

INTERNATIONAL STANDARD



**Medical electrical equipment –
Part 2-21: Particular requirements for the basic safety and essential
performance of infant radiant warmers**

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IEC 60601-2-21

Edition 3.0 2020-09
REDLINE VERSION

INTERNATIONAL STANDARD



**Medical electrical equipment –
Part 2-21: Particular requirements for the basic safety and essential
performance of infant radiant warmers**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.10

ISBN 978-2-8322-8922-8

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

International standard IEC 60601-2-21 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: alignment with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

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

FDIS	Report on voting
62D/1766/FDIS	62D/1776/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 standard 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT RADIANT WARMER 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, Annex AA does not form part of the requirements of this document.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT RADIANT WARMERS as defined in 201.3.204, 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 the safety requirements for INFANT RADIANT WARMERS, 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~~ IEC 60601-2-35;
- INFANT INCUBATORS; for information, see IEC 60601-2-19;
- INFANT TRANSPORT INCUBATORS, for information, see IEC 60601-2-20;
- INFANT PHOTOTHERAPY EQUIPMENT, for information, see IEC 60601-2-50.

SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED RADIANT WARMER including the displayed value are not considered to be a CLINICAL THERMOMETER in the sense of the particular standard ISO 80601-2-56.

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

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT RADIANT WARMERS as defined in 201.3.204, 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 2 of this particular standard.

IEC 60601-1-2:2014 ~~and IEC 60601-1-10~~ applies as modified in Clauses 202 ~~and 210~~ respectively. IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

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

For brevity, IEC 60601-1:2005 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 ~~3.139~~ 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:

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~~

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 the general standard apply, except as follows:~~

For the purposes of this document, the terms and definitions specified 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 beginning on page 35.

Addition:

201.3.201

BABY CONTROLLED RADIANT WARMER

mode of operation in which the power output varies automatically 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 RADIANT WARMER operating as a BABY CONTROLLED RADIANT WARMER is a PHYSIOLOGIC CLOSED-LOOP CONTROLLER as defined in IEC 60601-1-10.~~

201.3.202

CONTROL TEMPERATURE

temperature selected at the temperature control

201.3.203

INFANT

PATIENT up to 3 months and with a weight of less than 10 kg

201.3.204

INFANT RADIANT WARMER

electrically powered device with a radiant heating source intended to maintain the thermal balance of an INFANT by direct radiation of energy in the infrared region of the electromagnetic spectrum

201.3.205

MANUAL MODE

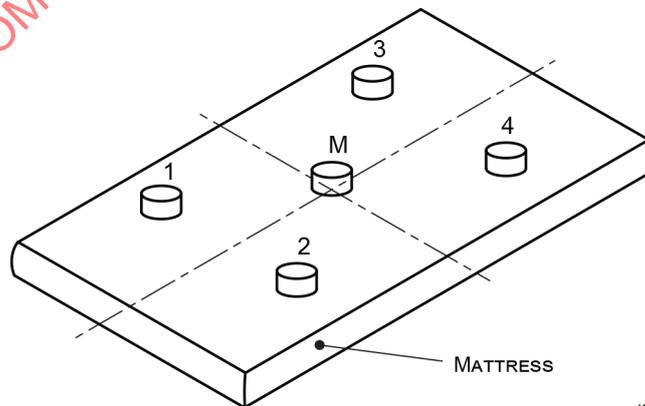
mode of operation in which the heater output is either at a fixed level or a proportion of its maximum output set by the OPERATOR

201.3.206

MID-POINT AVERAGE TEMPERATURE

T_M

~~TEST DEVICE~~ AVERAGE TEMPERATURE of the TEST DEVICE positioned at the mid-point of the INFANT RADIANT WARMER MATTRESS (see Figure 201.101)



Key

~~1 = Mattress~~

Figure 201.101 – Layout of TEST DEVICES

201.3.207***PREWARM MODE**

mode of operation in which the heater output is maintained at a preset level (set by the MANUFACTURER) for the purpose of pre-warming the INFANT RADIANT WARMER and maintaining the level of warmth of the INFANT RADIANT WARMER prior to an INFANT being placed on the device

201.3.208**SKIN TEMPERATURE SENSOR**

sensing device intended to measure the INFANT'S SKIN TEMPERATURE

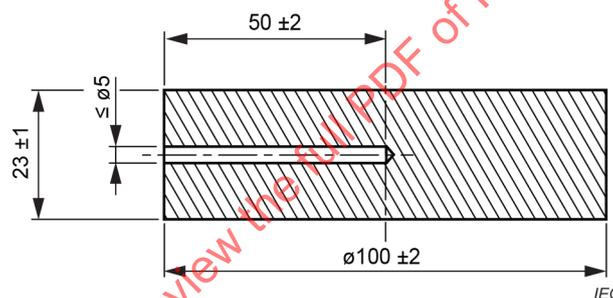
201.3.209**STEADY TEMPERATURE CONDITION**

condition which is reached when the temperature, measured at the centre of the TEST DEVICE positioned on the mid-point of the INFANT RADIANT WARMER MATTRESS, does not vary by more than 1 °C over a period of 1 h

201.3.210**TEST DEVICE**

totally matt blackened disc used as a reproducible receiver of radiant energy during testing of the INFANT RADIANT WARMER (see Figure 201.102)

Dimensions in millimetres

**Key**

1 = Mattress

Surface finish: non-reflective black paint

Disc mass: $500 \text{ g} \pm 10 \text{ g}$

Disc material: aluminium of density within the range $2,6 \text{ g/cm}^3$ and $2,9 \text{ g/cm}^3$

Figure 201.102 – TEST DEVICE

201.3.211**TEST DEVICE AVERAGE TEMPERATURE**

$(T_1, T_2, T_3, T_4 \text{ OR } T_M)$

AVERAGE TEMPERATURE reading taken during a STEADY TEMPERATURE CONDITION at regular intervals at the centre of a TEST DEVICE

Note 1 to entry: T_M, T_1, T_2, T_3, T_4 , are expressed in °C.

201.3.212*** TEST LOAD**

array of five TEST DEVICES used in a specified configuration (see Figure 201.101) for performance tests of the INFANT RADIANT WARMER

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 ME EQUIPMENT or ME SYSTEMS, which combines alternative heat sources, for instance incubators with integrated INFANT RADIANT WARMERS, devices supplying heat via BLANKETS, PADS or MATTRESSES etc., safety requirements of other relevant particular standards shall be considered. Further the safety requirements of this document shall be fulfilled with the combination of the other equipment, which is approved by the MANUFACTURER, as stated in the ACCOMPANYING DOCUMENTS according to Clause 16 ~~(ME SYSTEMS)~~.

Compliance is checked by the test of Clause 201.11 and 201.15.4.2.1 of the relevant particular standards (e.g. IEC 60601-2-19:2020, etc.).

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Additional 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	201.12.1.103, and generation of a visual and audible alarm in compliance with 201.15.4.2.1

201.5 General requirements for testing ~~of~~ ME EQUIPMENT

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

201.5.3 * Ambient temperature, humidity, atmospheric pressure

Addition to item a):

The ME EQUIPMENT shall comply with the requirements of this document when operating within the following conditions:

- an ambient temperature within the range 18 °C to 30 °C;
- an ambient air velocity is less than 0,3 m/s.

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

201.5.4 Other conditions

Addition:

Additional item to the existing list:

- aa) If not otherwise specified, the CONTROL TEMPERATURE shall be $36\text{ °C} \pm 1\text{ °C}$ 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 RADIANT WARMER 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"

201.7.2.102 Distance markings

The INFANT RADIANT WARMER without integral bed areas shall be permanently and clearly marked with an indication of the permissible distances between the INFANT RADIANT WARMER heating systems and any MATTRESS.

