SLOVENSKI STANDARD
SIST EN 60601-2-19:2009/A1:2017

01-februar-2017

Medicinska električna oprema - 2-19. del: Posebne zahteve za osnovno varnost in bistvene lastnosti otroških inkubatorjev - Dopolnilo A1 (IEC 60601-2-19:2009/A1:2016)

Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2009/A1:2016)

Medizinische elektrische Geräte - Teil 2-19: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglingsinkubatoren

Appareils électromédicaux - Partie 2-19: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs pour nouveau-nés

Ta slovenski standard je istoveten z: **EN 60601-2-19:2009/A1:2016**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN 60601-2-19:2009/A1:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-19:2009/A1

December 2016

ICS 11.040.10

English Version

Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2009/A1:2016)

Appareils électromédicaux - Partie 2-19: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs pour nouveau-nés (IEC 60601-2-19:2009/A1:2016)

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This amendment A1 modifies the European Standard EN 60601-2-19:2009; 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/1324/FDIS, future IEC 60601-2-19:2009/A1, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-19:2009/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 60601-2-19:2009/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-19:2009/A1:2016 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-19:2009, the following note has to be added for the standard indicated :

ISO 80601-2-56	NOTE	Harmonized as EN ISO 80601-2-56.

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 60601-2-19:2009, replace the existing reference to IEC 60601-1-2:2007 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
In Annex ZA of EN 60601-2-19:2009, delete IEC 60601-1-10:2007.				

IEC 60601-2-19

Edition 2.0 2016-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

Appareils électromédicaux –
Partie 2-19: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs pour nouveau-nés

INTERNATIONAL
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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/1324/FDIS	62D/1345/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.

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 60601-1:2005” *by* “IEC 60601-1”.

201.1 Scope, object and related standards

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

201.1.3 * Collateral standards

Delete the asterisk (*) from the title.

Replace the second paragraph by the following text:

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Add an asterisk at the beginning of the title, as follows:

201.1.4 * Particular standards

Add the following paragraph at the end of this subclause:

SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED INCUBATOR including the displayed value are considered to be not a CLINICAL THERMOMETER in the sense of the particular standard ISO 80601-2-56.

201.2 Normative references

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

Delete the IEC 60601-1-10:2007 reference.

201.3 Terms and definitions

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

201.3.204
BABY CONTROLLED INCUBATOR

Remove the note at the end of the entry.

201.7.9.2.2 * Warning and safety notices

Add, after the existing text, the following new text:

*l) a statement that the INFANT INCUBATOR cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and SKIN TEMPERATURE (hypothermia), and a recommendation to monitor the temperature of the PATIENT.

201.12.1.109 * Accuracy of indication of relative humidity

Replace, in the first paragraph, “of actual measured value” *by* “relative humidity”.

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 INFANT INCUBATOR and/or system shall

– continue to perform its intended function as specified by the MANUFACTURER at a level up to 3 V/m for the frequency range of the collateral standard for EMC.