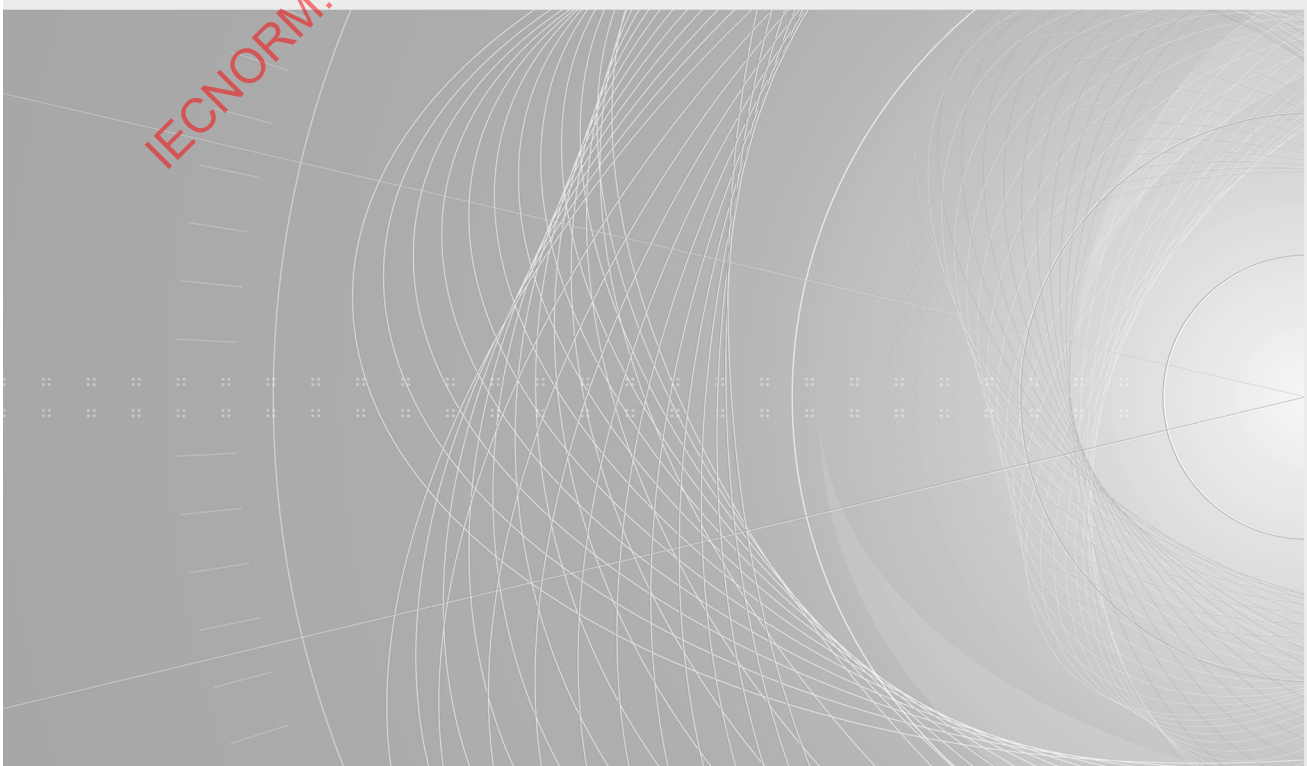
IEC 60601-2-19

Edition 3.0 2020-09

INTERNATIONAL STANDARD

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



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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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CONTENTS

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.

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

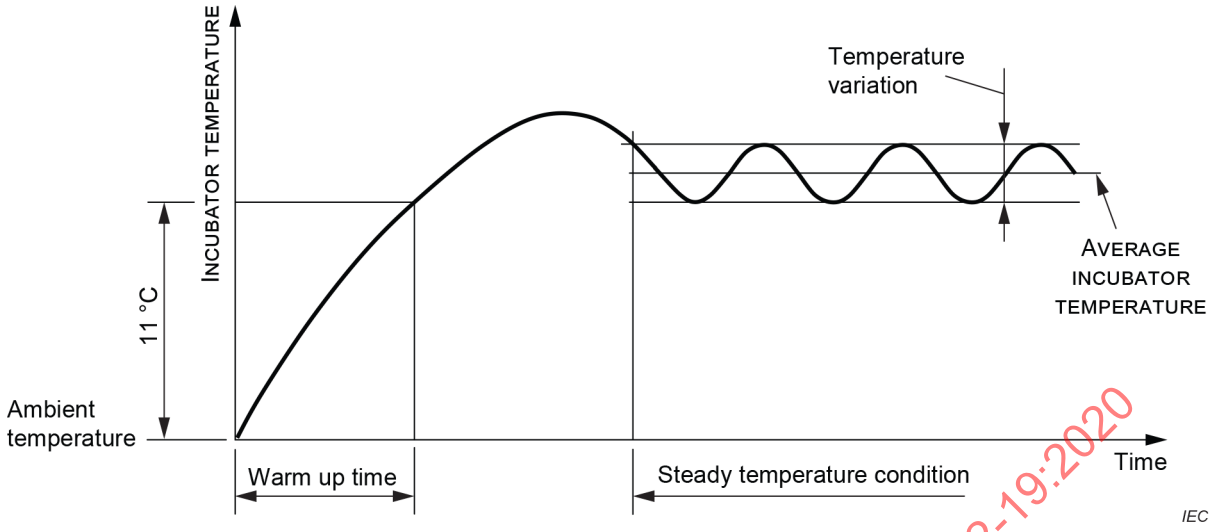


Figure 201.101 – Variation of INCUBATOR TEMPERATURE

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

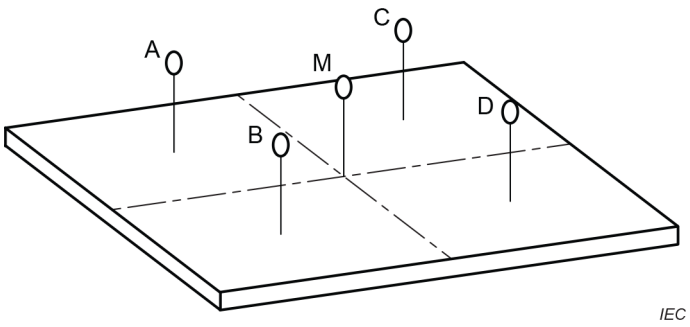
201.3.204
BABY CONTROLLED INCUBATOR
AIR CONTROLLED INCUBATOR which has the additional capability of automatically controlling the INCUBATOR air temperature in order to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR according to the CONTROL TEMPERATURE set by the OPERATOR

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).

