

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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PRICE CODE

C

For price, see current catalogue

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- withdrawn,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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