SLOVENSKI STANDARD
SIST EN 60601-2-23:2002

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Nadomešča:
SIST EN 60601-2-23:1998

Medicinska električna oprema - 2-23. del: Posebne varnostne zahteve za opremo za transkutano (skozikožno) nadzorovanje delnega tlaka (IEC 60601-2-23:1999)

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

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

Ta slovenski standard je istoveten z: **EN 60601-2-23:2000**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-23:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-23

March 2000

ICS 11.040.55

Supersedes EN 60601-2-23:1997

English version

Medical electrical equipment
Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment
(IEC 60601-2-23:1999)

Appareils électromédicaux
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Medizinische elektrische Geräte
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(IEC 60601-2-23:1999)

This European Standard was approved by CENELEC on 2000-01-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 European Standard 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and 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

Ref. No. EN 60601-2-23:2000 E

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.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60601-1-1	1992	Medical electrical equipment Part 1: General requirements for safety 1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 60601-1-2	1993	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. December	1993 1997
IEC 60601-1-4	1996	Part 1-4: General requirements for safety Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
IEC 61000-4-3 (mod)	1995	Electromagnetic compatibility (EMC) Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996
IEC 61000-4-6	1996	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996

Annex ZB (informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 60601-3-1	1996	Medical electrical equipment Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment	EN 60601-3-1	1996

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

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

IEC Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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.*

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