

BSI Standards Publication

Medical electrical equipment

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

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Full document details: BS EN IEC 60601-2-19:2021+A1:2023

National foreword

This British Standard is the UK implementation of EN IEC 60601-2-19:2021+A1:2023. It is identical to IEC 60601-2-19:2020, incorporating amendment 1:2023. It supersedes BS EN IEC 60601-2-19:2021, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Date	Text affected
31 January 2024	Implementation of IEC amendment 1:2023 with CENELEC endorsement A1:2023

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-19:2021+A1

December 2023

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)

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

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Ref. No. EN IEC 60601-2-19:2021 E

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

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

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Endorsement notice

The text of the International Standard IEC 60601-2-19:2020 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:

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

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European foreword to amendment A1

The text of document 62D/2067/FDIS, future IEC 60601-2-19/AMD1, 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/A1:2023.

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) 2024-09-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2026-12-14

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Endorsement notice

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

IEC 60601-1-10:2007	NOTE	Approved as EN 60601-1-10:2008 (not modified)
IEC 60601-1-10:2007/A1:2013	NOTE	Approved as EN 60601-1-10:2008/A1:2015 (not modified)
IEC 60601-1-10:2007/A2:2020	NOTE	Approved as EN 60601-1-10:2008/A2:2021 (not modified)
IEC 80601-2-49:2018	NOTE	Approved as EN IEC 80601-2-49:2019 (not modified)

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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:

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
+ A1	2012		+ A1	2013
			+ A12	2014
+ A2	2020		+ A2	2021

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 60601-1-12	2015
+A1	2020		+A1	2020
ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1	2020
ISO 18562-1	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process	EN ISO 18562-1	2020

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.

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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.

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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.

〈A1〉 INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1818/RR. 〈A1〉

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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 standard[1] 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.

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.

A1 1 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.* A1

2 Figures in square brackets refer to the Bibliography.

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201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT INCUBATORS as defined in 201.3.209, which minimize HAZARDS to PATIENT and OPERATOR, and to specify tests by which compliance with the requirements can be verified.

201.1.3 ⟦A1⟩ * ⟨A1⟧ Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

⟦A1⟩ IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply ⟨A1⟧ 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.

⟦A1⟩ If a BABY CONTROLLED INCUBATOR is based on a temperature measurement that is substantially influenced by the INFANT'S core or body temperature IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply. Examples for temperature measurements stipulating applicability of IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 are provided in Annex AA. ⟨A1⟧

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, ⟦A1⟩ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 ⟨A1⟧ are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

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"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

〈A1〉 IEC 80601-2-49 [15] applies to an INFANT INCUBATOR supplied with dedicated physiological monitoring. Measured parameters related to the inherent function of an INFANT INCUBATOR i.e. the SKIN TEMPERATURE, are not considered to be a physiological monitoring unit as per IEC 80601-2-49 [15]. 〈A1〉

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows:

Addition:

〈A1〉 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process* 〈A1〉

Replacement:

〈A1〉 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*
IEC 60601-1-2:2014/AMD1:2020 〈A1〉

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201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in A1 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 A1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found on page 42.

Addition:

201.3.201
AIR CONTROLLED INCUBATOR
INFANT INCUBATOR in which the air temperature is automatically controlled by an air temperature sensor according to the CONTROL TEMPERATURE set by the OPERATOR

201.3.202
AVERAGE INCUBATOR TEMPERATURE
average of the INCUBATOR TEMPERATURE readings taken at regular intervals achieved during STEADY TEMPERATURE CONDITION

SEE Figure 201.101

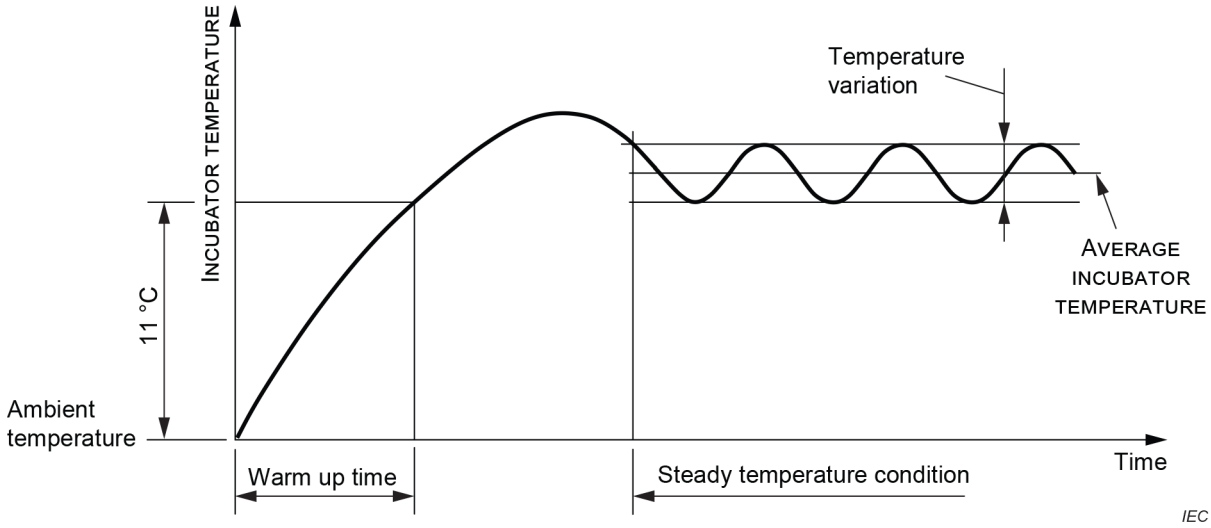


Figure 201.101 – Variation of INCUBATOR TEMPERATURE

201.3.203
AVERAGE TEMPERATURE
average of temperature readings taken at regular intervals at any specified point in the COMPARTMENT achieved during STEADY TEMPERATURE CONDITION

201.3.204
BABY CONTROLLED INCUBATOR
AIR CONTROLLED INCUBATOR which has the additional capability of automatically controlling the INCUBATOR air temperature in order to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR according to the CONTROL TEMPERATURE set by the OPERATOR

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