SLOVENSKI STANDARD
SIST EN 80601-2-35:2010/A1:2017

01-februar-2017

Medicinska električna oprema - 2-35. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za rjuhe, blazine in posteljne vložke, namenjene za ogrevanje pri medicinski uporabi - Dopolnilo A1 (IEC 80601-2-35:2009/A1:2016)

Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601-2-35:2009/A1:2016)

Medizinische elektrische Geräte - Teil 2-35: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Decken, Matten und Matratzen zur Erwärmung von Patienten in der medizinischen Anwendung

Appareils électromédicaux - Partie 2-35: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de réchauffage utilisant des couvertures, des coussins ou des matelas chauffants et destinés au réchauffage des patients en usage médical

Ta slovenski standard je istoveten z: **EN 80601-2-35:2009/A1:2016**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN 80601-2-35:2010/A1:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-35:2009/A1

December 2016

ICS 11.040.01

English Version

Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601-2-35:2009/A1:2016)

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This amendment A1 modifies the European Standard EN 80601-2-35:2009; it was approved by CENELEC on 2016-06-03. 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

European foreword

The text of document 62D/1328/FDIS, future IEC 80601-2-35:2009/A1, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" and SC 1 “Breathing attachments and anaesthetic machines” of ISO/TC 121 “Anaesthetic and respiratory equipment” was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80601-2-35:2009/A1:2016.

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) 2017-06-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-12-16

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(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 80601-2-35:2009/A11:2011.

Endorsement notice

The text of the International Standard IEC 80601-2-35:2009/A1:2016 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 80601-2-35:2009, replace the existing references [10], [11] and [12] by the following:

[10] IEC 60601-2-19	NOTE	Harmonized as EN 60601-2-19.
[11] IEC 60601-2-20	NOTE	Harmonized as EN 60601-2-20.
[12] IEC 60601-2-21	NOTE	Harmonized as EN 60601-2-21.

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.

Publication	Year	Title	EN/HD	Year
In Annex ZA of EN 80601-2-35:2009, replace the existing references to IEC 60601-1-2:2007, IEC 60601-1-8:2006 and IEC 60601-1-10:2007 as follows:				
IEC 60601-1-2	-	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1-8	-	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. Mar. + A1 + A1/AC	2007 2010 2013 2014
IEC 60601-1-10	-	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	EN 60601-1-10 + A1	2008 2015

In Annex ZA of EN 80601-2-35:2009, delete ISO 3743-1.

IEC 80601-2-35

Edition 2.0 2016-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use

Appareils électromédicaux – Partie 2-35: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de réchauffage utilisant des couvertures, des coussins ou des matelas chauffants et destinés au réchauffage des patients en usage médical

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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FOREWORD

This amendment has been prepared by a joint working group of IEC subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee TC121/SC1: Breathing attachments and anaesthetic machines, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo standard.

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

FDIS	Report on voting
62D/1328/FDIS	62D/1355/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 15 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 website 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.

INTRODUCTION

Replace, in the second paragraph, “IEC 60601-1 (third edition, 2005)” *by* “IEC 60601-1”.

201.1 Scope, object and related standards

Replace, in footnote 1), “IEC 60601-1:2005” *by* “IEC 60601-1”.

201.2 Normative references

Replace “IEC 60601-1-2:2007” *by* “IEC 60601-1-2”.

Replace “IEC 60601-1-8:2006” *by* “IEC 60601-1-8”.

Replace “IEC 60601-1-10:2007” *by* “IEC 60601-1-10”.

Delete the following reference:

ISO 3743-1:1994, *Acoustics – Determination of sound power levels of noise sources – Engineering methods for small, movable sources in reverberant fields – Part 1: Comparison method for hard-walled test rooms*

201.3 Terms and definitions

Replace, in the first paragraph, "IEC 60601-1:2005*" by* "IEC 60601-1".

201.7.2.1.101.2 CONTROLLERS

Replace the text in item a) by the following new text:

a) The HOSE shall be marked within 15 cm of the NOZZLE to caution that the NOZZLE needs to be connected to a BLANKET. The following statement and the safety sign ISO 7010-M002 (see IEC 60601-1, Table D.2, safety sign 10) shall accompany the "NO FREE HOSING" safety sign of IEC 60878, shown in Annex D of this particular standard:

201.8.5.1.2.101 * Additional requirements for MEANS OF PATIENT PROTECTION (MOPP)

Replace the first two paragraphs by the following:

The electrical circuit within the APPLIED PART shall be isolated from earth by at least one MOPP and from MAINS by at least two MOPP. Where a transformer is used to achieve this isolation, it need not meet 15.5.3.

201.12.3.104 Disconnection or short-circuiting of sensors ALARM CONDITION

Replace the second paragraph by the following:

The HEATING DEVICE shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION for HIGH HEAT TRANSFER DEVICES and at least a LOW PRIORITY ALARM for LOW HEAT TRANSFER DEVICES and FORCED AIR DEVICES that indicates when leads to either the temperature control sensors or the THERMAL CUT-OUT sensors are damaged or otherwise disconnected from the control unit.

202 Electromagnetic compatibility – Requirements and tests

Replace, in the first paragraph, "IEC 60601-1-2:2007" *by* "IEC 60601-1-2".

202.6.2.3 Radiated RF electromagnetic fields

Replace the number, title and entire text by the following new subclause number, title and text:

202.8.9 IMMUNITY TEST LEVELS

Addition:

For radiated radio-frequency electromagnetic fields, the HEATING DEVICE and/or system shall