SLOVENSKI STANDARD
SIST EN 60601-2-30:2002

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Nadomešča:
SIST EN 60601-2-30:1998

Medicinska električna oprema - 2-30. del: Posebne varnostne zahteve za opremo, vključno z njenimi osnovnimi lastnostmi, za posredno nadzorovanje krvnega tlaka z avtomatičnim cikliranjem (IEC 60601-2-30:1999)

Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999)

Medizinische elektrische Geräte - Teil 2-30: Besondere Festlegungen für die Sicherheit, einschließlich der wesentlichen Leistungsfähigkeit von automatischen, zyklischen, nicht-invasiven Blutdrucküberwachungsgeräten (IEC 60601-2-30:1999)

Appareils électromédicaux - Partie 2-30: Règles particulières de sécurité et performances essentielles des appareils de surveillance de la pression sanguine prélevée indirectement, automatiquement et périodiquement (CEI 60601-2-30:1999)

Ta slovenski standard je istoveten z: **EN 60601-2-30:2000**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-30:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-30

May 2000

ICS 11.040.01

Supersedes EN 60601-2-30:1995

English version

Medical electrical equipment
Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
(IEC 60601-2-30:1999)

Appareils électromédicaux
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(IEC 60601-2-30:1999)

This European Standard was approved by CENELEC on 2000-02-01. 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 60601-2-30:2000 E

Foreword

The text of document 62D/339/FDIS, future edition 2 of IEC 60601-2-30, 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 60601-2-30 on 2000-02-01.

This European Standard supersedes EN 60601-2-30:1995.

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) 2000-11-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-02-01

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, BB and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-30:1999 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 60601-1-4	1996	Medical electrical equipment Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
IEC 60601-2-2	1982	Part 2: Particular requirements for the safety of high frequency surgical equipment	HD 395.2.2 S1[1)]	1985
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
IEC 61000-4-8	1993	Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	1993
CISPR 11 (mod)	1990	Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	EN 55011[2)]	1991
ISO 1000	1992	SI units and recommendations for the use of their multiples and of certain other units	-	-

1) HD 395.2.2 is superseded by EN 60601-2-2:1993, which is based on IEC 60601-2-2:1991.

2) EN 55011 is superseded by EN 55011:1998, which is based on CISPR 11:1997, mod.

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 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
IEC 60601-1	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 + corr. June	1995 1995		A2 A13	1995 1996
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	1993

INTERNATIONAL STANDARD

IEC 60601-2-30

Second edition
1999-12

Medical electrical equipment –

Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

Appareils électromédicaux –

Partie 2-30: Règles particulières de sécurité et performances essentielles des appareils de surveillance de la pression sanguine prélevée indirectement, automatiquement et périodiquement

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood 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 60601-2-30 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-30 cancels and replaces the first edition published in 1995, and constitutes a technical revision.

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

FDIS	Report on voting
62D/339/FDIS	62D/350/RVD

Full information on the voting for the approval of this 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.

Annexes AA and BB are 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, headings of subclauses and headings of items: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD 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.

INTRODUCTION

This Particular Standard concerns the safety of automatic cycling non-invasive blood pressure monitoring equipment. It amends and supplements IEC 60601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled *"Medical electrical equipment – Part 1: General requirements for safety"*.

A "General guidance and rationale" for the requirements of this Particular Standard is included in annex AA.

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 practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in annex AA.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section 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 AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as defined in 2.102, hereinafter referred to as EQUIPMENT. The EQUIPMENT may be attended or unattended.

This Particular Standard does not apply to blood pressure measuring equipment which uses finger transducers or to semi-automatic blood pressure measuring equipment, typically in which each determination needs to be initiated manually.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT, with special attention being paid to the avoidance of hazards due to the inflation process.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1: 1988, Medical electrical equipment – Part 1: General requirements for safety, as amended by its amendment 1 (1991) and amendment 2 (1995). The General Standard also takes into account 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 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses or 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 additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard and Collateral Standards mentioned above.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Replacement:

The occluding cuff and any integral transducers, their connecting leads and pressure tubes.

Additional definitions:

2.101 ALARM

A signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT.

2.102 AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT (EQUIPMENT)

A device, or part of a physiological monitoring or measuring system, including its associated accessories used for intermittent assessment of a PATIENT's blood pressure by an externally applied means.

2.103 INHIBITION

Disabling or SILENCING and disabling an ALARM until revoked intentionally.

2.104 LATCHED ALARM

An ALARM, the visual and auditory manifestation of which does not stop when the parameter (which caused the alarm) returns to a value which no longer exceeds the alarm limit or if the abnormal PATIENT condition does not exist any longer.

2.105 LONG TERM AUTOMATIC MODE

A mode in which a timer, set by the OPERATOR, initiates the measurements.

2.106 MANUAL MODE

A mode in which the OPERATOR has full control of the initiation of each measurement.

2.107 NON-LATCHED ALARM

An ALARM, the visual and auditory manifestation of which stops when the parameter (which caused the alarm) returns to a value which no longer exceeds the alarm limit or if the abnormal PATIENT condition does not exist any longer.

2.108 PHYSIOLOGICAL ALARM

A signal which either indicates that a monitored physiological parameter is out of specified limits or indicates an abnormal PATIENT condition.

*2.109 SHORT TERM AUTOMATIC MODE

A mode in which as many automatic measurements as possible are made within a specified time period.

2.110 SILENCING

The stopping of an auditory ALARM manifestation by manual action.

2.111 SILENCING/RESET

The stopping of a visual and/or auditory ALARM manifestation and re-enabling of the EQUIPMENT's response to an abnormal PATIENT condition.

2.112 SUSPENSION

Disabling or SILENCING and disabling an ALARM temporarily.

2.113 TECHNICAL ALARM

A signal which indicates that the EQUIPMENT or part(s) of the EQUIPMENT is not capable of accurately monitoring the PATIENT's condition.

3 General requirements

This clause of the General Standard applies except as follows:

3.6 SINGLE FAULT CONDITION

Addition:

Any single defect which:

aa) results in a failure of the normal pressure regulating means, or,

bb) prevents deflation of the cuff within the specified period, or,

cc) results in a failure of the normal cuff pressurization timing.