201.7.4.2 Control devices

Addition:

Means shall be provided for the clear selection and indication of CONTROL TEMPERATURE on or adjacent to the controls. The means provided shall allow resolution at intervals not greater than $0,2\text{ °C}$.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall additionally contain:

- a) a statement that independent monitoring of the temperature of the INFANT by the OPERATOR is essential and it is inadvisable to leave an INFANT unattended under the INFANT RADIANT WARMER;
- b) recommendations on the permissible distances between the INFANT RADIANT WARMER heating system and any MATTRESS used with it, and a statement on the effects which any changes in this distance may have;
- c) instructions on the recommended positions and methods of use and attachment of the temperature sensors provided for use with the INFANT RADIANT WARMER;
- d) for INFANT RADIANT WARMER with TYPE B APPLIED PART in which the INFANT might 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;
- e) if applicable, a recommendation to the OPERATOR to inspect regularly latches and closing devices of barriers to prevent the INFANT falling out;

- f) a statement of the maximum loads which can be applied to all supports and mounting brackets for ACCESSORIES and ancillary equipment;
- g) * information on the effects on the functioning of the INFANT RADIANT WARMER of detachment of the SKIN TEMPERATURE SENSOR from the PATIENT skin;
- h) if applicable, a statement that the tilting of the MATTRESS from its horizontal position relative to the INFANT RADIANT WARMER heater can affect the performance of the INFANT RADIANT WARMER (see 201.12.1.102);
- i) a statement that ACCESSORIES, e.g. for phototherapy or heated MATTRESSES, or sunlight can cause an increase in INFANT temperature to dangerous levels;
- j) a statement that the INFANT RADIANT WARMER is not suitable for use in the presence of flammable anaesthetic gases or other flammable materials, such as some types of cleaning fluids;
- k) a statement that rectal temperatures are not appropriate for controlling the heater output of the INFANT RADIANT WARMER;
- l) * a statement that the INFANT RADIANT WARMER 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;
- m) a statement that environmental conditions (e.g. air movement) can affect the thermal balance of the INFANT;
- n) * a statement that an INFANT RADIANT WARMER shall be used only by appropriately trained personnel and under the direction of qualified medical personnel who are familiar with currently known RISKS and benefits of radiant warmer use;
- o) a statement that an INFANT RADIANT WARMER can increase the PATIENT's insensible water loss;
- p) concentration of carbon dioxide (CO₂): If the MATTRESS of an INFANT RADIANT WARMER is fitted with a COMPARTMENT which encloses the baby, the MANUFACTURER shall specify (see 201.12.4.2.101) in the ACCOMPANYING DOCUMENTS the maximum CO₂ concentration which will occur in the COMPARTMENT during NORMAL CONDITIONS;
- q) a statement that the INFANT RADIANT WARMER does not adjust for PATIENT temperature in PREWARM MODE and that the mode shall be changed to MANUAL MODE or BABY CONTROLLED RADIANT WARMER (baby mode) immediately when the PATIENT is placed on the device. The MANUFACTURER shall disclose the level of heat in mW/cm² when operating in PREWARM MODE.

201.7.9.2.9 Operating instructions

Addition:

The instructions for use shall also contain

- a) for each mode of control, a detailed statement describing the method by which the amount of radiation is controlled and the temperature of the baby is maintained;
- b) * if BABY CONTROLLED RADIANT WARMER operation is available, a statement to explain why the OPERATOR should use this mode whenever possible.

201.7.9.2.13 * Maintenance

Addition:

If the source of radiation has a limited lifetime, the MANUFACTURER shall state, in the ACCOMPANYING DOCUMENTS, the time after which the source of radiation shall be replaced because of ageing.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall include details of any specified combinations of INFANT RADIANT WARMER with other equipment (see 201.4.1).

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 MANUFACTURER shall specify in the ACCOMPANYING DOCUMENTS the maximum CO₂ 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:

201.9.4.2.1 Instability in transport position

Addition:

The INFANT RADIANT WARMER and the mounting brackets and shelves are provided with the most unfavourable combination of detachable parts and ACCESSORIES and are loaded with the recommended maximum load.

~~**201.9.6.2 Acoustic energy**~~

201.9.6.2.1 Audible acoustic energy

Addition:

201.9.6.2.1.101 * Audible alarms sound level

Auditory ALARM SIGNALS shall have a sound level of at least 65 dB(A) at a distance of 3 m from the front of the INFANT RADIANT WARMER in a reflecting room. Other than the AUDIO PAUSED specified in 201.12.3.103, the auditory ALARM SIGNAL may be adjusted by the OPERATOR to a minimum lower level of 50 dB(A).

The sound pressure level of the ALARM SIGNAL shall not exceed 80 dB(A) on the MATTRESS.

If the frequency of the auditory ALARM SIGNAL is adjustable by the OPERATOR, these requirements shall apply to all the individual selectable frequencies.

Compliance is checked with the microphone of a sound level meter complying with the requirements of IEC 61672-1 placed 1,5 m above the floor and 3 m from the front of the INFANT RADIANT WARMER.

Compliance of the maximum level is checked with each alarm sound means activated, the sound level being measured at a point 5 cm above the centre of the MATTRESS.

Ensure that the background sound pressure level is at least 10 dB(A) below the measured levels.

201.9.8 MECHANICAL HAZARDS associated with support systems

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.

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.1 General

Addition:

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

Additional subclause:

201.9.8.3.101 Barriers

For INFANT RADIANT WARMERS with an integral bed area, suitable barriers shall be provided to prevent the PATIENT from falling off the MATTRESS. Such barriers as intended to be opened or removed to allow access to the PATIENT shall latch in their closed positions and shall remain locked under the test conditions.

Compliance is checked by inspection and the following test: Apply to all the barriers (other than those secured with the use of a TOOL) an outward horizontal force of 20 N to the centre of each barrier for 5 s. The barriers shall remain closed.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies except as follows:

201.10.6 * Infrared radiation

Addition:

The maximum irradiance level at any point on the MATTRESS shall not exceed 60 mW/cm² in the total infrared spectrum.

The maximum irradiance level shall not exceed 10 mW/cm² in the near infrared spectrum (760 nm to 1 400 nm).

Compliance is checked by measurements.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

Replacement:

The temperature of surfaces accessible to an INFANT on the MATTRESS shall not exceed 40 °C for metal surfaces and 43 °C for other materials when the INFANT RADIANT WARMER is operating under STEADY TEMPERATURE CONDITION at its maximum CONTROL TEMPERATURE.

Under conditions of warm-up to STEADY TEMPERATURE CONDITION or that of a SINGLE FAULT CONDITION, these surfaces shall not exceed 42 °C for metal or 45 °C for other materials.

These requirements apply under NORMAL CONDITION and SINGLE FAULT CONDITIONS including:

- failure of the heater control circuit;
- failure of a SKIN TEMPERATURE SENSOR;
- disconnection of a SKIN TEMPERATURE SENSOR from the INFANT RADIANT WARMER.

201.11.1.4 * GUARDS

Addition:

If the heater element surface temperature exceeds 85 °C in NORMAL USE, heater GUARDS which cannot exceed 85 °C in NORMAL USE shall be fitted.

Compliance is checked by measurement of the temperature and by performing the rigidity test as described in 15.3.2 of the general standard. The heater GUARD shall not touch the heater element.

201.11.2 *Fire prevention

Subclause 11.2 of the general standard applies.

