IEC 60601-2-19

Edition 2.1 2016-04
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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 60601-2-19:2009-02+AMD1:2016-04 CSV(en-fr)

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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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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-2-19 edition 2.1 contains the second edition (2009-02) [documents 62D/727/FDIS and 62D/756/RVD], its corrigendum 1 (2012-02) and its amendment 1 (2016-04) [documents 62D/1324/FDIS and 62D/1345/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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 second edition cancels and replaces the first edition published in 1990 and its Amendment 1 (1996). This edition constitutes a technical revision. It was revised to structurally align with the third edition (2005) of IEC 60601-1.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “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 the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site 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.

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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.

This particular standard amends and supplements IEC 60601-1~~:2005~~, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

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 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT INCUBATORS, as defined in 201.3.209 of this standard, 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 standard are not covered by specific requirements in this standard 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:

– devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information see IEC 80601-2-35 [3][2)];
– INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [2];
– INFANT TRANSPORT INCUBATORS, for information, see IEC 60601-2-20 [1];
– INFANT PHOTOTHERAPY EQUIPMENT, for information see IEC 60601-2-50 [4].

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 201.3.208, which minimize HAZARDS to PATIENT and OPERATOR, and to specify tests by which compliance with the requirements can be verified.

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

2) Figures in square brackets refer to the Bibliography.

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 2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-10 applies as modified in Clause 202 and 210 respectively. 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 is 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 standard 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard 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 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures 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 standard" 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.

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

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

Amendment:

IEC 60601-1-2~~:2007~~, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

~~IEC 60601-1-10:2007, *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*~~

NOTE Informative references are listed in the bibliography beginning on page 34.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1~~:2005,~~ apply, except as follows:

NOTE An index of defined terms is found beginning on page 35.

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 201.102)

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
an 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

~~NOTE An INFANT INCUBATOR operating as a BABY CONTROLLED INCUBATOR is a PHYSIOLOGIC CLOSED-LOOP CONTROLLER as defined in IEC 60601-1-10.~~

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

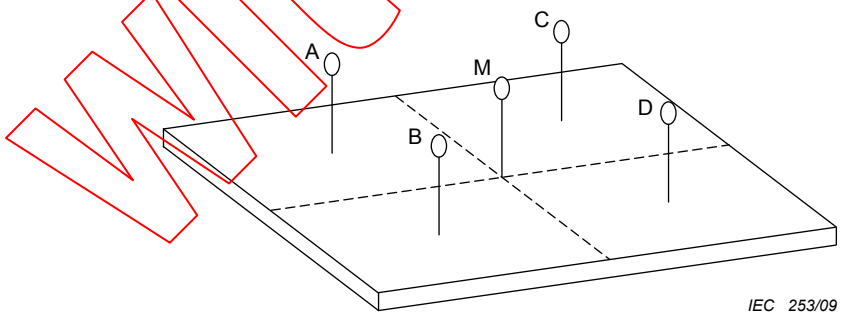
201.3.207
INCUBATOR TEMPERATURE
temperature of the air at a point 10 cm above the centre of the MATTRESS surface in the COMPARTMENT (see Figure 201.101, point M)

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



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 201.101 – Positioning of air temperature sensors