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

l) * A statement that the INFANT INCUBATOR cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and SKIN TEMPERATURE (hypothermia), and a recommendation to monitor the temperature of the PATIENT.

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 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 (see also Table C.6 of the general standard)

201.7.9.3.1 General

Additional item to the first paragraph:

– the maximum CO_2 concentration (see 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 MECHANICAL 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

In NORMAL USE, the sound level within the COMPARTMENT shall not exceed a sound pressure level of 60 dB(A) except as specified in 201.9.6.2.1.103.

Compliance is checked by the following test:

With the microphone of a sound level meter complying with the requirements of IEC 61672-1 [5] positioned 100 mm to 150 mm above the centre of the INFANT tray, the measured sound level shall not exceed the specified values. For this test, the INFANT INCUBATOR shall be operated at a CONTROL TEMPERATURE of 36 °C and at a maximum humidity. The background sound level measured inside the COMPARTMENT shall be at least 10 dB below that which is measured during the test.

201.9.6.2.1.102 * Audible alarm sound level

Audible ALARM SIGNALS shall have a sound level of at least 65 dB(A) at a distance of 3 m perpendicular to the front of the control unit in a reflecting room. The auditory alarm may be adjusted by the OPERATOR to a minimum lower level of 50 dB(A). If the frequency of the auditory alarms is adjustable by the OPERATOR, these requirements shall apply to all the individual selectable frequencies.

Compliance is checked by inspection and measurement of the audible alarm level using a sound level meter, as required in subclause 201.9.6.2.1.101 of this particular standard, placed 1,5 m above the floor and 3 m from the control unit. For this test, the INFANT INCUBATOR shall be operated at a CONTROL TEMPERATURE of 36 °C and at a maximum humidity. The background sound level measured shall be at least 10 dB(A) below that which is measured during the test.

201.9.6.2.1.103 * Audible alarms sound level within COMPARTMENT

When any INFANT INCUBATOR alarm is sounding, the sound level in the COMPARTMENT shall not exceed 80 dB(A). If the frequency of the auditory alarms is adjustable by the OPERATOR, this shall apply to all the individual selectable frequencies.

Compliance is checked by the following test:

The alarm shall be actuated and the measurement shall be carried out as described in 201.9.6.2.1.101.

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.1 General

Amendment:

The normal load for an INFANT is reduced to 10 kg.

Additional subclauses:

201.9.8.3.101 * Barriers

The INFANT shall be safely retained within the COMPARTMENT by barriers such as walls or side panels. Barriers intended to be opened or removed to allow access to the INFANT, such as doors, ports etc., shall close so as not to open under the test conditions specified below. It shall not be possible for barriers to be insecurely closed or latched whilst appearing to be engaged. The mechanical integrity of the INFANT INCUBATOR shall be maintained under the following test conditions.

Compliance is checked by inspection and by the following test:

With all access port doors deliberately made as insecure as possible, without the use of a TOOL, whilst still appearing to be engaged, a horizontal force shall be applied to the centre of the access port door. The force shall be increased gradually from zero to 20 N in an interval of 5 s to 10 s and shall be held at maximum for 5 s.

201.9.8.3.102 MATTRESS tray

If the MATTRESS tray can be extended outside the enclosure, it shall be restrained to ensure that the tray remains attached to the INFANT INCUBATOR, is supported and does not tip under the weight of the INFANT.

Compliance is checked by the following test:

A gradually increasing downward force is applied to the middle of the outside edge of the MATTRESS tray whilst in the fully extended position. The force is increased over 5 s to 10 s intervals until it equals 100 N and shall be maintained for a period of 1 min. The tray shall not incline by more than 5° to the horizontal axis of the INFANT INCUBATOR and there shall be no visible evidence of damage to the supporting structures.

Additional subclause:

201.9.8.101 Supports and mounting brackets for ACCESSORIES

Supports and mounting brackets for accessories shall be suitable and of adequate strength for their purpose.

Compliance is checked by inspection and by the following test:

A gradually increasing force is applied so as to act vertically through the centre of the supports and mounting brackets, for example an ACCESSORY shelf in the extended position with a MANUFACTURER's recommended load. The force is increased from zero in a 5 s to 10 s interval, until it equals three times the recommended load and is sustained for a period of 1 min. There shall be no evidence of damage to the items under test.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1 Excessive temperature in ME EQUIPMENT

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Replacement:

The temperature of the surfaces intended to be in contact with a PATIENT shall not exceed 40 °C. The temperature of other surfaces accessible to the PATIENT shall not exceed 40°C for metal surfaces and 43 °C for other materials.

These requirements apply in NORMAL CONDITIONS and SINGLE FAULT CONDITIONS including:

– failure of the air circulation;
– failure of a THERMOSTAT;
– disconnection of the SKIN TEMPERATURE SENSOR.

Compliance is checked by the following test:

The maximum temperature of surfaces intended to be in contact with and surfaces accessible to the INFANT shall be measured according to 11.1.2 of the general standard and include test conditions as described in the compliance test of 201.12.3.101 and 201.15.4.2.1 of this particular standard.

201.11.2 * Fire prevention

Subclause 11.2 of the general standard applies.

201.11.6.2 * Overflow in ME EQUIPMENT

Addition:

If a water reservoir is provided as an integral part of the INFANT INCUBATOR, it shall have a water level indicator with "max." and "min." markings if the level of the water in the tank cannot be seen. The tank shall be so designed that it can be drained without tilting the INFANT INCUBATOR.

Compliance is checked by inspection.

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Replacement:

INFANT INCUBATORS shall be so constructed that spillage does not wet parts which if wetted might cause a safety HAZARD.

Such spillage is considered a SINGLE FAULT CONDITION.

Compliance is checked by the following test:

The ME EQUIPMENT shall be positioned as for NORMAL USE with the canopy in the normal position; 200 ml of water is poured on any point of the top surface of the ME EQUIPMENT. After this test, the ME EQUIPMENT shall comply with the requirements of this document.

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Addition:

A humidifier, if provided, shall be designed to permit the application of PROCEDURES that effect microbiological decontamination between uses.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

The ME EQUIPMENT shall be so designed that an interruption and a restoration of the power supply of up to 10 min does not change the CONTROL TEMPERATURE or other preset values.

