SLOVENSKI STANDARD

SIST EN 60601-3-1:1998

01-september-1998

Medical electrical equipment - Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment (IEC 60601-3-1:1996)

Medical electrical equipment -- Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment

Medizinische elektrische Geräte -- Teil 3-1: Wesentliche Anforderungen an die Leistungsfähigkeit für Geräte für die transkutane Partialdrucküberwachung von Sauerstoff und Kolhlendioxid

Appareils électromédicaux -- Partie 3-1: Prescriptions essentielles de performances pour les appareils de surveillance de la pression partielle transcutanée de l'oxygène et du dioxyde de carbone

Ta slovenski standard je istoveten z: **EN 60601-3-1:1996**

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Medical electrical equipment
Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment
(IEC 601-3-1:1996)

Appareils électromédicaux
Partie 3-1: Prescriptions essentielles de performances pour les appareils de surveillance de la pression partielle transcutanée de l'oxygène et du dioxyde de carbone
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Teil 3-1: Wesentliche Anforderungen an die Leistungsfähigkeit für Geräte für die transkutane Partialdrucküberwachung von Sauerstoff und Kolhlendioxid
(IEC 601-3-1:1996)

This European Standard was approved by CENELEC on 1996-10-01. 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, 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

Foreword

The text of document 62D/189/FDIS, future edition 1 of IEC 601-3-1, 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 60601-3-1 on 1996-10-01.

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) 1997-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-07-01

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 annex A is informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-3-1:1996 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
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2 A13	1995 1996
IEC 601-2-23	1993	Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment	-	-

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Appareils électromédicaux –

Partie 3-1:
Prescriptions essentielles de performances pour les appareils de surveillance de la pression partielle transcutanée de l'oxygène et du dioxyde de carbone

Medical electrical equipment –

Part 3-1:
Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide 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 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. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 601-3-1 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/189/FDIS	62D/209/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.

Annex A 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, introductions, general statements, exceptions and references: in smaller type;

– *test specifications: in italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 3 AND IN IEC 601-1: SMALL CAPITALS

INTRODUCTION

These performance requirements, while different in presentation from ASTM standard specification for transcutaneous gas monitoring devices for oxygen and carbon dioxide F984-86, are closely aligned with those requirements.

Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment constitute a Part 3 of IEC 601, as long as these requirements for the functional performance do not directly affect safety.

A particular standard for functional performance does not normally specify minimum levels of performance but requires the disclosure of the functional performance of the equipment in a standardized way in order that users, manufacturers and test authorities have a common understanding of the parameters concerned.

A Part 3 contains the terminology, terms and definitions applicable to a particular kind of medical electrical equipment as well as the tests to be used in order that a manufacturer's declared performance can be tested in a uniform and acceptable way.

The numbering of clauses and subclauses of this Particular Standard do not relate to those of the General Standard IEC 601-1.

A 'Guidance and rationale' section for the more important requirements is given in annex A.

Clauses or subclauses for which there are explanatory notes in annex A are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practices or as a result of developments in clinical technology. However, this annex does not form part of the requirements of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment

1 Scope and object

1.1* *Scope*

This part of IEC 601 is a Particular Standard which specifies essential requirements for the performance of TRANSCUTANEOUS OXYGEN AND CARBON DIOXIDE PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 3.1, hereinafter referred to as EQUIPMENT.

It applies to transcutaneous monitors intended for use with adults, children and neonates, and 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 such as conjunctiva or mucosa.

1.2 *Object*

The object of this standard is to establish certain requirements for a satisfactory level of performance for EQUIPMENT and to establish test conditions for certain disclosure requirements.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 601. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 601 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 601-2-23: 1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment*