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

Reference number
IEC 60601-2-23:1999(E)

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Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* See web site address on title page.

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.*

For brevity, IEC 60601-1 is referred to, in this Particular Standard, either as the "General Standard" or as the "General Requirement(s)".

The term "this Standard" covers the Particular Standard used together with the General Standard and any Collateral Standards.

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

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and any additional items *aa), bb),* etc.

Clauses and subclauses for which there is a rationale are marked with an asterisk*. These rationales can be found in an informative annex AA. Annex AA should be used in determining the relevance of the requirements addressed, but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or Collateral Standard takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5
APPLIED PART

Replacement:

TRANSDUCER and its connecting lead.

Additional definitions:

2.101
TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT (EQUIPMENT)
device and associated TRANSDUCERS for the monitoring of partial pressures of oxygen and/or carbon dioxide at the skin surface

2.102
TRANSDUCER
device for converting the partial pressure of a gas into a signal for monitoring or recording

2.103
TEMPERATURE LIMITER
means of limiting the temperature of the APPLIED PART INTERFACE

2.104
SET TEMPERATURE
desired applied part interface temperature

2.105
WARNING SIGNAL
means of signalling a predetermined state of a physiological parameter or EQUIPMENT

2.106
APPLIED PART INTERFACE
that portion of the APPLIED PART intended to come into contact with the PATIENT's skin

2.2.102
MULTIFUNCTION PATIENT MONITORING EQUIPMENT
stationary or mobile EQUIPMENT powered by an electrical power source and including one or more physiological monitoring units designed to collect information from a PATIENT, process it and generate ALARMS

2.12.101
ALARM
signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT

2.12.102
PHYSIOLOGICAL ALARM
signal which either indicates that a monitored physiological parameter is out of the specified limits or indicates an abnormal PATIENT condition

2.12.103
TECHNICAL ALARM
signal which indicates that an EQUIPMENT is not capable of accurately monitoring or no longer monitors the PATIENT's condition

2.12.104
SILENCING
stopping an auditory ALARM manifestation by manual action

2.12.105
SILENCING/RESET
stopping a visual and/or auditory ALARM manifestation and re-enabling the equipment response to an abnormal PATIENT condition

2.12.106
INHIBITION
disabling, or SILENCING and disabling, an ALARM until intentionally revoked

2.12.107
SUSPENSION
disabling, or SILENCING and disabling, an ALARM temporarily

2.12.108
LATCHED ALARM
an ALARM, the visual and auditory manifestation of which does not stop when the parameter returns to a value which no longer exceeds the ALARM limit or when the abnormal PATIENT condition does not exist any longer

2.12.109
NON-LATCHED ALARM
an ALARM, the visual and auditory manifestation of which stops when the parameter returns to a value which no longer exceeds the ALARM limit or when the abnormal PATIENT condition does not exist any longer

3 General requirements

This clause of the General Standard applies except as follows:

3.6 SINGLE FAULT CONDITION

Additional item:

aa) Any single failure in the EQUIPMENT resulting in a transfer of energy to the APPLIED PART which is greater than that necessary to maintain the SET TEMPERATURE value.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.11 Sequence

Amendment:

The tests called for in item h) of clause 17 shall be performed prior to the LEAKAGE CURRENT and dielectric strength tests of clauses C.24 and C.25 of the General Standard.

5 Classification

This clause of the General Standard applies except as follows:

***5.2** According to the degree of protection against electric shock:

Amendment:

Delete TYPE B APPLIED PART.