRONMENTAL TESTS

Page 23

*Correct the spelling of the word "*operation*" in the title of Clause 52 to read as follows:*

52 Abnormal operation and fault conditions

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