Compliance is checked by switching the SUPPLY MAINS off and then switching on and inspecting the ME EQUIPMENT.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 * Stability of INCUBATOR TEMPERATURE

During STEADY TEMPERATURE CONDITION, the INCUBATOR TEMPERATURE shall not differ from the AVERAGE INCUBATOR TEMPERATURE by more than 0,5 °C.

Compliance is checked by measurement at CONTROL TEMPERATURES of 32 °C and 36 °C over a period of at least 1 h.

201.12.1.102 * Uniformity of INCUBATOR TEMPERATURE

With an INFANT INCUBATOR working as an AIR CONTROLLED INCUBATOR and the CONTROL TEMPERATURE set at any temperature within its range, the AVERAGE TEMPERATURE in each of the points A, B, C, and D as specified in the test instruction shall not differ from the AVERAGE INCUBATOR TEMPERATURE by more than 0,8 °C in NORMAL USE. In any position of the tilted MATTRESS, it shall not differ by more than 1 °C.

Compliance is checked by the following test:

Calibrated temperature sensors shall be placed at five points in a plane parallel to and 10 cm above the MATTRESS surface. Point M shall be a point 10 cm above the centre of the MATTRESS (see Figure 201.102, point M). The other points shall be the centres of the four areas formed by lines, which divide both the width and the length in two parts (see Figure 201.102, points A to D). The AVERAGE TEMPERATURE at each of these five points shall be measured at CONTROL TEMPERATURES of 32 °C and 36 °C.

The difference between the AVERAGE INCUBATOR TEMPERATURE (point M) and the measured values at points A, B, C, and D shall be compared as specified. The test shall be undertaken with the INFANT INCUBATOR MATTRESS tray horizontal and at the two extremes of its tilt angle.

201.12.1.103 * Accuracy of SKIN TEMPERATURE SENSOR

The accuracy of the SKIN TEMPERATURE SENSOR for measuring SKIN TEMPERATURE shall be within ±0,3 °C.

Compliance is checked by the following test:

The SKIN TEMPERATURE SENSOR shall be immersed in a water bath which has the capability of controlling the temperature of the water such that it fluctuates by less than ±0,1 °C around its controlled value. The water bath temperature shall be at a nominal 36 °C. A standard thermometer shall be positioned with its temperature sensitive element adjacent to the SKIN TEMPERATURE SENSOR. The displayed SKIN TEMPERATURE shall not differ from the water bath temperature, measured within an uncertainty not greater than 0,05 °C, by more than 0,3 °C.

201.12.1.104 * Accuracy between SKIN TEMPERATURE and CONTROL TEMPERATURE

With an INFANT INCUBATOR working in the BABY CONTROLLED INCUBATOR mode with horizontal MATTRESS orientation, the temperature as measured by the SKIN TEMPERATURE SENSOR shall not differ from the CONTROL TEMPERATURE by more than 0,7 °C in STEADY TEMPERATURE CONDITION.

Compliance is checked by the following test:

The SKIN TEMPERATURE SENSOR shall be freely suspended 10 cm above the centre of the MATTRESS surface. The SKIN TEMPERATURE shall be measured at CONTROL TEMPERATURES of 36 °C.

If it can be demonstrated that an alternative test method is more relevant for this test, the MANUFACTURER may use that method to verify the performance requirement.

201.12.1.105 * Accuracy of INCUBATOR TEMPERATURE indication

An indication of INCUBATOR TEMPERATURE shall be provided by a means which is independent of any device used for control of the INCUBATOR TEMPERATURE. It shall be exclusively used for indication of INCUBATOR TEMPERATURE and it shall be so located as to be easily read without opening the INFANT INCUBATOR even when working at a maximum humidity setting.

A mercury-in-glass thermometer shall not be used.

The AVERAGE TEMPERATURE device reading shall not differ from the AVERAGE INCUBATOR TEMPERATURE, measured by a standard thermometer, by more than 0,8 °C, less the standard thermometer error. The standard thermometer shall be accurate within ±0,05 °C. It shall have a measuring range of at least 20 °C to 40 °C. If the temperature sensitive component of any device is located at a point where the air temperature consistently differs from the INCUBATOR TEMPERATURE, the device may be specially calibrated with an offset in order to meet the above requirements. However, in this case, full details of the special calibration shall be specified in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection and measurement at CONTROL TEMPERATURES of 32 °C and 36 °C.

201.12.1.106 * Accuracy of INCUBATOR TEMPERATURE control

With an INFANT INCUBATOR operating as an AIR CONTROLLED INCUBATOR, the AVERAGE INCUBATOR TEMPERATURE shall not differ from the CONTROL TEMPERATURE by more than ±1,5 °C.

Compliance is checked by measuring the AVERAGE INCUBATOR TEMPERATURE at a CONTROL TEMPERATURE of 36 °C and at STEADY TEMPERATURE CONDITION.

201.12.1.107 * Warm-up time

The warm-up time of the ME EQUIPMENT shall not differ by more than 20 % from the warm-up time specified in the instructions for use (see 201.7.9.2.8).

Compliance is checked by the following test:

With the CONTROL TEMPERATURE set to 12 °C above ambient temperature, the supply voltage being equal to the rated voltage, and the ME EQUIPMENT operating as an AIR CONTROLLED INCUBATOR, the INFANT INCUBATOR is switched on, starting from COLD CONDITION. The time for the INCUBATOR TEMPERATURE to rise by 11 °C is measured (see Figure 201.101). The humidity control, if fitted, shall be set to its maximum value. The water level of a humidifier water container shall be normal. The water in such a container shall be at ambient temperature.

201.12.1.108 * Overshoot of INCUBATOR TEMPERATURE after adjustment

After adjustment of the CONTROL TEMPERATURE in the manner described in the following test, the overshoot in INCUBATOR TEMPERATURE shall not exceed 2 °C and STEADY TEMPERATURE CONDITION shall be restored within 15 min.

Compliance is checked by the following test:

The INFANT INCUBATOR is operated as an AIR CONTROLLED INCUBATOR at a CONTROL TEMPERATURE of 32 °C until STEADY TEMPERATURE CONDITION is reached. The temperature control is then adjusted to a CONTROL TEMPERATURE of 36 °C. The overshoot of INCUBATOR TEMPERATURE and the time to reach the new STEADY TEMPERATURE CONDITION from the first passage of 36 °C shall be measured.

201.12.1.109 * Accuracy of indication of relative humidity

Any indicated value of relative humidity shall have an accuracy of ±10 % relative humidity.

Compliance is checked by the measurement of the relative humidity with a humidity measuring device at the centre of the enclosure. The CONTROL TEMPERATURE shall be set at a value between 32 °C and 36 °C.