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Replacement:

The INFANT RADIANT WARMER or ME SYSTEM shall be so constructed that in the event of spillage of water (accidental wetting) on the PATIENT support or SKIN TEMPERATURE SENSOR, no HAZARD shall result from the ingress of water.

Compliance is checked by the following tests: Position the INFANT RADIANT WARMER or ME SYSTEM in the least favourable position of NORMAL USE. In the case of an INFANT RADIANT WARMER or ME SYSTEM with BABY CONTROLLED RADIANT WARMER operation, the SKIN TEMPERATURE SENSOR shall be placed at the centre of the upper surface of the MATTRESS. Pour 200 ml of isotonic water (0,9 % saline) steadily on the centre of the MATTRESS over a period of 15 s.

After this test, the INFANT RADIANT WARMER or ME SYSTEM shall meet the dielectric strength requirements specified in 8.8.3 of the general standard and the INFANT RADIANT WARMER or ME-EQUIPMENT SYSTEM shall function normally.

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

Addition:

The INFANT RADIANT WARMER shall be so designed that an interruption and restoration of the power supply 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 INFANT RADIANT WARMER.

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 * Accuracy of SKIN TEMPERATURE SENSOR

The temperature measured by the SKIN TEMPERATURE SENSOR shall be continuously displayed and clearly visible. The temperature displayed shall have an accuracy of $\pm 0,3$ °C. If the display is used to present any other parameter, this shall only be obtained on demand, using a momentary action switch. The range of displayed temperature shall be at least 30 °C to 40 °C.

Compliance is checked by inspection and the following test:

Immerse the SKIN TEMPERATURE SENSOR in a water bath maintained at 36 °C $\pm 0,1$ °C. Position a calibrated thermometer, accurate to within $\pm 0,05$ °C, with its bulb adjacent to the SKIN TEMPERATURE SENSOR. The reading of the standard thermometer shall be compared with the displayed temperature and their difference shall not exceed $0,3$ °C less the calibrated thermometer error.

201.12.1.102 * Accuracy of distribution of irradiation to the MATTRESS

The difference between the MID-POINT AVERAGE TEMPERATURE and the TEST DEVICE AVERAGE TEMPERATURE of any of the other devices comprising the TEST LOAD shall not exceed 2 °C.

Compliance is checked by the following test: Prepare five TEST DEVICES consisting of aluminium discs each with a mass of 500 g ± 10 g and a diameter of 100 mm ± 2 mm. Drill 5 mm diameter holes 50 mm ± 2 mm deep as shown in Figure 201.102 and coat the entire disc surface with non-reflective black paint.

NOTE The disc thickness will be approximately 23 mm.

Subject the INFANT RADIANT WARMER to the following test in a room in which the maximum air velocity is $0,1$ m/s and the ambient temperature is maintained at 23 °C ± 2 °C.

Place four individually identified TEST DEVICES, marked 1, 2, 3 and 4 on the horizontal MATTRESS at the centres of each of four rectangles formed by bisecting the length and width of the MATTRESS as shown in Figure 201.101. Place a fifth TEST DEVICE marked "M" on the mid-point of the MATTRESS. Insert a temperature sensor in each of the five TEST DEVICE centres and, in the case of an INFANT RADIANT WARMER with BABY CONTROLLED RADIANT WARMER operation, attach the SKIN TEMPERATURE SENSOR to the centre of the upper surface of the TEST DEVICE "M", assuring a good thermal conductive contact (e.g. thermal paste). In the case of an INFANT RADIANT WARMER with a BABY CONTROLLED RADIANT WARMER operation, set the

temperature control to a CONTROL TEMPERATURE of $36\text{ °C} \pm 0,1\text{ °C}$ and operate the INFANT RADIANT WARMER until a STEADY TEMPERATURE CONDITION is obtained. In the case of an INFANT RADIANT WARMER with only a MANUAL MODE, set the heater output so that the TEST DEVICE will warm up to approximately 36 °C under STEADY TEMPERATURE CONDITION. Take at least 20 readings of temperature of each TEST DEVICE at regular intervals over a 60 min period.

Calculate the five values of the TEST DEVICE AVERAGE TEMPERATURE for each TEST DEVICE as follows:

$$T_1 = \frac{(t_{11} + t_{12} + t_{13} + t_{14} + \dots + t_{1n})}{n}$$

where

T_1 is the TEST DEVICE AVERAGE TEMPERATURE for TEST DEVICE no. 1;

t_{11}, \dots, t_{1n} are the individual temperature readings taken of TEST DEVICE no. 1 at regular intervals during the STEADY TEMPERATURE CONDITION;

n is the number of readings during the STEADY TEMPERATURE CONDITION.

Calculate the remaining TEST DEVICE AVERAGE TEMPERATURES T_2 , T_3 , T_4 and T_M in the same way.

Compare TEST DEVICE AVERAGE TEMPERATURES T_1 , T_2 , T_3 , T_4 with T_M and verify the maximum difference does not exceed $2,0\text{ °C}$.

201.12.1.103 * Accuracy of BABY CONTROLLED RADIANT WARMER operation

With the INFANT RADIANT WARMER working in the BABY CONTROLLED RADIANT WARMER operation with horizontal MATTRESS orientation in NORMAL CONDITION, the temperature as measured by the SKIN TEMPERATURE SENSOR shall not differ from the CONTROL TEMPERATURE by more than $0,5\text{ °C}$.

Compliance is checked during the tests of 201.12.1.102.

201.12.1.104 * Oxygen control

If an oxygen controller forms an integral part of the INFANT RADIANT WARMER, 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 set level by more than $\pm 5\text{ vol. \% } O_2$.

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 $35\text{ vol. \% } O_2$. 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. \% .

201.12.1.105 * Weighing scale

If a weighing scale is supplied as an integral part of the INFANT RADIANT WARMER or as an ACCESSORY specifically for use with the INFANT RADIANT WARMER, 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 RADIANT WARMER with horizontal MATTRESS orientation. Each value measured shall remain latched on the scale display at the conclusion of any individual measurement cycle and be retained until discarded by the OPERATOR. If the scale may be exposed to an OXYGEN RICH ENVIRONMENT in use, it shall comply with 6.5 of the general standard.

NOTE Device calibration ~~may be able to~~ can 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 with the ME EQUIPMENT operating at NORMAL CONDITIONS of use.

The accuracy of the measurement test shall be verified with the TEST LOADS positioned in locations M and A through D in Figure 201.101.

201.12.2 USABILITY of ME EQUIPMENT

Addition:

201.12.2.101 USABILITY of 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.

201.12.2.102 USABILITY of mode of operation

In the case of an INFANT RADIANT WARMER which can be operated in various modes of operation, the mode of operation shall be clearly displayed.

Compliance is checked by inspection.

201.12.2.103 * Time and irradiance limits in the MANUAL MODE

In the case of INFANT RADIANT WARMERS which are operated in the MANUAL MODE, an auditory and visual alarm shall be given at least every 15 min and the heater deactivated if the maximum irradiance at any point of the MATTRESS area exceeds a total irradiance level of 10 mW/cm². The heater can be reactivated and the alarm can be reset in compliance with 201.12.3.103 (see 201.12.3).

Compliance is checked by inspection and measurements at an ambient temperature of 23 °C \pm 2 °C.

201.12.2.104 * Heat output level at PREWARM MODE

While operating in PREWARM MODE, it shall not be possible for the OPERATOR to modify the heat output level preset by the MANUFACTURER. The level of heat when operating in the PREWARM MODE shall be displayed.

Compliance is checked by inspection.

201.12.3 ALARM SYSTEMS

Addition:

201.12.3.101 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 RADIANT WARMER.

