

Medical electrical equipment —

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

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/96, Monitoring equipment, which has the responsibility to:

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- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, the EN foreword page, pages 3 to 35, the annex ZA and ZB pages and a back cover.

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Partie 2-23: Règles particulières de sécurité et performances essentielles des appareils de surveillance de la pression partielle transcutanée
(CEI 60601-2-23:1999)

Medizinische elektrische Geräte
Teil 2-23: Besondere Festlegungen für die Sicherheit einschließlich wesentlicher Leistungsmerkmale von Geräten für die transkutane Partialdrucküberwachung
(IEC 60601-2-23:1999)

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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.

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CENELEC

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

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Foreword

The text of document 62D/335/FDIS, future edition 2 of IEC 60601-2-23, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-23 on 2000-01-01.

This European Standard supersedes EN 60601-2-23:1997.
This European Standard also covers the scope of EN 60601-3-1:1996.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2000-10-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-01-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-23:1999 was approved by CENELEC as a European Standard without any modification.

CONTENTS

Page

SECTION ONE – GENERAL

1	Scope and object.....	4
2	Terminology and definitions	5
3	General requirements	8
4	General requirements for tests.....	8
5	Classification.....	8
6	Identification, marking and documents	9

SECTION TWO – ENVIRONMENTAL CONDITIONS

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

14	Requirements related to classification	10
17	Separation	10
20	Dielectric strength	10

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21	Mechanical strength	10
----	---------------------------	----

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

*36	Electromagnetic compatibility	11
-----	-------------------------------------	----

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.....	14
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	15
49	Interruption of the power supply.....	15

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
Annex ZA (normative) Normative references to international publications with their corresponding European publicatins	32
Annex ZB (informative) Other international publications mentioned in this standard with the references of the relevant European publications.....	33

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.

5.6 According to the mode of operation:

Amendment:

Delete all but CONTINUOUS OPERATION.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.8.2 Instructions for use

Additional item:

aa) Supplementary instructions for use

Advice shall be given on the following:

- 1) Procedures affecting the safety of operation, in particular the temperature selection and duration of monitoring time, on that particular site at that temperature, based upon clinical evaluation of the PATIENT, for example age, weight and physiological condition.
- 2) Choice of TRANSDUCERS and ACCESSORIES, where the use of other TRANSDUCERS and ACCESSORIES could degrade the safety of the EQUIPMENT.
- *3) Use of the EQUIPMENT with high frequency surgical EQUIPMENT, to avoid burns to the PATIENT and damage to the TRANSDUCER, including, if applicable, a statement that the TRANSDUCER shall be removed from the PATIENT during the high frequency surgical procedures.
- 4) The ACCOMPANYING DOCUMENTS shall contain information on protection against the effects of defibrillation.
- 5) Those parts of the EQUIPMENT which are protected against the effects of a discharge of a cardiac defibrillator.
- 6) Any precautions to be taken when a defibrillator is used on a PATIENT and information on any effects of a discharge of a cardiac defibrillator on the EQUIPMENT and the TRANSDUCER.
- 7) The ACCOMPANYING DOCUMENTS shall contain a statement to the effect: "This EQUIPMENT is not a blood gas device".
- *8) For TRANSDUCERS and cables, particularly disposable TRANSDUCERS, the manufacturer shall state the recommended usable safe life.
- *9) Proper handling of TRANSDUCERS and their ACCESSORIES to avoid damage to these delicate components, thereby extending their useful life. In addition, these instructions shall refer, in particular, to the TRANSDUCER to cable connection and provide information on the measures that the USER should adopt to prevent damage to this connection.
- 10) If the EQUIPMENT can be connected to other medical or non-medical EQUIPMENT, this combination shall comply with IEC 60601-1-1.
- 11) Information on the warm-up time for the TRANSDUCER and EQUIPMENT.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.