201.12.1.110 * Oxygen control

If an oxygen controller forms an integral part of the INFANT INCUBATOR, then there shall be independent sensors for monitoring and control of O_2.

A visual and auditory alarm shall be given if the displayed oxygen concentration deviates from the control setting level by more than ±5 vol. % O_2.

Compliance is checked by the following test:

Set the oxygen control to 35 vol. %. When steady condition has been reached, decrease the concentration quickly to less than 29 vol. %. Verify that the alarm activates at a displayed oxygen concentration no less than 30 vol. %.

Restore the oxygen concentration to 35 vol. % O_2. When steady condition has been reached, increase the concentration quickly to more than 41 vol. %. Verify that the alarm activates at a displayed oxygen concentration no more than 40 vol. %.

201.12.1.111 * Air velocity

In NORMAL USE, the air velocity over the MATTRESS shall not exceed 0,35 m/s.

Compliance is checked by measurement at the five points specified in the test specification of 201.12.1.102.

201.12.1.112 * Weighing scale

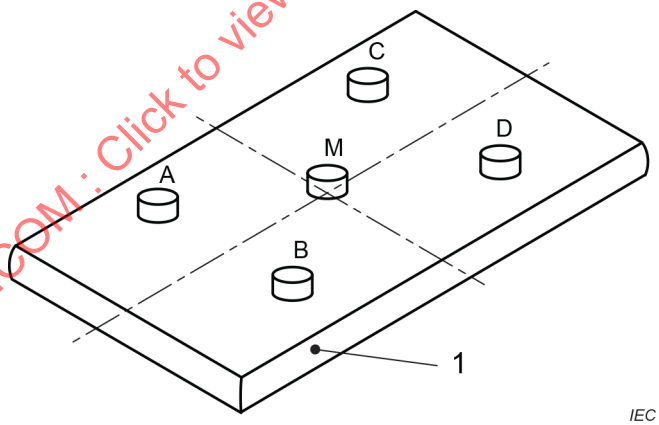
If a weighing scale is supplied as an integral part of the INFANT INCUBATOR or as an ACCESSORY specifically for use with the INFANT INCUBATOR, the weight displayed value shall not differ from the test weights by more than the MANUFACTURER's specifications in the ACCOMPANYING DOCUMENTS when operating in an INFANT INCUBATOR with horizontal MATTRESS orientation. Each value measured shall remain latched on the weighing scale display at the conclusion of any individual measurement cycle and be retained until discarded by the OPERATOR. If the weighing scale may be exposed to an oxygen-enriched environment in use, it shall comply with the requirements of 6.5 of the general standard.

Device calibration should be able to be both verified and updated by the OPERATOR during usage.

Compliance is checked by the following test:

Test measurements shall be demonstrated using values of 500 g ± 1 g and 2 000 g ± 1 g. Tests shall be conducted in an INFANT INCUBATOR operating as an AIR CONTROLLED INFANT INCUBATOR with an INCUBATOR TEMPERATURE of 36 °C.

The accuracy of measurement test shall be verified with the test loads positioned in locations M and A through D in Figure 201.103.



Key

1 MATTRESS

Figure 201.103 – Layout of weight test devices

201.12.2 USABILITY of ME EQUIPMENT

Addition:

201.12.2.101 * Indication of SKIN TEMPERATURE

BABY CONTROLLED INCUBATORS shall be equipped with a SKIN TEMPERATURE SENSOR; the temperature measured by the sensor shall be continuously displayed and clearly visible. If, in addition, the display is used to present any other parameter, this shall be obtained only on demand using a momentary action switch. The displayed temperature range shall minimally be 33 °C to 38 °C.

Compliance is checked by inspection.

201.12.2.102 * Indication of the mode of operation

When a BABY CONTROLLED INCUBATOR operates as an AIR CONTROLLED INCUBATOR, there shall be a clear indication of the mode of operation in use.

Compliance is checked by inspection.

201.12.2.103 Temperature control

Each temperature control, if it has a rotary action, shall be so arranged that a clockwise rotation produces an increase in temperature.

Compliance is checked by inspection.

201.12.3 ALARM SYSTEMS

Addition:

201.12.3.101 * Air circulation fan

If the INFANT INCUBATOR is provided with an air circulation fan, an audible alarm, visually identifiable, shall be given and the supply to the heater shall be disconnected before a HAZARDOUS SITUATION is created in the event of:

– failure of the fan to rotate, or
– blocking of the air outlets from the INFANT INCUBATOR COMPARTMENT, and
– when possible, blocking of the air inlet.

In the event of a failure of the fan, the ME EQUIPMENT shall not emit flames, molten metal, or poisonous or ignitable gas, and the parts accessible to the INFANT shall not exceed the temperatures specified in 201.11.1.2.2 of this particular standard.

Compliance is checked by running the INFANT INCUBATOR as an AIR CONTROLLED INCUBATOR until STEADY TEMPERATURE CONDITION is achieved at a CONTROL TEMPERATURE of 34 °C. It shall then be checked that the requirement is met when in turn:

– *the fan is disabled;*
– *the air circulation outlet to the COMPARTMENT enclosure is blocked by a piece of closely woven cloth; where a number of separated air inputs are provided or if protected from inadvertent blockage, the second part of the test is not required;*
– *the air inlet is blocked when applicable.*

201.12.3.102 * Connector to SKIN TEMPERATURE SENSOR

A BABY CONTROLLED INCUBATOR shall be provided with an audible alarm visually identifiable, which sounds in the event of the connector to the SKIN TEMPERATURE SENSOR

– becoming electrically disconnected,
– having open-circuited leads, or
– having short-circuited leads.

The supply to the heater shall be automatically disconnected or the INFANT INCUBATOR shall be automatically switched over to the air control mode with a CONTROL TEMPERATURE of 36 °C ± 0,5 °C or a CONTROL TEMPERATURE set by the OPERATOR.

Compliance is checked by simulating the specified fault conditions and observing the effects.

The MANUFACTURER's recommended sensor shall be connected to the control unit by slowly inserting its plug into the corresponding socket in order to determine if there are any intermediate positions that inhibit an alarm activation.

201.12.3.103 Interruption of power supply

Audible alarm and visible indication shall be provided to give warning in the event of interruption of the power supply to the INFANT INCUBATOR.

Compliance is checked by disconnecting the power supply while the INFANT INCUBATOR is switched on.

The audible and visual indication of the failure of power supply shall be provided for a minimum time of 10 min.

