IEC 60601-2-19

Edition 3.0 2020-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

IEC 60601-2-19:2020-09(en-fr)

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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.

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.

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.

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.

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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.

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 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.

IEC 60601-1-2:2014 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

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, IEC 60601-1 and IEC 60601-1:2005/AMD1:2012 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.

"*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.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Addition:

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

Replacement:

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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 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 38.

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

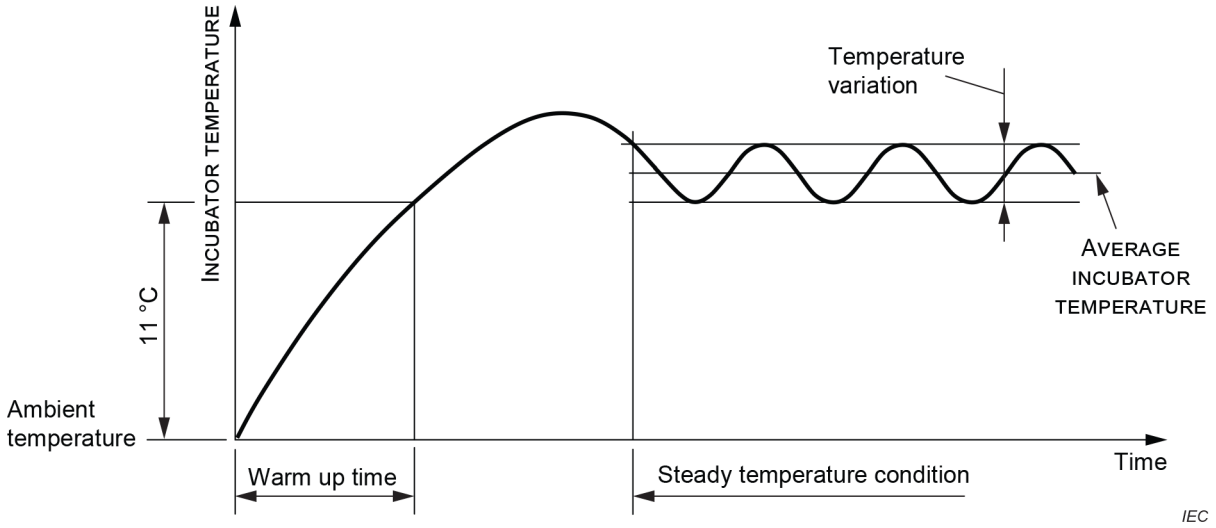


Figure 201.101 – Variation of INCUBATOR TEMPERATURE

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

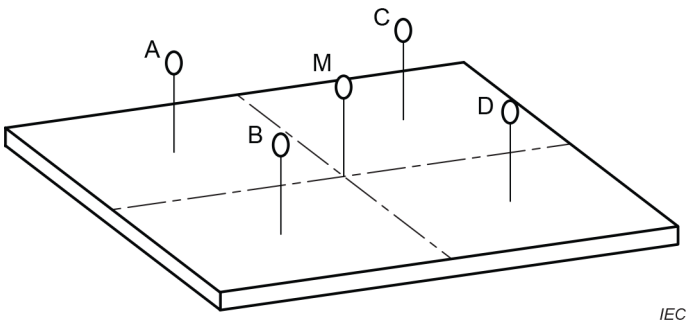
201.3.204
BABY CONTROLLED INCUBATOR
AIR CONTROLLED INCUBATOR which has the additional capability of automatically controlling the INCUBATOR air temperature in order to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR according to the CONTROL TEMPERATURE set by the OPERATOR

201.3.205
COMPARTMENT
environmentally-controlled enclosure intended to contain an INFANT and with transparent section(s) which allows for viewing of the INFANT

201.3.206
CONTROL TEMPERATURE
temperature selected at the temperature control

201.3.207
INCUBATOR TEMPERATURE
temperature of the air at a point 10 cm above the centre of the MATTRESS surface in the COMPARTMENT

SEE Figure 201.102, point M



Key

M INCUBATOR TEMPERATURE sensor

A, B, C, D air temperature sensor

The measuring points A to D and M are in a plane parallel to and at a distance of 10 cm from the MATTRESS.

