

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – **STANDARD PREVIEW**
Part 2-19: Particular requirements for the basic safety and essential performance
of infant incubators (standards.iteh.ai)

Appareils électromédicaux – IEC 60601-2-19:2009
Partie 2-19: Exigences particulières pour la sécurité de base et les performances
essentiels des incubateurs pour nouveau-nés



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2009 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.

Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

[IEC 60601-2-19:2009](mailto:IEC.60601-2-19:2009)

- Electropedia: www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: csc@iec.ch

Tel.: +41 22 919 02 11

Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,...). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

- Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

- Electropedia: www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:

Email: csc@iec.ch

Tél.: +41 22 919 02 11

Fax: +41 22 919 03 00



IEC 60601-2-19

Edition 2.0 2009-02

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
essentiels des incubateurs pour nouveau-nés

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

W

ICS 11.040.10

ISBN 978-2-88910-217-4

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
201.1 Scope, object and related standards	6
201.2 Normative references	8
201.3 Terms and definitions.....	8
201.4 General requirements.....	10
201.5 General requirements for testing ME EQUIPMENT.....	11
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	11
201.7 ME EQUIPMENT identification, marking and documents.....	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	13
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	13
201.10 Protection against unwanted and excessive radiation HAZARDS.....	15
201.11 Protection against excessive temperatures and other HAZARDS.....	15
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	17
201.13 HAZARDOUS SITUATIONS and fault conditions.....	22
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	22
201.15 Construction of ME EQUIPMENT	23
201.16 ME SYSTEMS	25
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	25
202 Electromagnetic compatibility Requirements and tests.....	25
210 Requirements for the development of physiologic closed-loop controllers.....	26
Annexes	26
Annex AA (informative) Particular guidance and rationale	27
Bibliography.....	34
Index of defined terms used in this particular standard.....	35
Figure 201.101 – INFANT SKIN TEMPERATURE measurement	9
Figure 201.102 – Variation of INCUBATOR TEMPERATURE.....	10
Figure 201.103 – Layout of weight test devices.....	20
Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements.....	11

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/727/FDIS	62D/756/RVD

Full information on the voting for the approval of this particular 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 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.

iTeh STANDARD PREVIEW

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 this publication will remain unchanged until the maintenance result 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.

The contents of the corrigendum of February 2012 have been included in this copy.

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[IEC 60601-2-19:2009](https://standards.iteh.ai/catalog/standards/sist/fea0c40a-1b3a-43e3-bd47-5e1698f23b2b/iec-60601-2-19-2009)

<https://standards.iteh.ai/catalog/standards/sist/fea0c40a-1b3a-43e3-bd47-5e1698f23b2b/iec-60601-2-19-2009>

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 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. [IEC 60601-2-19:2009](https://standards.iteh.ai/catalog/standards/sist/fea0c40a-1b3a-43e3-bd47-5162f2b4c911189-609)
<https://standards.iteh.ai/catalog/standards/sist/fea0c40a-1b3a-43e3-bd47-5162f2b4c911189-609>

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.

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 apply as modified in Clauses 202 and 210 respectively. IEC 60601-1-3 does 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.

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.
<https://standards.iec.ch/catalog/standards/sis/fea0c40a-1b3a-43e3-bd47-5e1698f23b2b/iec-60601-2-19-2009>

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**

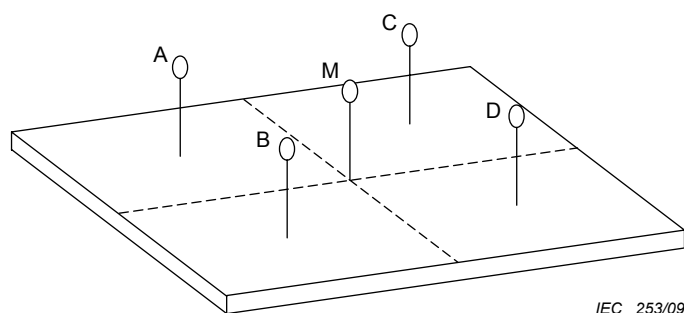
ME EQUIPMENT having a COMPARTMENT which is provided with the means to control the environment of the INFANT primarily by heated air within the COMPARTMENT