201.12.3.104 AUDIO PAUSED of audible alarm

Deliberately silenced audible alarms shall have a maintained visual indication.

Such alarms shall automatically resume their normal function within a time specified by the MANUFACTURER.

The AUDIO PAUSED for an INFANT INCUBATOR warming up from COLD CONDITION may be up to 30 min.

Compliance is verified by functional check and time measurement.

201.12.3.105 Alarm function test

Means shall be provided for the OPERATOR to check the operation of audible and visual alarms. Such means shall be described in the instructions for use.

Compliance is checked by inspection.

201.12.4.2 Indication relevant to safety

Addition:

201.12.4.2.101 * CO_2 concentration

The MANUFACTURER shall disclose the value of the maximum CO_2 concentration which will occur in the COMPARTMENT under NORMAL CONDITIONS.

Compliance is checked by the following test:

A 4 % mixture of CO_2 in air shall be administered at a rate of 750 ml/min at a point 10 cm above the centre of the MATTRESS *(see Figure 201.102, point M) through an 8 mm diameter tube in vertical direction from the* MATTRESS *to the top. CO_2 concentration at a point 15 cm from point M shall be measured when stability is achieved. The measured value shall be equal to or less than the value specified by the* MANUFACTURER.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.2.6 * Leakage of liquid

Addition:

An INFANT INCUBATOR shall be so constructed that liquids deposited on the inside surface of the COMPARTMENT, including the INFANT tray, cannot reduce the safety of the INFANT INCUBATOR.

Leakage of 200 ml is considered as NORMAL CONDITION.

Compliance is checked by the following tests:

Such an amount of water shall be sprayed on all inner surfaces of the COMPARTMENT *that drops coalesce and flow down the walls. In addition, 200 ml of water shall be poured steadily on the* INFANT *tray. After this test,* ME EQUIPMENT *shall satisfy all requirements of this document.*

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3 Mechanical strength

201.15.3.5 Rough handling test

Addition:

Following the tests in 15.3.5 of the general standard, the INFANT INCUBATOR shall be suitable for future NORMAL USE. Mechanical and structural integrity of the INFANT INCUBATOR shall be verified; for example latches and doors shall remain closed and ancillary equipment supplied by or available from the MANUFACTURERS shall remain secure.

Additional subclause:

201.15.3.101 Access to INFANT

The INFANT INCUBATOR shall have means by which the INFANT can be taken in and out without the need to remove the canopy completely, or to disconnect tubes, cords, leads and the like from the INFANT.

201.15.4.1 Construction of connectors

Addition:

201.15.4.1.101 * Temperature sensors

All temperature sensors (including SKIN TEMPERATURE SENSORS) shall be clearly marked with their intended function. It shall not be possible to connect a sensor to an inappropriate socket on the ME EQUIPMENT.

Compliance is checked by inspection.

201.15.4.2 Temperature and overload control devices

201.15.4.2.1 Application

Addition:

aa) * An AIR CONTROLLED INCUBATOR shall be equipped with a THERMAL CUT-OUT which operates independently of any THERMOSTAT. It shall be so arranged that the heater is disconnected and an auditory and visual warning is given at an INCUBATOR TEMPERATURE which does not exceed 38 °C.

INFANT INCUBATORS with means for overriding the CONTROL TEMPERATURE up to 39 °C according to 201.15.4.2.2.101 of this document shall be equipped with a second THERMAL CUT-OUT function that works at an INCUBATOR TEMPERATURE of 40 °C. In this case, the action of the 38 °C THERMAL CUT-OUT shall be inhibited automatically or by means of a special action of the OPERATOR.

The THERMAL CUT-OUT(S)

– shall be non-self-resetting but capable of being manually reset, or

– shall be self-resetting at an INCUBATOR TEMPERATURE between 34 °C and 39 °C and the alarm shall operate continuously until manually reset.

Compliance is checked by inspection and the following tests.

With the INFANT INCUBATOR set to operate as an AIR CONTROLLED INCUBATOR, the THERMOSTAT is disabled and the INFANT INCUBATOR is switched on. At the time the alarm operates, the INCUBATOR TEMPERATURE shall not exceed the temperature specified in 201.15.4.2.1 aa) and the supply to the heater shall be disconnected. The heater supply shall not be restored until either:

– *the THERMAL CUT-OUT(S) is (are) manually reset, or*

– *the INCUBATOR TEMPERATURE falls below 39 °C.*

bb) A BABY CONTROLLED INCUBATOR shall be equipped with a THERMAL CUT-OUT which operates independently of any THERMOSTAT. It shall be so arranged that the heater is disconnected and an auditory and visual warning is given at an INCUBATOR TEMPERATURE which does not exceed 40 °C.

The THERMAL CUT-OUT(S)

– shall be non-self-resetting but capable of being manually reset, or

– shall be self-resetting at an INCUBATOR TEMPERATURE between 34 °C and 39 °C and the alarm shall operate continuously until manually reset.

Compliance is checked by inspection and the following tests:

With the INFANT INCUBATOR set to operate as a BABY CONTROLLED INCUBATOR the THERMOSTAT is disabled and the SKIN TEMPERATURE SENSOR is separately maintained at a temperature below the CONTROL TEMPERATURE. At the time the alarm operates, the INCUBATOR TEMPERATURE shall not exceed the temperature specified in 201.15.4.2.1 aa) and the supply to the heater shall be disconnected. The heater supply shall not be restored until either:

– *the THERMAL CUT-OUT is manually reset, or*

– *the INCUBATOR TEMPERATURE falls below 39 °C.*

cc) In the NORMAL CONDITION of a BABY CONTROLLED INCUBATOR where the INFANT temperature as measured by the SKIN TEMPERATURE SENSOR is below the CONTROL TEMPERATURE, STEADY TEMPERATURE CONDITION shall be achieved without the operation of the THERMAL CUT-OUT.

Compliance is checked by temperature measurement and functional check with the INFANT INCUBATOR set to operate as a BABY CONTROLLED INCUBATOR at maximum CONTROL TEMPERATURE and the SKIN TEMPERATURE SENSOR separately maintained at least 2 °C below the CONTROL TEMPERATURE.

dd) * After STEADY TEMPERATURE CONDITIONS of an AIR CONTROLLED INCUBATOR have been achieved, any sensed temperature deviation of the displayed air temperature exceeding ±3 °C compared with the CONTROL TEMPERATURE shall cause an auditory and visual alarm to operate. The ME EQUIPMENT heater shall switch off if the displayed air temperature exceeds the CONTROL TEMPERATURE by 3 °C and shall remain on if the displayed air temperature is below the CONTROL TEMPERATURE.

