

INTERNATIONAL STANDARD

IEC 60601-2-23

Second edition
1999-12

Medical electrical equipment –

Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment

Appareils électromédicaux –

Partie 2-23: Règles particulières de sécurité et performances essentielles des appareils de surveillance de la pression partielle transcutanée

© IEC 1999 — Copyright - all rights reserved

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Electrotechnical Commission 3, rue de Varembeé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site <http://www.iec.ch>



Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE

V

For price, see current catalogue

CONTENTS

	Page
FOREWORD	4
SECTION ONE – GENERAL	
1 Scope and object.....	6
2 Terminology and definitions.....	7
3 General requirements.....	9
4 General requirements for tests	9
5 Classification.....	9
6 Identification, marking and documents.....	10
SECTION TWO – ENVIRONMENTAL CONDITIONS	
SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
14 Requirements related to classification	11
17 Separation.....	11
20 Dielectric strength	11
SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS	
21 Mechanical strength	11
SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
*36 Electromagnetic compatibility	12
SECTION SIX – PROTECTION AGAINST THE HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES	
SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	
42 Excessive temperatures	15
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility.....	16
49 Interruption of the power supply.....	16
SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	
51 Protection against hazardous output.....	17
SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS	
52 Abnormal operation and fault conditions	23
SECTION TEN – CONSTRUCTIONAL REQUIREMENTS	
56 Components and general assembly	23
57 MAINS PARTS, components and layout	24

Figure 101 – TRANSDUCER cable strain relief test..... 24

Figure 102 – Foam block test 25

Figure 103a – Linearity and hysteresis test set-up – Gas mix chamber, assembled 26

Figure 103b – Linearity and hysteresis test set-up – Gas mix chamber,
manufacturing dimensions..... 27

Figure 103c – Linearity and hysteresis test set-up – Gas mix chamber, dimensions
of hose connector..... 28

Figure 104 – EMC test set-up for conducted and radiated emission,
and radiated immunity test 29

Appendix L (normative) References – Publications mentioned in this standard..... 30

Annex AA (informative) General guidance and rationale..... 31

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-23 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-23 cancels and replaces the first edition published in 1993, and constitutes a technical revision. This second edition also covers the scope of IEC 60601-3-1 published in 1996.

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

FDIS	Report on voting
62D/335/FDIS	62D/345/RVD

Full information on the voting for the approval of this Particular 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.

A bilingual version of this standard may be issued at a later date.

Appendix L forms an integral part of this Standard.

Annex AA is for information only.

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, instructions, general statements, exceptions and references: in smaller roman type;
- *test specifications: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that this publication remains valid until 2005. At this date, in accordance with the committee's decision, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment

SECTION ONE – GENERAL

The clauses and subclauses of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety, including essential performance, of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT, as defined in 2.101 and hereinafter referred to as EQUIPMENT, whether this EQUIPMENT is stand alone or part of a system.

It applies to transcutaneous monitors used with adults, children and neonates, and it includes the use of these devices in foetal monitoring during birth.

It does not apply to haemoglobin saturation oximeters or to devices applied to surfaces of the body other than the skin (for example conjunctiva, mucosa).

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 2.101.

1.3 Particular standards

Addition:

This Particular Standard amends and supplements a set of IEC publications consisting of:

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1, amendment 2,

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests* and

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*.