SLOVENSKI STANDARD
SIST EN 80601-2-30:2010

01-december-2010

Nadomešča:
SIST EN 60601-2-30:2002

Medicinska električna oprema - 2-30. del: Posebne zahteve za osnovno varnost in bistvene lastnosti avtomatiziranih neinvazivnih sfigmomanometrov (IEC 80601-2-30:2009 + popravek Jan. 2010)

Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2009 + corrigendum Jan. 2010)

Medizinische elektrische Geräte - Teil 2-30: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von nicht-invasiven Sphygmomanometern von automatisierten Typ (IEC 80601-2-30:2009 + corrigendum Jan. 2010)

Appareils électromédicaux - Partie 2-30: Exigences particulières pour la sécurité de base et les performances essentielles de sphygmomanomètres non invasifs automatiques (CEI 80601-2-30:2009 + corrigendum Jan. 2010)

Ta slovenski standard je istoveten z: **EN 80601-2-30:2010**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 80601-2-30:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-30

September 2010

ICS 11.040

Supersedes EN 60601-2-30:2000

English version

Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

(IEC 80601-2-30:2009 + corrigendum Jan. 2010)

Appareils électromédicaux -
Partie 2-30: Exigences particulières
pour la sécurité de base
et les performances essentielles
de sphygmomanomètres non invasifs
automatiques
(CEI 80601-2-30:2009 + corrigendum Jan. 2010)

Medizinische elektrische Geräte -
Teil 2-30: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von nicht-invasiven Sphygmomanometern
von automatisierten Typ
(IEC 80601-2-30:2009 + corrigendum Jan. 2010)

This European Standard was approved by CENELEC on 2010-09-01. 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, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 80601-2-30:2010 E

Foreword

The text of document 62D/721/FDIS, future edition 1 of IEC 80601-2-30, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and SC 3, Lung ventilators and related equipment, of ISO TC 121, Anaesthetic and respiratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 80601-2-30 on 2010-09-01.

This European Standard supersedes EN 60601-2-30:2000.

EN 80601-2-30:2010 constitutes a major technical revision as well as an alignment with EN 60601-1:2006. Specific technical changes include: expansion of the scope to include all AUTOMATED SPHYGMOMANOMETERS including those where the PATIENT is the OPERATOR, identification of ESSENTIAL PERFORMANCE, new clinical accuracy requirements, additional mechanical strength requirements and prohibition of OPERATOR accessible 'Luer' connectors in the PNEUMATIC SYSTEM.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

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) 2011-06-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2013-09-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 80601-2-30:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

[1] ISO 9919:2005 NOTE Harmonized as EN ISO 9919:2005 (not modified).

[3] ISO 21647:2004 NOTE Harmonized as EN ISO 21647:2004 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace *the reference to IEC 60601-1-2 by:*				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
Addition:				
IEC 60068-2-27	2008	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	EN 60068-2-27	2009
IEC 60068-2-31	2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	EN 60068-2-31	2008
IEC 60068-2-64	2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	EN 60068-2-64	2008
IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2	2009
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	EN 20594-1	1993
ISO 594-2	1991	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings	-	-
ISO 81060-2	2009	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC with the exception of ERs 3, 4, 7.1 and 12.1.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

IEC 80601-2-30

Edition 1.0 2009-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Appareils électromédicaux –
Partie 2-30: Exigences particulières pour la sécurité de base et les performances essentielles des sphygmomanomètres non invasifs automatiques

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. 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 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 IEC National Committees.

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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 80601-2-30 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electrical equipment, of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This first edition of IEC 80601-2-30 cancels and replaces the second edition of IEC 60601-2-30, published in 1999. This edition constitutes a major technical revision as well as an alignment with the third edition of IEC 60601-1. Specific technical changes include: expansion of the scope to include all AUTOMATED SPHYGMOMANOMETERS including those where the PATIENT is the OPERATOR, identification of ESSENTIAL PERFORMANCE, new clinical accuracy requirements, additional mechanical strength requirements and prohibition of OPERATOR accessible 'Luer' connectors in the PNEUMATIC SYSTEM.

This publication is published as a double logo standard.

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

FDIS	Report on voting
62D/721/FDIS	62D/737/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. In ISO, the standard has been approved by 13 P-members out of 17 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
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In referring to the structure of this standard, the term

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– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this particular standard will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

The contents of the corrigendum of January 2010 have been included in this copy.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of an AUTOMATED SPHYGMOMANOMETER.

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

It is considered that 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.