Figure 201.102 – Positioning of air temperature sensors

201.3.208
INFANT
PATIENT up to the age of three months and a weight less than 10 kg

201.3.209
INFANT INCUBATOR
ME EQUIPMENT having a COMPARTMENT which is provided with the means to control the environment of the INFANT primarily by heated air within the COMPARTMENT

201.3.210
SKIN TEMPERATURE
temperature of the skin of the INFANT at a point on which the SKIN TEMPERATURE SENSOR is placed

201.3.211
SKIN TEMPERATURE SENSOR
sensing device intended to measure the INFANT SKIN TEMPERATURE

201.3.212
STEADY TEMPERATURE CONDITION
condition reached when the INCUBATOR TEMPERATURE does not vary by more than 1 °C over a period of 1 h

SEE Figure 201.101

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Addition:

For INFANT INCUBATORS which combine alternative heat sources, for instance INFANT INCUBATORS with integrated radiant warmers, devices supplying heat via BLANKETS, PADS or MATTRESSES, etc., the safety requirements of the particular standards for these alternative heat sources, if any, shall be met. The safety requirements of this particular standard shall not be altered by such additional heat sources specified by the MANUFACTURER, details of which are provided in the instruction for use.

Compliance is checked by the tests of Clause 201.11 and 201.15.4.2.1 of the relevant particular standards (e.g. IEC 60601-2-21:2020 or IEC 60601-2-35:2020).

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 ESSENTIAL PERFORMANCE of INFANT INCUBATORS

ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
ESSENTIAL PERFORMANCE requirement 1	201.12.1.104 or generation of a visual and audible alarm in compliance with 201.15.4.2.1 ee)
ESSENTIAL PERFORMANCE requirement 2	201.12.1.106 or generation of a visual and audible alarm in compliance with 201.15.4.2.1 dd)

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.3 Ambient temperature, humidity, atmospheric pressure

Replacement of item a):

a) * After the ME EQUIPMENT to be tested has been set up for NORMAL USE (according to 5.7), the ME EQUIPMENT shall comply with the requirements of this document when operating within the following conditions:
   - ambient temperature between +20 °C and +30 °C;
   - ambient air velocity less than 0,3 m/s.

Addition:

If not otherwise specified in this particular standard, all tests shall be carried out at an ambient temperature within the range of 21 °C to 26 °C.

201.5.4 Other conditions

Additional item to the existing list:

aa) If not otherwise specified, the CONTROL TEMPERATURE shall be 36 °C ± 1 °C and shall always exceed the ambient temperature by at least 3 °C.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

(see also Table C.1 of the general standard)

Additional subclauses:

201.7.2.101 * Oxygen monitor

An INFANT INCUBATOR not equipped with an integral oxygen monitor and which provides means for oxygen administration shall be marked in a prominent position with a text which states: "Use an oxygen monitor when oxygen is administered".

NOTE See also 7.5 of the general standard.

201.7.2.102 Heater surface temperature

If a heater is accessible without the use of a TOOL, a notice sign (see 7.5 of the general standard) or marking shall be displayed adjacent to the heater giving warning of high surface temperature.

201.7.4.2 * Control devices

Addition:

Temperature controls shall be clearly marked with temperature settings on or adjacent to the control. The markings shall be provided at intervals of not greater than 0,5 °C for AIR CONTROLLED INCUBATORS and not greater than 0,25 °C for BABY CONTROLLED INCUBATORS.

Marking of the maximum and the minimum values of controls and indicators shall be such that no confusion can arise with regard to the position of the control or the indicated values.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall contain the following additional items.

a) * A statement that an INFANT INCUBATOR should be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known RISKS and benefits of INFANT INCUBATOR use.

b) * A warning that direct sunlight or other radiant heat sources can cause an increase in INCUBATOR TEMPERATURE to dangerous levels.

c) * A statement that the use of oxygen increases the danger of fire and that auxiliary equipment producing sparks shall not be placed in the INFANT INCUBATOR.

d) * A warning that even small quantities of flammable agents, such as ether and alcohol, left in the INFANT INCUBATOR can cause fire in connection with oxygen.

e) * A statement of the maximum allowed weight of additional equipment which might be placed on shelves connected to the INFANT INCUBATOR.

f) For an INFANT INCUBATOR having a TYPE B APPLIED PARTS where the INFANT may not be isolated from earth, a warning that particular care shall be taken to ensure that additional equipment connected to the INFANT is electrically safe.

g) A warning stating that administration of oxygen may increase the noise level for the INFANT within the INFANT INCUBATOR.

h) Explanation of the operation of supplementary oxygen equipment supplied for use with the INFANT INCUBATOR or as specified in the ACCOMPANYING DOCUMENTS.

i) A statement that an oxygen analyzer shall be used when oxygen is delivered to the INFANT.

j) Details of any specified combinations of ME EQUIPMENT (see 201.4.1).