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

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

201.12.3.102 Open and short circuit of the SKIN TEMPERATURE SENSOR in BABY CONTROLLED RADIANT WARMER operation

The INFANT RADIANT WARMER shall be provided with an auditory and visual ALARM SIGNAL which operates in the event of the SKIN TEMPERATURE SENSOR having open circuit or short circuit leads in the BABY CONTROLLED RADIANT WARMER operation.

Both open and short circuit leads shall disconnect the supply to the heater.

Compliance is checked by simulating both fault conditions and observing the effect.

201.12.3.103 * AUDIO PAUSED of auditory ALARM SIGNALS during MANUAL MODE

If the INFANT RADIANT WARMER incorporates a MANUAL MODE, the auditory and visual ALARM SIGNALS (see 201.12.2.103) shall operate within 15 min of commencement of use in this mode. The auditory ALARM SIGNAL shall be AUDIO PAUSED. Following any AUDIO PAUSED, the auditory ALARM SIGNAL shall operate again within 15 min. This sequence shall continue until the manual control mode is changed.

Compliance is checked by inspection, operating the INFANT RADIANT WARMER and timing the alarm.

201.12.3.104 AUDIO PAUSED

With the exception of the alarm specified in 201.12.3.101, it is allowable for the auditory ALARM SIGNAL to be AUDIO PAUSED or switched to a lower sound pressure level by the OPERATOR, but it shall revert automatically to a full value after not more than 15 min. The visual ALARM SIGNAL shall continue after the auditory ALARM SIGNALS has been AUDIO PAUSED until the alarm conditions have been corrected.

Compliance is checked by inspection, operating the INFANT RADIANT WARMER and timing the alarm.

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 instruction for use.

Compliance is checked by inspection.

201.12.4.2 Indication ~~of parameters~~ relevant to safety

Addition:

201.12.4.2.101 * CO₂ concentration

If the INFANT RADIANT WARMER is fitted with a COMPARTMENT that encloses the baby, the MANUFACTURER shall disclose the maximum value of CO₂ concentration which will occur in the COMPARTMENT under NORMAL CONDITIONS.

Compliance is checked by the following test:

A 4 % mixture of CO₂ 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 201.101, middle point) through an 8 mm diameter tube in vertical direction from the MATTRESS to the top. CO₂ concentration at a point 15 cm from the middle point shall be measured after 1 h. 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.

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:

201.15.3.5 Rough handling test

Addition:

Following the above tests, the INFANT RADIANT WARMER shall be suitable for future NORMAL USE. Mechanical and structural integrity of the INFANT RADIANT WARMER shall be verified; for example, latches and barriers shall remain closed and ancillary equipment supplied by or available from the MANUFACTURER shall remain secure.

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

201.15.4.2.1 Application

Addition to item a):

After STEADY TEMPERATURE CONDITIONS have been achieved, any sensed temperature deviation exceeding ± 1 °C compared with the CONTROL TEMPERATURE shall cause an auditory and visual alarm to operate, and the INFANT RADIANT WARMER heater shall switch off when the sensed temperature exceeds the CONTROL TEMPERATURE by 1 °C.

Compliance is checked by inspection and both of the following tests:

Test 1

Set the CONTROL TEMPERATURE to 36 °C and immerse the SKIN TEMPERATURE SENSOR in a water bath maintained at 36 °C ± 0,1 °C. Position a calibrated thermometer accurate to within ±0,05 °C with its bulb adjacent to the SKIN TEMPERATURE SENSOR. After a steady temperature indication is achieved and maintained for at least 10 min, increase the water bath temperature control setting to 38 °C. Report whether the auditory and visual alarms operate at a water bath temperature not exceeding 37 °C ± 0,3 °C and whether the INFANT RADIANT WARMER heater switches off.

Test 2

As for test 1, but in this instance the temperature control setting of the water bath is reduced from 36 °C ± 0,1 °C to 34 °C ± 0,1 °C. Report whether the auditory and visual alarms operate above 35 °C ± 0,3 °C and the INFANT RADIANT WARMER heater remains in operation.

Addition to item b):

The INFANT RADIANT WARMER shall not permit the SKIN TEMPERATURE of the PATIENT to exceed 40 °C under NORMAL CONDITION and each SINGLE FAULT CONDITION.

Compliance is checked by the following test: Place a TEST DEVICE at the centre of the MATTRESS, with the INFANT RADIANT WARMER operating under STEADY TEMPERATURE CONDITIONS at the maximum CONTROL TEMPERATURE, and under any SINGLE FAULT CONDITION.

The TEST DEVICE shall not exceed 40 °C without the auditory and visual alarms operating and the heater being disconnected.

201.15.4.2.2 Temperature settings

Addition:

201.15.4.2.2.101 Range of CONTROL TEMPERATURE

The range of the CONTROL TEMPERATURE in the BABY CONTROLLED RADIANT WARMER operation of an INFANT RADIANT WARMER shall be from 36 °C or less to not more than 38 °C.

Compliance is checked by inspection.

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 compatibility – Requirements and tests~~

~~IEC 60601-1-2:2007 applies, except as follows:~~

~~202.6.2.3 Radiated RF electromagnetic fields~~

~~202.6.2.3.1 *Requirements~~

~~Replacement:~~

~~For radiated radio-frequency electromagnetic fields the INFANT RADIANT WARMER and/or ME SYSTEM shall~~

- ~~a) continue to perform its intended function as specified by the MANUFACTURER at a level up to 3 V/m for the frequency range stated in the collateral standard for EMC;~~
- ~~b) continue to perform its intended function as specified by the MANUFACTURER or fail without creating a HARM at a level up to 10 V/m for the frequency range stated in the collateral standard for EMC.~~

~~210 Process requirements for the development of physiologic closed-loop controllers~~

~~IEC 60601-1-10:2007 applies except as follows:~~

~~210.5.1 *Instructions for use~~

~~Subclause 5.1 of IEC 60601-1-10 does not apply.~~

~~210.5.2 Technical description~~

~~The information specified in subclause 5.1 of IEC 60601-1-10 shall be included in the technical description.~~

~~210.6.1 USABILITY~~

~~Replacement:~~

~~Subclause 6.1 of IEC 60601-1-10 does not apply.~~

~~NOTE Requirements for USABILITY are specified elsewhere in this particular standard.~~

~~210.6.3 *PCLCS VARIABLE logging~~

~~Replacement:~~

~~Subclause 6.3 of IEC 60601-1-10 does not apply.~~

~~210.8.2.2.6 *Responses of the PCLCS~~

~~Replacement:~~

~~Subclause 8.2.2.6 of IEC 60601-1-10 does not apply.~~

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 RADIANT WARMER 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 stated in the collateral standard for EMC.

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

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Annexes

The annexes of the general standard apply.