Compliance is checked by inspection and the following two tests:

Test 1

Set the CONTROL TEMPERATURE to 32 °C. After the temperature indication has not varied by more than ±0,5 °C for at least 10 min, increase the displayed air temperature. Report whether the auditory and visual alarms operate and whether the ME EQUIPMENT heater switches off.

Test 2

As for test 1, but in this instance the CONTROL TEMPERATURE is set to 35 °C. After the temperature indication has not varied by more than ±0,5 °C for at least 10 min, decrease the displayed air temperature. Report whether the auditory and visual alarms operate and whether the heater remains in operation.

ee) * After STEADY TEMPERATURE CONDITIONS of a BABY CONTROLLED INCUBATOR have been achieved, any deviation of the displayed SKIN TEMPERATURE exceeding ±1 °C compared with the CONTROL TEMPERATURE shall cause an auditory and visual alarm to operate. The ME EQUIPMENT heater shall switch off when the displayed SKIN TEMPERATURE exceeds the CONTROL TEMPERATURE by more than 1 °C.

Compliance is checked by inspection and the following two tests:

Test 1

Set the CONTROL TEMPERATURE of the *BABY CONTROLLED INCUBATOR to 36 °C and immerse the SKIN TEMPERATURE SENSOR in a water bath maintained at 36 °C ± 0,1 °C. After the temperature indication has not varied by more than ±0,5 °C for at least 10 min, increase the water bath temperature control setting to 38 °C. Report whether the auditory and visual alarms operate and whether the ME EQUIPMENT heater switches off.*

Test 2

Set the CONTROL TEMPERATURE of the BABY CONTROLLED INCUBATOR to 36 °C and immerse the SKIN TEMPERATURE SENSOR in a water bath maintained at 36 °C ± 0,1 °C. After the temperature indication has not varied by more than ±0,5 °C for at least 10 min, decrease the water bath temperature control setting to 34 °C. Report whether the auditory and visual alarms operate.

201.15.4.2.2 Temperature settings

Addition:

201.15.4.2.2.101 * AIR CONTROLLED INCUBATOR range

For an AIR CONTROLLED INCUBATOR, the range of the CONTROL TEMPERATURE shall be from 30 °C or less to not more than 37 °C, unless it can be overridden by a special action of the OPERATOR. In this case, the maximum CONTROL TEMPERATURE shall not exceed 39 °C and this mode of operation shall be indicated with an easily recognizable warning light including or combined with relevant temperature range indication. The maximum setting of the CONTROL TEMPERATURE shall not be less than 36 °C.

201.15.4.2.2.102 * BABY CONTROLLED INCUBATOR range

For a BABY CONTROLLED INCUBATOR, the range of the CONTROL TEMPERATURE shall be from 35 °C or less to not more than 37,5 °C, unless it can be overridden by a special action of the OPERATOR. In this case, the maximum CONTROL TEMPERATURE shall not exceed 39 °C and this mode of operation shall be indicated with an easily recognizable warning light including or combined with relevant temperature range indication.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 applies, except as follows:

202.8.9 IMMUNITY TEST LEVELS

Addition:

For radiated radio-frequency electromagnetic fields, the INFANT INCUBATOR and/or system shall continue to perform its intended function as specified by the MANUFACTURER at a level up to 3 V/m for the frequency range of the collateral standard for EMC.

NOTE An INFANT INCUBATOR is not considered to be used in a HOME HEALTHCARE ENVIRONMENT.

Annexes

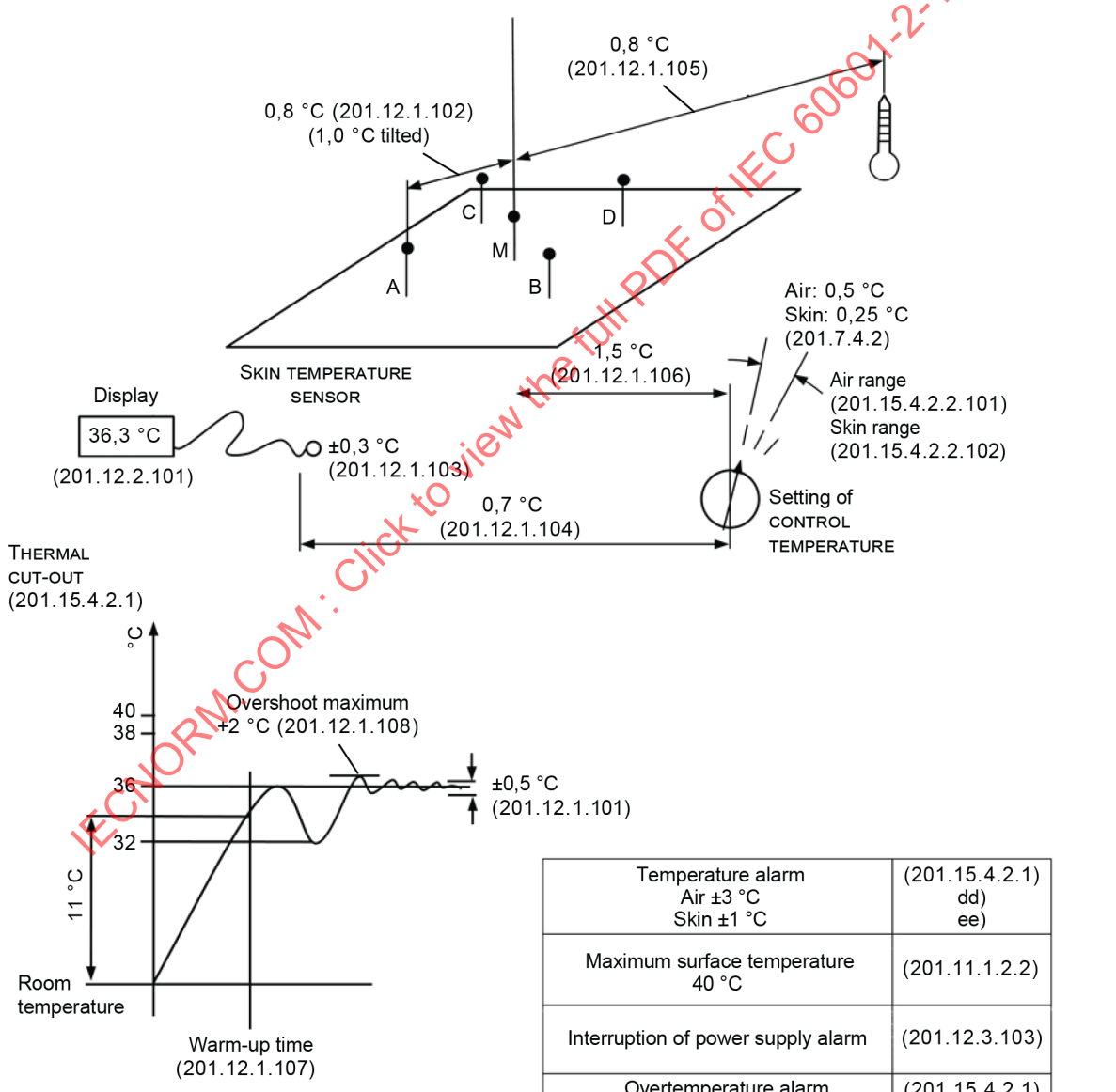
The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Compliance with the minimum safety requirements specified in this particular standard is predominantly checked by measurement of physical quantities such as the temperature. In most cases, the spatial location of the measuring site or the temporal development of the quantity is of interest. Therefore, the expert group of this document considered it helpful to provide a synopsis of the requirements of this document. Hence, Figure AA.1 illustrates the requirements and their schematic measuring sites or expected temporal development. The requirements as given by their clauses are set in brackets.