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



IEC 253/09

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

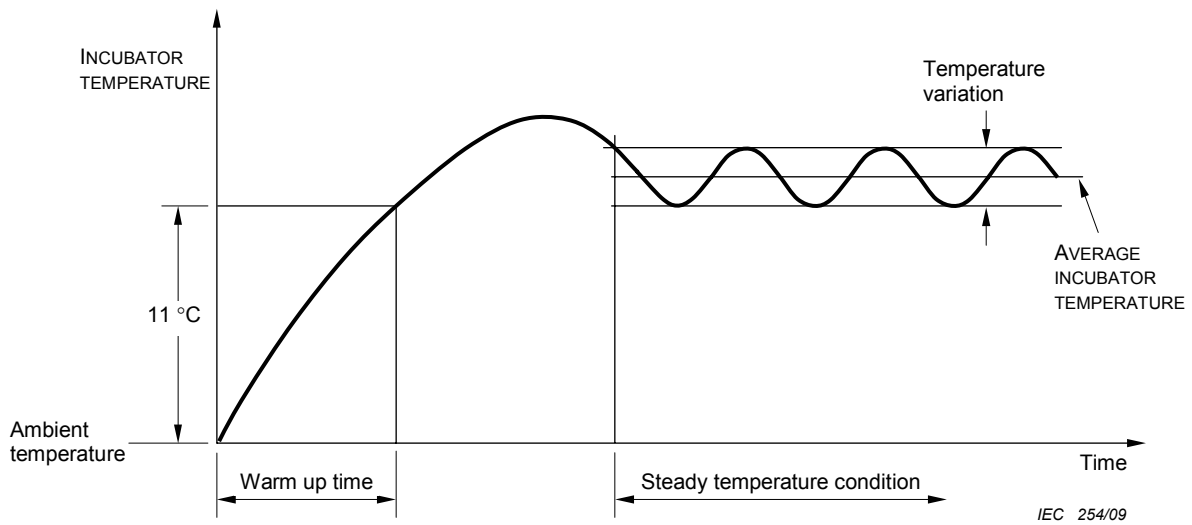


Figure 201.102 – Variation of INCUBATOR TEMPERATURE

201.3.212

STEADY TEMPERATURE CONDITION

condition reached when the INCUBATOR TEMPERATURE does not vary by more than 1 °C over a period of one hour (see Figure 201.102)

IEC STANDARD PREVIEW
(standards.iteh.ai)

201.4 General requirements

IEC 60601-2-19:2009

Clause 4 of the general standard applies, except as follows:
<https://standards.iteh.ai/catalog/standards/si/61040a-1b3a-43e3-bd47-5e1698f23b2b/iec-60601-2-19-2009>

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 subclause 201.15.4.2.1 of the relevant particular standards (e.g. IEC 60601-2-21 or IEC 80601-2-35).

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 standard when operating within the following conditions
- an ambient temperature between +20 °C and +30 °C;
 - an ambient air velocity less than 0,3 m/s.

Addition:

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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,"

<https://standards.iteh.ai/catalog/standards/sist/fea0c40a-1b3a-43e3-bd47-5e1698f23b2b/iec-60601-2-19-2009>

201.5.4 Other conditions

[5e1698f23b2b/iec-60601-2-19-2009](https://standards.iteh.ai/catalog/standards/sist/fea0c40a-1b3a-43e3-bd47-5e1698f23b2b/iec-60601-2-19-2009)

Addition:

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)

Addition:

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 Markings of controls and instruments (see also Table C.3 of the general standard)

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 include the following:

- *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 must 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).
- *k) A warning against the use of the SKIN TEMPERATURE SENSOR as a rectal temperature sensor, if such a warning is applicable.

201.7.9.2.8 * Start-up PROCEDURE

Addition:

The instructions for use shall additionally contain a specification of the warm-up time of the INFANT INCUBATOR measured as specified in subclause 201.12.1.107.

201.7.9.2.9 * Operating instructions

Addition:

The instructions for use shall contain the following additional items:

- a) a recommendation of the position and method of use of the SKIN TEMPERATURE SENSOR
- b) information on how and when to verify the functionality of the ALARM SYSTEM
- c) information about the range of CONTROL TEMPERATURE and relative humidity of the INFANT INCUBATOR. If the INFANT INCUBATOR is not supplied with means for control of the degree of humidity this shall be stated in the instructions for use
- d) a statement of the maximum allowed weight of additional equipment which might be placed on shelves connected to the INFANT INCUBATOR

201.7.9.3 Technical description**201.7.9.3.1 General**

Additional item:

- the MANUFACTURER shall specify in the ACCOMPANYING DOCUMENTS the maximum CO₂ concentration (see subclause 201.12.4.2.101)

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2 HAZARDS associated with moving parts**201.9.2.1 General**

Addition:

This requirement is not applicable to an air circulating fan if it is accessible only when no INFANT is present in the INFANT INCUBATOR and appropriate ME EQUIPMENT parts are removed for cleaning.

201.9.6.2 Acoustic energy**201.9.6.2.1 Audible acoustic energy**

Additional subclauses:

201.9.6.2.1.101 * Sound level within the COMPARTMENT