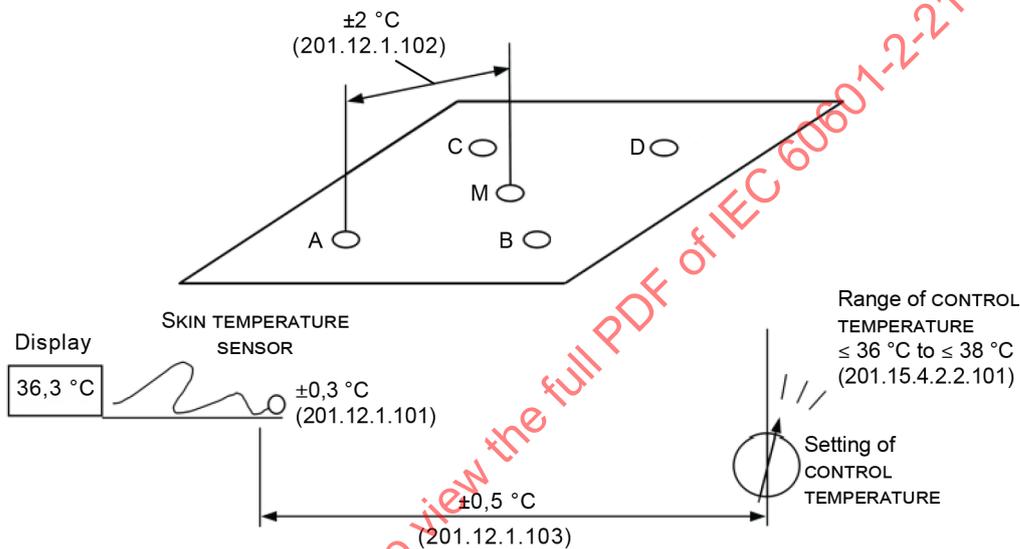
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Annex AA (informative)

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 ±1 °C	(201.15.4.2.1)
Overtemperature alarm 40 °C	(201.15.4.2.1, Test 2 addition to item b)
Interruption of power supply alarm	(201.12.3.101)
Maximum surface temperature (normal condition) 40 °C (for metals) 43 °C (for other materials) Maximum surface temperature (single fault condition) 42 °C (for metals) 45 °C (for other materials)	(201.11.1.2.2)
Every 15 min alarm in manual mode for irradiance level > 10 mW/cm ²	(201.12.2.103)

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NOTE Number in brackets indicate the relevant subclauses.

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

AA.2 Particular guidance

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

~~Subclause 201.1.3 – Collateral standards~~

~~The experts of the working group have discussed and determined that some of the requirements and terminology of the collateral standard IEC 60601-1-10 are not applicable.~~

~~These are addressed in the particular clauses.~~

~~For a usual INFANT RADIANT WARMER:~~

- ~~— COMMAND VARIABLE is the SKIN CONTROL TEMPERATURE setting.~~
- ~~— CONTROLLER OUTPUT VARIABLE is heater power.~~
- ~~— MANIPULATED VARIABLE is air temperature.~~
- ~~— PHYSIOLOGIC VARIABLE is the measured SKIN TEMPERATURE of the INFANT.~~
- ~~— FEEDBACK VARIABLE is the output of the SKIN TEMPERATURE SENSOR.~~

~~One of the FALL-BACK MODES may be to cut off the heater power.~~

~~These definitions are for information and may differ for an INFANT RADIANT WARMER using different technologies.~~

Subclause 201.1.1 – Scope

It is the primary purpose of a BABY CONTROLLED RADIANT WARMER to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR. Hence, SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED RADIANT WARMER, including the displayed value, are considered to be not 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 as defined in IEC 60601-2-19:2020.

Subclause 201.3.207 – PREWARM MODE

INFANT RADIANT WARMERS require significant time for the heater to warm up and, subsequently, for the MATTRESS area to warm up. INFANTS who are placed on INFANT RADIANT WARMERS are often cold stressed from transport or cold stressed and wet from recent birth and cannot tolerate continued cooling while waiting for the warming device to heat up. A MANUAL MODE level of heat below 10 mW/cm² is not sufficient for prewarming the INFANT RADIANT WARMER for these cold stressed INFANTS. These cold stressed INFANTS cannot tolerate the time for the warmers to heat to a level appropriate for their needs without experiencing further cold stress. The PREWARM MODE allows the INFANT RADIANT WARMER to remain warmed to a level suitable for these INFANTS so that the INFANT may immediately begin warming from a cold stressed condition when placed on the INFANT RADIANT WARMER.

Subclause 201.3.212 – TEST LOAD

With respect to irradiation distribution of 201.12.1.102, the aluminium 500 g TEST DEVICES were developed in 1984 on the basis that they were simple to reproduce to specific dimensions, and they respond to temperature changes due to variations in warmer output. Different MANUFACTURERS of INFANT warmers have considered them to be a suitable reference

for tests of their products. Other TEST DEVICES of this nature tended to be more complicated to reproduce and more expensive.

This TEST LOAD configuration is not intended to represent a specific INFANT size, but only to test the operation of a radiant warmer.

This TEST LOAD configuration is intended to demonstrate the radiant warmer temperature control mechanism, and indicates the uniformity of heating across the MATTRESS.

A matt black finish of the TEST LOAD should provide a high emissivity value for consistent test data reproduction.

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

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, heated MATTRESS, etc.) ~~must~~ shall comply to.

As an example, the intended use of an incubator or warmer is to apply heat to a baby and to keep the temperature stable within a safe region. The accuracy of the set temperature to the real temperature ~~must~~ shall be maintained within the range required by the standard and listed as a requirement in the ESSENTIAL PERFORMANCE table. If the temperature varies beyond the range listed in the requirement, then the device ~~must~~ 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 (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, combined with the requirement to define thermal performance, a failure to maintain this state if accompanied by an audible alarm, which would allow a clinician the appropriate mitigating actions, would be the total summation of essential requirements for these type devices.

Subclause 201.5.3 – Ambient temperature, humidity, atmospheric pressure

INFANT RADIANT WARMERS are commonly used in areas where ambient temperatures range from 18 °C to 30 °C.

INFANT RADIANT WARMERS are intended for use in nurseries as well as in labour and delivery rooms; the latter could be cooler than nurseries.

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 201.7.9.2.2 – Warning and safety notices, item g)

It is desirable that the INFANT RADIANT WARMER should be provided with an auditory alarm and visual indication which operates when the SKIN TEMPERATURE SENSOR is detached from the

INFANT's skin. Technically this has not been reliably achieved and has therefore not been made a requirement of this document.

Subclause 201.7.9.2.2 – Warning and safety notices, item l)

The INFANT RADIANT WARMER 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 201.7.9.2.2 – Warning and safety notices, item n)

It is inherent in INFANT RADIANT WARMER 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 be responsible for ordering all aspects of INFANT RADIANT WARMER use.

Subclause 201.7.9.2.9 – Operating instructions, item b)

An INFANT RADIANT WARMER in the MANUAL MODE of operation emits a preset amount of energy to the child continuously, regardless of the temperature of the INFANT. If the heater is set at the maximum in order to warm up the INFANT rapidly, the skin of the INFANT can become dangerously hot. It is therefore essential to attend to ME EQUIPMENT operation and INFANT condition at frequent intervals. It is recommended that the PATIENT under the INFANT RADIANT WARMER be supervised.

Subclause 201.7.9.2.13 – Maintenance

There have been reports of hot fragments (e.g. metal oxide particles) from aged warmer heaters falling onto the MATTRESS.

Subclause 201.9.6.2.1.101 – Audible alarms sound level

Temporary threshold shifts of hearing in adults have been associated with 8 h of significantly higher sound levels. While data on INFANTS is not available, a lower value was chosen to provide an added margin of safety.

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 radiant warmer 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 semi-anechoic 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 201.10.6 – Infrared radiation

INFANT RADIANT WARMERS provide thermal support by directing invisible infrared light to the INFANT's body. The source of this infrared light is an overhead heater whose electrical power input is limited by design, thereby limiting the amount of infrared energy output that can be directed at the INFANT.

The limits proposed in this document are based upon a review of literature regarding the effect of infrared radiation upon the eyes and skin of humans [1 to 14]².

Infrared measurements can be made in the 760 nm to 1 400 nm wavelength (IR-A region) as well as the 1 400 nm to 4 500 nm segment of the wavelength IR-B and IR-C regions.

