SLOVENSKI STANDARD
SIST EN 80601-2-30:2010/A1:2015

01-september-2015

Medicinska električna oprema - 2-30. del: Posebne zahteve za osnovno varnost in bistvene lastnosti avtomatiziranih neinvazivnih sfigmomanometrov - Dopolnilo A1

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

Medizinische elektrische Geräte - Teil 2-30: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von automatisierten nicht-invasiven Blutdruckmessgeräten

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

Ta slovenski standard je istoveten z: **EN 80601-2-30:2010/A1:2015**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 80601-2-30:2010/A1:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-30:2010/A1

May 2015

ICS 11.040

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/A1:2013)

Appareils électromédicaux - Partie 2-30: Exigences particulières pour la sécurité de base et les performances essentielles de sphygmomanomètres non invasifs automatiques
(IEC 80601-2-30:2009/A1:2013)

Medizinische elektrische Geräte - Teil 2-30: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von automatisierten nicht-invasiven Blutdruckmessgeräten
(IEC 80601-2-30:2009/A1:2013)

This amendment A1 modifies the European Standard EN 80601-2-30:2010; it was approved by CENELEC on 2015-04-14. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 CEN-CENELEC Management Centre or to any CENELEC member.

This amendment 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 CEN-CENELEC Management Centre 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 80601-2-30:2010/A1:2015 E

Foreword

The text of document 62D/1072/FDIS, future IEC 80601-2-30:2009/A1, prepared by SC 62D "Electrical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80601-2-30:2010/A1:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-14

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 80601-2-30:2010.

Endorsement notice

The text of the International Standard IEC 80601-2-30:2009/A1:2013 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Modifications in Annex ZA of EN 80601-2-30:2010:

Publication	Year	Title	EN/HD	Year
Add after the existing reference to IEC 60601-1-2:2007, the following new references:				
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+A1	2013		+A1	2015
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8 + corr. March	2007 2010
+A1	2012		+A1 +A1/AC	2013 2014
Add to the list of references under the existing instruction "Addition:" the following new references:				
IEC 60601-1-11	2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	EN 60601-1-11	2010
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008
Replace the existing reference to ISO 81060-2 by the following:				
ISO 81060-2	2013	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	-	-

IEC 80601-2-30

Edition 1.0 2013-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

PRICE CODE
CODE PRIX L

ICS 11.040

ISBN 978-2-8322-1003-1

FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/1072/FDIS	62D/1079/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 14 P-members out of 15 having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability 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 and Member Bodies 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 or ISO 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

INTRODUCTION TO THE AMENDMENT

This amendment deals primarily with editorial corrections and clarifications, clarifies requirements for operation in the loss of SUPPLY MAINS and references new and updated collateral standards.

To meet needs for change which were identified by users of this particular standard, it was necessary to amend the standard before the previously approved maintenance cycle date.

201.1 Scope, object and related standards

Add at the end of footnote 1), “including Amendment 1:2012”.

201.1.1 Scope

In the first paragraph, replace “intermittent” *with* “non-continuous”.

201.2 Normative references

Replace the initial instruction concerning amendment of the reference to IEC 60601-1-2 by the same instruction in the plural form, as follows:

Amendment of the following references:

Add, after the existing reference to IEC 60601-1-2:2007, the following new references:

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012

Add to the list of references under the existing instruction "Addition:" the following new references:

IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

Replace the existing reference to ISO 81060-2 by the following:

ISO 81060-2:2013, *Non-invasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type*