

SLOVENSKI STANDARD

SIST EN IEC 60601-2-19:2021

01-september-2021

Nadomešča:

SIST EN 60601-2-19:2009

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

SIST EN 60601-2-19:2009/A11:2012

Medicinska električna oprema - 2-19. del: Posebne zahteve za osnovno varnost in bistvene lastnosti otroških inkubatorjev (IEC 60601-2-19:2020)

Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2020)

Medizinische elektrische Geräte - Teil 2-19: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglingsinkubatoren (IEC 60601-2-19:2020)

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Appareils électromédicaux - Partie 2-19: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs pour nouveau-nés (IEC 60601-2-19:2020)

Ta slovenski standard je istoveten z: EN IEC 60601-2-19:2021

ICS:

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

EN IEC 60601-2-19

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2021

ICS 11.040.10

Supersedes EN 60601-2-19:2009 and all of its
amendments and corrigenda (if any)

English Version

Medical electrical equipment - Part 2-19: Particular requirements
for the basic safety and essential performance of infant
incubators
(IEC 60601-2-19:2020)

Appareils électromédicaux - Partie 2-19: Exigences
particulières pour la sécurité de base et les performances
essentielles des incubateurs pour nouveau-nés
(IEC 60601-2-19:2020)

Medizinische elektrische Geräte - Teil 2-19: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Säuglingsinkubatoren
(IEC 60601-2-19:2020)

This European Standard was approved by CENELEC on 2020-10-07. 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 CEN-CENELEC Management Centre or to any CENELEC member.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 60601-2-19:2021 (E)**European foreword**

The text of document 62D/1764/FDIS, future edition 3 of IEC 60601-2-19, 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 IEC 60601-2-19:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2022-01-16 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2024-07-16 document have to be withdrawn

This document supersedes EN 60601-2-19:2009 and all of its amendments and corrigenda (if any).

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

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Endorsement notice
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The text of the International Standard IEC 60601-2-19:2020 was approved by CENELEC as a European Standard without any modification. IEC 60601-2-19:2021

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

IEC 60601-2-20:2020	NOTE	Harmonized as EN IEC 60601-2-20:2020 (not modified)
IEC 60601-2-21:2020	NOTE	Harmonized as EN IEC 60601-2-21:2020 (not modified)
IEC 60601-2-35:2020	NOTE	Harmonized as EN IEC 80601-2-35:2020 (not modified)
IEC 60601-2-50:2020	NOTE	Harmonized as EN IEC 60601-2-50:2020 (not modified)
IEC 61672-1	NOTE	Harmonized as EN 61672-1
ISO 80601-2-56	NOTE	Harmonized as EN ISO 80601-2-56
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where 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.

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following additions:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following replacements:

IEC 60601-1-2	2014	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
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INTERNATIONAL STANDARD

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

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.10

ISBN 978-2-8322-8711-8

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-19: Particular requirements for the basic safety
and essential performance of infant incubators**

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.
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International standard IEC 60601-2-19 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2009 and Amendment 1:2016. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: re-dating of normative references.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62D/1764/FDIS	62D/1774/RVD

Full information on the voting for the approval of this International 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 2.

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "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 document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

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

NOTE The attention of users of this document 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.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT INCUBATOR equipment.

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MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT INCUBATORS, as defined in 201.3.209, also referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document, except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.
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This particular standard specifies safety requirements for INFANT INCUBATORS, but alternate methods of compliance with a specific clause, by demonstrating equivalent safety, will not be judged as non-compliant, if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISK presented by the HAZARD has been found to be of an acceptable level when weighed against the benefit of treatment from the device.

This particular standard does not apply to:

- INFANT TRANSPORT INCUBATORS; for information, see IEC 60601-2-20 [1]²;
- INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [2];
- devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information, see IEC 60601-2-35 [3];
- INFANT PHOTOTHERAPY EQUIPMENT; for information see IEC 60601-2-50 [4].

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

¹ The general standard is IEC 60601-1 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

² Figures in square brackets refer to the Bibliography.