The IR-A region is associated with potential for damage to the crystalline lens of the eye which may lead to a cataract. The IR-B and IR-C regions are almost completely absorbed by the cornea (the outermost layer of the eyes) with a resulting potential for burn.

From a review of the literature, the following statements can be made.

- a) There have been no reports from any sources describing any harmful effects of infrared radiant energy on either the eyes or skin in INFANTS nursed under INFANT ~~RADIATION~~ RADIANT WARMERS. Retrospective examinations specifically looking for any eye effects have produced no evidence of harmful effects for either short-term or long-term evaluations. The long-term evaluations were performed from 30 days to 6 years after the INFANTS were nursed under radiant warmers.
- b) Spectral irradiance measurements on several commercially available radiant warmers show the absolute peak irradiance that the INFANT could be exposed to is less than 60 mW/cm² across the entire electromagnetic spectrum, with less than 10 mW/cm² in the IR-A wavelength region. The irradiance the INFANT would normally be exposed to at maintenance heat levels is much less than these levels. Clinical reports have documented that the mean irradiance needed to maintain a stable SKIN TEMPERATURE could be anywhere from 12 mW/cm² to approximately 25 mW/cm² for very small INFANTS. Higher levels would be needed routinely during warming of cold INFANTS and/or warming newly born INFANTS with skin still wet with amniotic fluid. Generally, the smaller premature INFANTS require more irradiance to maintain their SKIN TEMPERATURE because they have a relatively larger surface-area-to-mass ratio that permits larger heat losses per unit weight.
- c) Wheldon and Rutter [15] accurately report absolute irradiance levels, observing a maintenance irradiance level of (58 ± 3) mW/cm² for INFANTS averaging 1,6 kg.

Similar levels of irradiance have been used in neonatal intensive care units for at least the last 15 years to provide thermal support to premature INFANTS.

No reports have identified a corneal opacity or skin inflammation caused by the nursing of the INFANT under a radiant warmer.

- d) The recommendation of AAMI is 60 mW/cm².

Both cataracts and retinal lesions have been documented as being caused by IR-A wavelengths. Absorption of the infrared energy by the iris, which indirectly heats the lens (and forms opacities), has been identified as the most likely cause of infrared induced cataracts. INFANT RADIANT WARMERS possess very little IR-A energy when compared to sources that have caused cataract formation.

² Figures in square brackets refer to the Bibliography.

Retinal lesions have been reported to be caused primarily by shorter visible light wavelengths and the actual IR-A component may be a negligible contributor to any retinal damage that could occur.

The proposed radiant warmer threshold values put forth by the Emergency Care Research Institute in 1973 have been observed and maintained by MANUFACTURERS of radiant warmers on the market today. These limits of less than 300 mW/cm² for the IR-B and IR-C regions and less than 40 mW/cm² for the IR-A region are based on data that have since been updated and re-evaluated and confirm their appropriateness.

Photobiologists have not yet determined absolute maximum safe levels of incoherent infrared light in the IR-A, B and C regions. It has been proposed that for IR-A wavelengths, a safe, chronic exposure level probably is in the order of 10 mW/cm² with allowances for incidental exposures for several minutes up to 100 mW/cm². In a 1980 publication from one of these same authors [15, 16, 17, 18], it was concluded that 100 mW/cm² for IR-B and IR-C regions is the safe threshold limit for chronic exposure of the cornea. Since the time these limits were proposed, these authors have documented that more recent investigations indicate that infrared radiation may not be as hazardous as was once thought.

Since no harmful effects from the irradiance levels now present in radiant warmers have been reported, these levels can serve as a maximum threshold limit until further data are made available.

Although further study of threshold levels could be useful to further define limits, the actual benefits derived from the use of radiant warmers far outweigh the potential, unreported, and theoretical RISKS associated with radiant infrared energy from INFANT RADIANT WARMERS. No reports of any harmful infrared energy induced effects have been documented in the medical literature after nearly 15 years of clinical use.

- e) The spectral characteristics for human eye and skin media have been documented in the literature. No studies of the neonatal eye spectral characteristics have been reported. Only the spectral characteristics of neonatal skin with respect to visible light have been reported.

Although the neonatal eye is not completely developed at birth, the spectral characteristics are believed to be similar to those of an adult. Examinations of neonatal eyes after being nursed in radiant warmers have not shown any harmful effects from the level of IR-A delivered by the radiant warmers.

Neonatal excised skin specimens have been shown to have similar spectral absorption characteristics to adult skin in the visible light regions. However, for the IR-A regions, the skin absorption can vary with the skin thickness.

Since the skin's reflectance is greatest in the IR-A regions, much of the incident light will be reflected away, and only a small portion of the total incident light would actually penetrate the skin.

Most infra-red energy is in the IR-B and IR-C regions and is absorbed by the top 1 mm to 2 mm of skin. No harmful effect from absorption of the radiant energy from a radiant warmer has been reported. Since infrared energy is not energetic enough to enter into photochemical reactions with skin components, the only effect of the absorption of the energy is heating, which is the primary reason the INFANT is under a radiant warmer.

- f) The associated HAZARDS from exposure to infrared energy for humans and animals, using both coherent and incoherent light have been documented in the literature [19 to 23]. The HAZARDS, reported in the literature, from exposure of humans to incoherent infrared light are cutaneous skin burns, corneal opacities and inflammation, lenticular opacities (cataracts), retinal lesions, and skin inflammation. Recent reports have shown that the cutaneous skin burns, corneal opacities and inflammation, and skin inflammation are due entirely to the IR-B and IR-C portions of the infra-red spectrum; because the outermost layer of the skin and eye absorb all of the incident radiation in the wavelength regions, they do not transmit any significant portion of incident energy below this outermost layer. Skin pain thresholds have been documented at approximately 45 °C.

Several commercially available radiant warmers have SKIN TEMPERATURE limits to prevent the SKIN TEMPERATURE from exceeding 40 °C. Corneal opacities have been reported in neonates, but usually are associated with other pathological conditions (in association with

congenital glaucoma, or as a result of an infection from either congenital rubella or herpes virus).

Subclause 201.11.1.2.2 – APPLIED PARTS not intended to supply heat to a PATIENT

The requirements of this subclause can be based upon the BSI publication [24], and the drafting committee having noted the potential RISK of babies under warmers coming into contact with hot metallic or other surface; hence the stated limits.

Subclause 201.11.1.4 – GUARDS

Heater GUARDS are intended to prevent the OPERATOR from inadvertently touching the hot heater element surface.

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 subclause.

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 neonates 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 RADIANT WARMER, 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 enriched environment have been met. No incident has been reported concerning fire ignition inside the bassinet of a warmer for many years. Also, even with warmer MATTRESSES, additional concerns were discussed around the toxicity of fumes that can be produced by materials that have been treated with flame retardant additives. Therefore, with the exception of elevating (accelerant) the RISK of fire from the cover material, no specific flammability rating is required of the ~~pad~~ PAD's cover and the inner filler.

Subclause 201.12.1.101 – Accuracy of SKIN TEMPERATURE SENSOR

The SKIN TEMPERATURE SENSOR indication of temperature error is only a part of the total error associated with skin surface temperature measurement. Other errors can be introduced by variation of the area of sensor contact, contact pressure and heat exchange between the sensor and its environment. The accuracy is most important at 36 °C, which is around the normal PATIENT SKIN TEMPERATURE. Accuracy to this degree is required to establish the best possible function of the SKIN TEMPERATURE SENSOR control system.