Temperature alarm Air ±3 °C Skin ±1 °C	(201.15.4.2.1) dd) ee)
Maximum surface temperature 40 °C	(201.11.1.2.2)
Interruption of power supply alarm	(201.12.3.103)
Overtemperature alarm Air controlled 38 °C Baby controlled 40 °C	(201.15.4.2.1) aa) bb)

IEC

NOTE Numbers in brackets indicate the relevant subclauses.

Figure AA.1 – Illustration of the main requirements of this document

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

Subclause 201.1.1 – Scope

It is the primary purpose of a BABY CONTROLLED INCUBATOR to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR. Hence, 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, unless they are specifically extended to measure the body temperature.

The term "body temperature" is used for all other temperatures of the human body except SKIN TEMPERATURE.

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

The experts of the working group have discussed and determined that these requirements are the essential requirements or essence that a warming therapy device (i.e. INFANT INCUBATOR, INFANT RADIANT WARMER, HEATING DEVICES supplying heat via BLANKETS, PADS or MATTRESSES, etc.) shall comply to.

As an example, the intended use of an INFANT INCUBATOR or warmer is to apply heat to an INFANT and to keep the temperature stable within a safe region. The accuracy of the set temperature to the real temperature shall be maintained within the range required by this document and listed as a requirement in the ESSENTIAL PERFORMANCE table. If the temperature varies beyond the range listed in the requirement, then the device shall supply an alarm.

It should be noted that the time relationship between PATIENT and warming therapy treatment was evaluated in the discussion to resolve essential requirements. These types of devices (INFANT INCUBATOR/warmer) have real measurable response times built into most failure mode activities as opposed to ventilators or implantable devices. Therefore, it was considered appropriate that this requirement, combined with the requirement which stipulates that a failure to maintain a state of thermal performance shall be accompanied by an audible alarm that would allow a clinician to take the appropriate mitigating actions, would cover all of the essential requirements for this type of device.

Subclause 201.5.3 a) – Ambient temperature, humidity, atmospheric pressure

Relatively precise requirements on temperature accuracy and constancy of INFANT INCUBATORS are of great importance for satisfactory treatment of the PATIENT. It is considered that these requirements should be as restrictive as generally technically possible within the ambient temperature range, which is normal for INFANT INCUBATORS within the scope of this document. The test ambient temperature range has therefore been limited to 21 °C to 26 °C.

Subclause 201.7.2.101 – Oxygen monitor

INFANTS requiring supplemental oxygen are at added RISK since their arterial oxygenation is not considered adequate while breathing ambient air. Inadequate amounts of supplemental oxygen may result in brain damage or death, and excessive amounts of supplemental oxygen have been associated with an increased RISK of retinopathy of prematurity (ROP) (retrolental fibroplasia, RLF). While known concentrations of oxygen cannot be directly related to the adequacy of arterial blood gas values, it is important that attending personnel be aware of inspired concentrations (as well as other factors influencing arterial oxygenation) in order to be able to determine the reason for observed changes in the physiologic state of the INFANT.

Subclause 201.7.4.2 – Control devices

In the clinical situation, the range of temperature used for BABY CONTROLLED INCUBATORS is usually between 35 °C and 37 °C. Therefore, narrower intervals are required for BABY CONTROLLED INCUBATORS.

Situations have been reported whereby incorrect settings of the oxygen control have been made due to close proximity of the "max." and "min." markings on the control knob scale. 100% oxygen has thus been administered instead of 21 %, which was intended.

Subclause 201.7.9.2.2 – Warning and safety notices

a) It is inherent in INFANT INCUBATOR design and function that in order for it to be effective for one PATIENT, it may be potentially harmful to another. It is necessary, therefore, that qualified personnel with the necessary individual PATIENT information and medical knowledge are responsible for ordering all aspects of INFANT INCUBATOR use.

b) The air temperature control system of an INFANT INCUBATOR cannot be expected to provide protection against overheating of the INFANT due to direct radiation from sunlight or other radiant sources. Protection against this HAZARD can only be achieved by preventing its occurrence.

c), d) Several oxygen fire accidents in INFANT INCUBATORS have been reported [14]. Alcohol left in the enclosure after a cleaning PROCEDURE is suspected to be the primary ignited material. Arcs from contacts in the THERMOSTAT are thought to be the source of ignition.

e) The overloading of shelves could result in the INFANT INCUBATOR tipping over or mechanical damage which could result in a HAZARD. Subclause 9.4.2.2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 meets the test requirement necessary for INFANT INCUBATORS.

k) See rationale to 201.15.4.1.101.

l) The INFANT INCUBATOR cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and SKIN TEMPERATURE (hypothermia). Therefore, in all situations it is recommended that the temperature of the PATIENT be monitored separately.

Subclause 201.7.9.2.8 – Start-up PROCEDURE

It is necessary to know the warm-up time in order to prepare the INFANT INCUBATOR for its function.

Subclause 201.7.9.2.9 – Operating instructions

a) Improper location or means of attachment of the SKIN TEMPERATURE SENSOR could cause an incorrect temperature reading or inadequate control of SKIN TEMPERATURE which would result in possible hypothermia or hyperthermia.

c) See rationale for 201.12.1.108.

d) See rationale for 201.7.9.2.2, e).