Subclause 201.12.1.102 – Accuracy of distribution of irradiation to the MATTRESS

Long experience of both the medical and technical requirements for INFANT RADIANT WARMERS has shown that this level of performance (2 °C) is satisfactory in maintaining the temperature of the baby, and readily achievable technically.

Subclause 201.12.1.103 – Accuracy of BABY CONTROLLED RADIANT WARMER operation

The OPERATOR of the INFANT RADIANT WARMER ~~must~~ shall be confident that the temperature that is set will be the actual temperature achieved within $\pm 0,5$ °C.

Subclause 201.12.1.104 – Oxygen control

Relatively low oxygen concentrations for the PATIENT may cause brain damage. Relatively high oxygen concentration for the PATIENT may cause a retinopathy of prematurity. In SINGLE FAULT CONDITION, the use of one sensor may cause a HAZARD for the baby, therefore for this operation the sensors are required to operate independently.

Subclause 201.12.1.105 – Weighing scale

Weight scales used in paediatric medical equipment have unique requirements that differ significantly from those of weight scales used in general commercial or domestic weighing applications. Absolute accuracy is important, however not to the degree of accuracy (1/1 000) required by commercial scales used for monetary transactions. More important from a clinical application is the information provided by weight trends, demonstrating an increase or decrease trend in the weight of the INFANT PATIENT. Absolute accuracy is very difficult at best due to electrical leads, tubing, and other PATIENT care devices that cannot be completely eliminated from the measurement.

Because weighing an INFANT is a difficult process requiring both hands of the OPERATOR in the manipulation of the INFANT PATIENT, it is necessary that the weight reading be held and displayed until such time as the OPERATOR has completed the PROCEDURE. The weight reading should be displayed until the OPERATOR has recorded it or stored it, if electronic storage is an option.

An INFANT PATIENT needs to be contained in a heated, controlled environment for an extended period of time. Moving an INFANT for any reason can be harmful to the INFANT PATIENT's well being. INFANT PATIENTS often remain in their controlled environment, INFANT INCUBATOR or INFANT RADIANT WARMER, for 2 or more weeks. During this time it is necessary for the OPERATOR to assure the calibration of the weight scale. Additionally, it may be necessary for the OPERATOR to be able to adjust the calibration should the weight scale be out of calibration without the necessity to remove the scale or move the INFANT for calibration.

Subclause 201.12.2.103 – Time and irradiance limits in the MANUAL MODE

It is necessary to have in the MANUAL MODE a mode of operation without alarm function on a low heater output level to keep the INFANT RADIANT WARMER previously warmed (as a stand-by function) or to provide only a small proportion of heat to the baby (usually bigger babies). The experts of this working group and the paediatric doctors from the German National Committee are of the opinion that, at a level of 10 mW/cm², there is no RISK to babies under radiant warmers. Long experience with the use of radiant warmers with low output levels confirms this statement. There are no known HAZARDS.

Subclause 201.12.2.104 – Heat output level at PREWARM MODE

The PREWARM MODE is not appropriate for care of an INFANT after the INFANT has been placed on the INFANT RADIANT WARMER. See 201.3.207.

Subclause 201.12.3.103 – AUDIO PAUSED of auditory ALARM SIGNALS during MANUAL CONTROL

An INFANT RADIANT WARMER operating in the MANUAL MODE continuously emits a preset amount of energy to the INFANT regardless of his/her temperature. If this energy is at a maximum in order to rapidly warm up the INFANT, the INFANT's skin can become dangerously hot. A considerable source of RISK is that there is not necessarily an automatic monitoring of the INFANT's temperature. It is therefore essential to have a periodic alarm operation and the condition of the INFANT under the warmer assessed at frequent intervals.

Subclause 201.12.4.2.101 – CO₂ concentration

It is considered that a general test, applicable to all INFANT RADIANT WARMERS, should be prescribed, giving definite performance features. It was recognized that mixing of CO₂ within the air of the COMPARTMENT is not so easy to realize and therefore a mixture of CO₂/air should be administered, instead.

Subclause 201.15.4.1.101 – Temperature sensors

The response of the rectal temperature of the INFANT to environmental temperature changes is slow and is not suitable for controlling the INFANT RADIANT WARMER CONTROL TEMPERATURE. The requirement of this subclause is intended to eliminate wrong applications of the SKIN TEMPERATURE SENSOR.

Subclause 202.6.2.3.1 – Requirements

~~The expert group do not consider the warming therapy devices to be a LIFE SUPPORTING EQUIPMENT as defined in the collateral standard for EMC.~~

Subclause 210.5.1 – Instructions for use

~~The information required by 5.1 of IEC 60601-1-10 is necessary for SERVICE PERSONNEL but not for other OPERATORS~~

Subclause 210.6.3 – PCLCS VARIABLE logging

~~The experts of the working group have discussed and determined that the requirement for VARIABLE logging of the collateral standard IEC 60601-1-10 is not applicable, because many BABY CONTROLLED RADIANT WARMER s which do not have this facility have been used safely for many decades.~~

Subclause 210.8.2.2.6 – Responses of the PCLCS

~~The experts of the working group have discussed and determined that the requirement for responses of the PCLCS of the collateral standard IEC 60601-1-10 is not applicable, because relevant requirements are specified in other subclauses of this particular standard.~~

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-21: Particular requirements for the basic safety and essential
performance of infant radiant warmers**

**Appareils électromédicaux –
Partie 2-21: Exigences particulières pour la sécurité de base et
les performances essentielles des incubateurs radiants pour nouveau-nés**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers**

FOREWORD

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International standard IEC 60601-2-21 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: alignment with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

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

FDIS	Report on voting
62D/1766/FDIS	62D/1776/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 standard 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.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT RADIANT WARMER equipment.

This particular standard amends and supplements IEC 60601-1, *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, Annex AA does not form part of the requirements of this document.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT RADIANT WARMERS as defined in 201.3.204, 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 the safety requirements for INFANT RADIANT WARMERS, 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 60601-2-35;
- INFANT INCUBATORS; for information, see IEC 60601-2-19;
- INFANT TRANSPORT INCUBATORS, for information, see IEC 60601-2-20;
- INFANT PHOTOTHERAPY EQUIPMENT, for information, see IEC 60601-2-50.

SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED RADIANT WARMER including the displayed value are not considered to be a CLINICAL THERMOMETER in the sense of the particular standard ISO 80601-2-56.

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

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT RADIANT WARMERS as defined in 201.3.204, 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 2 of this particular standard.

IEC 60601-1-2:2014 applies as modified in Clauses 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 60601-1:2005 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 specified 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 beginning on page 36.