Subclause 201.9.6.2.1.101 – Sound level within the COMPARTMENT

Current knowledge indicates that it is unwise to keep preterm INFANTS in an environment with ambient sound levels above 50 dB(A) and with alarm impulses as high as 80 dB(A). This knowledge has developed along three fronts:

1) What is the level of background noise that will interfere with INFANT sleep?

2) What is the level of background noise that will interfere with an INFANT'S ability to discern the nuances of its mother's voice?

3) What is the level of impulse noise that will cause dangerous changes in the preterm newborn brain?

With respect to the last item, there is data from as far back as 1980, in a study from Long et al. [6], that showed marked elevations of intracranial pressure to noise impulses of 70 dB(A) to 75 dB(A) in the preterm INFANT, when superimposed on an ambient noise level of 55 dB(A) to 60 dB(A). On the other fronts, considerable data has been gathered in recent years that documented difficulty with INFANT sleep and intelligibility of speech at ambient sound levels above 50 dB(A). Much of this information is summarized by Philbin et al. [7].

Based on the research, recommended standards for newborn intensive care unit (NICU) design have now been reduced to require ambient sound levels to not exceed a L_{eq} of 45 dB(A), and an L_{max} of 65 dB(A) [8]. The American Institute of Architects Guidelines for Design and Construction of Health Care Facilities [9] and the American Academy of Pediatrics Guidelines for Perinatal Care [10] currently specify an L_{eq} of 50 dB(A) and L_{max} of 70 dB(A) and will likely lower these to match the lower levels recommended in the standard for NICU construction.

Although INFANT INCUBATORS meeting the minimum requirements of this document are considered safe and effective, clearly the research points toward the benefits of even lower INFANT environment sound levels. As the noise level of the NICU is lowered, the impact of the INFANT INCUBATOR'S contribution to the INFANT'S environment noise is increased. Both the INFANT INCUBATOR'S steady background sound level and impulse sounds resulting from alarms, door or drawer closures and the like should be considered in future device designs. MANUFACTURERS should strive for INFANT chamber sound levels that are compatible with the Recommended Standards for Newborn ICU Design [11].

Subclause 201.9.6.2.1.102 – Audible alarm sound level

65 dB(A) is a rather high noise level in an intensive care nursery. Recent improvements in nursing care practices reduce noise levels and PATIENT disturbances to a minimum. Therefore, the OPERATOR should have the option to reduce this sound level. OPERATORS have requested the option for adjusting frequency of auditory alarms for better identification of the particular INFANT INCUBATOR which is sounding the alarm.

Reflecting rooms represent the acoustic situation in an intensive care nursery more realistically than non-reflecting or semi-anechoic rooms that are very often used for sound pressure measurements. However, reflecting rooms are not well defined and deliver less reproducible values due to their variable size and geometry. The more idealized reverberation chambers deliver very reproducible results but are sometimes difficult to get for tests.

Henceforth, the test can alternatively be performed in a semi-anechoic chamber that is very often used to measure operating sound pressure level. Using a semi-anechoic chamber for the measurements, the thresholds are lowered. This takes into account that reverberation chambers, when compared with semi-anechoic chambers, obtain sound pressure levels that are reflected mainly at the ceiling which can be considered as low compared to the typical height of a device and to a minor extent by the lateral walls. For measurements in a semianechoic chamber and with a measurement distance of 3 m, the thresholds of 65 dB(A) and 50 dB(A) are lowered by 5 dB to 60 dB(A) and 45 dB(A), respectively.

Furthermore, if in the semi-anechoic chamber a distance of 3 m between the device and the microphone as required is not feasible, the distance can be decreased to no less than 2 m. The thresholds of 65 dB(A) and 50 dB(A) are then lowered by 1,5 dB to 63,5 dB(A) and 48,5 dB(A), respectively. This takes into account that the measured sound pressure level is increased by 3,5 dB, compared to a test with a 3 m distance (reciprocal distance 1/r law).

Subclause 201.9.6.2.1.103 – Audible alarms sound level within COMPARTMENT

See rationale for 201.9.6.2.1.101.

Subclause 201.9.8.3.101 – Barriers

An INFANT can crawl out of an open INFANT INCUBATOR port and can fall to the floor. Side panels can collapse allowing an INFANT to roll out of a bassinet. Poorly designed barriers may fail to retain the INFANT.

Subclause 201.11.2 – Fire prevention

During the review of this document, the committee was requested to consider adding a flammability requirement to the INFANT MATTRESS. Because the committee could find no evidence to support an addition of this type, this brief rationale was added to the clause.

MATTRESSes or PADS usually consist of two materials which serve two different functions. The filler functions to support or cradle the INFANT while the surface material acts as a barrier from the inner material. The primary requirement of the surface material is to present no HAZARD to the PATIENT which could contact the PATIENT under a system single fault failure. In most clinical applications, the outer surface has been observed to be covered with additional coverings consisting of a natural fibre (cotton or materials supplied by PATIENT's parent) based material which is not specifically flame retardant but functions to further reduce the low abrasion qualities of the PAD's cover with the neonate's skin. The primary requirements of the filler material are to provide a comfortable surface for long term stay of the PATIENT.

Since there is no source of ignition inside the bassinet of an INFANT INCUBATOR, the RISK of fire ignition in the area of the MATTRESS is limited since the requirements of 6.5 of the general standard for an OXYGEN RICH ENVIRONMENT have been met. No incident has been reported for many years concerning fire ignition inside the bassinet of an incubator. Also, even with incubator MATTRESSES, additional concerns were discussed around the toxicity of fumes that can be produced by materials that have been treated with flame retardant additives.

Subclause 201.11.6.2 – Overflow in ME EQUIPMENT

"Min." indication is required because lack of humidity may be hazardous for the PATIENT. "Max." indication is needed to prevent overfilling and spillage.

Subclause 201.11.6.6 – Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

See rationale 201.7.9.2.2.

Subclause 201.12.1.101 – Stability of INCUBATOR TEMPERATURE

It is recognized that apnoea can result from variations in an INCUBATOR TEMPERATURE. While there is no scientific evidence to show that temperature variations normally encountered in INFANT INCUBATORS result in apnoea, a conservative value has been selected.

Subclause 201.12.1.102 – Uniformity of INCUBATOR TEMPERATURE

Long experience of both the medical and technical requirements for INFANT INCUBATORS has shown that this level of performance (1 °C) is satisfactory in maintaining the temperature of the INFANT and readily achievable technically.