Addition:

201.3.201

BABY CONTROLLED RADIANT WARMER

mode of operation in which the power output varies automatically in order to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR according to the CONTROL TEMPERATURE set by the OPERATOR

201.3.202

CONTROL TEMPERATURE

temperature selected at the temperature control

201.3.203

INFANT

PATIENT up to 3 months and with a weight of less than 10 kg

201.3.204

INFANT RADIANT WARMER

electrically powered device with a radiant heating source intended to maintain the thermal balance of an INFANT by direct radiation of energy in the infrared region of the electromagnetic spectrum

201.3.205

MANUAL MODE

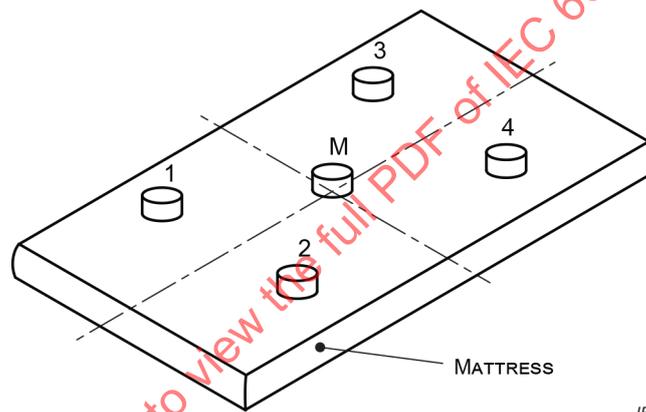
mode of operation in which the heater output is either at a fixed level or a proportion of its maximum output set by the OPERATOR

201.3.206

MID-POINT AVERAGE TEMPERATURE

T_M

AVERAGE TEMPERATURE of the TEST DEVICE positioned at the mid-point of the INFANT RADIANT WARMER MATTRESS (see Figure 201.101)



IEC

Figure 201.101 – Layout of TEST DEVICES

201.3.207

***PREWARM MODE**

mode of operation in which the heater output is maintained at a preset level (set by the MANUFACTURER) for the purpose of pre-warming the INFANT RADIANT WARMER and maintaining the level of warmth of the INFANT RADIANT WARMER prior to an INFANT being placed on the device

201.3.208

SKIN TEMPERATURE SENSOR

sensing device intended to measure the INFANT'S SKIN TEMPERATURE

201.3.209

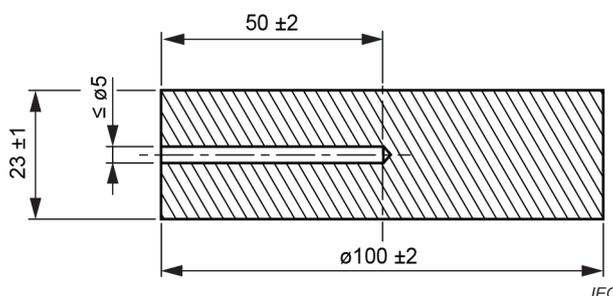
STEADY TEMPERATURE CONDITION

condition which is reached when the temperature, measured at the centre of the TEST DEVICE positioned on the mid-point of the INFANT RADIANT WARMER MATTRESS, does not vary by more than 1 °C over a period of 1 h

201.3.210**TEST DEVICE**

totally matt blackened disc used as a reproducible receiver of radiant energy during testing of the INFANT RADIANT WARMER (see Figure 201.102)

Dimensions in millimetres



Surface finish: non-reflective black paint

Disc mass: 500 g ± 10 g

Disc material: aluminium of density within the range 2,6 g/cm³ and 2,9 g/cm³

Figure 201.102 – TEST DEVICE

201.3.211**TEST DEVICE AVERAGE TEMPERATURE**

$(T_1, T_2, T_3, T_4 \text{ OR } T_M)$

AVERAGE TEMPERATURE reading taken during a STEADY TEMPERATURE CONDITION at regular intervals at the centre of a TEST DEVICE

Note 1 to entry: T_M, T_1, T_2, T_3, T_4 , are expressed in °C.

201.3.212*** TEST LOAD**

array of five TEST DEVICES used in a specified configuration (see Figure 201.101) for performance tests of the INFANT RADIANT WARMER

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 ME EQUIPMENT or ME SYSTEMS, which combines alternative heat sources, for instance incubators with integrated INFANT RADIANT WARMERS, devices supplying heat via BLANKETS, PADS or MATTRESSES etc., safety requirements of other relevant particular standards shall be considered. Further the safety requirements of this document shall be fulfilled with the combination of the other equipment, which is approved by the MANUFACTURER, as stated in the ACCOMPANYING DOCUMENTS according to Clause 16.

Compliance is checked by the test of Clause 201.11 and 201.15.4.2.1 of the relevant particular standards (e.g. IEC 60601-2-19:2020, etc.).

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Additional 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	201.12.1.103, and generation of a visual and audible alarm in compliance with 201.15.4.2.1

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

Addition to item a):

The ME EQUIPMENT shall comply with the requirements of this document when operating within the following conditions:

- an ambient temperature within the range 18 °C to 30 °C;
- an ambient air velocity is less than 0,3 m/s.

If not otherwise specified in this document, 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 RADIANT WARMER 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".

201.7.2.102 Distance markings

The INFANT RADIANT WARMER without integral bed areas shall be permanently and clearly marked with an indication of the permissible distances between the INFANT RADIANT WARMER heating systems and any MATTRESS.

201.7.4.2 Control devices

Addition:

Means shall be provided for the clear selection and indication of CONTROL TEMPERATURE on or adjacent to the controls. The means provided shall allow resolution at intervals not greater than 0,2 °C.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall additionally contain:

- a) a statement that independent monitoring of the temperature of the INFANT by the OPERATOR is essential and it is inadvisable to leave an INFANT unattended under the INFANT RADIANT WARMER;
- b) recommendations on the permissible distances between the INFANT RADIANT WARMER heating system and any MATTRESS used with it, and a statement on the effects which any changes in this distance may have;
- c) instructions on the recommended positions and methods of use and attachment of the temperature sensors provided for use with the INFANT RADIANT WARMER;
- d) for INFANT RADIANT WARMER with TYPE B APPLIED PART in which the INFANT might 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;
- e) if applicable, a recommendation to the OPERATOR to inspect regularly latches and closing devices of barriers to prevent the INFANT falling out;
- f) a statement of the maximum loads which can be applied to all supports and mounting brackets for ACCESSORIES and ancillary equipment;
- g) * information on the effects on the functioning of the INFANT RADIANT WARMER of detachment of the SKIN TEMPERATURE SENSOR from the PATIENT skin;
- h) if applicable, a statement that the tilting of the MATTRESS from its horizontal position relative to the INFANT RADIANT WARMER heater can affect the performance of the INFANT RADIANT WARMER (see 201.12.1.102);
- i) a statement that ACCESSORIES, e.g. for phototherapy or heated MATTRESSES, or sunlight can cause an increase in INFANT temperature to dangerous levels;
- j) a statement that the INFANT RADIANT WARMER is not suitable for use in the presence of flammable anaesthetic gases or other flammable materials, such as some types of cleaning fluids;
- k) a statement that rectal temperatures are not appropriate for controlling the heater output of the INFANT RADIANT WARMER;
- l) * a statement that the INFANT RADIANT WARMER 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;
- m) a statement that environmental conditions (e.g. air movement) can affect the thermal balance of the INFANT;
- n) * a statement that an INFANT RADIANT WARMER shall be used only by appropriately trained personnel and under the direction of qualified medical personnel who are familiar with currently known RISKS and benefits of radiant warmer use;

- o) a statement that an INFANT RADIANT WARMER can increase the PATIENT's insensible water loss;
- p) concentration of carbon dioxide (CO₂): If the MATTRESS of an INFANT RADIANT WARMER is fitted with a COMPARTMENT which encloses the baby, the MANUFACTURER shall specify (see 201.12.4.2.101) in the ACCOMPANYING DOCUMENTS the maximum CO₂ concentration which will occur in the COMPARTMENT during NORMAL CONDITIONS;
- q) a statement that the INFANT RADIANT WARMER does not adjust for PATIENT temperature in PREWARM MODE and that the mode shall be changed to MANUAL MODE or BABY CONTROLLED RADIANT WARMER (baby mode) immediately when the PATIENT is placed on the device. The MANUFACTURER shall disclose the level of heat in mW/cm² when operating in PREWARM MODE.

201.7.9.2.9 Operating instructions

Addition:

The instructions for use shall also contain

- a) for each mode of control, a detailed statement describing the method by which the amount of radiation is controlled and the temperature of the baby is maintained;
- b) * if BABY CONTROLLED RADIANT WARMER operation is available, a statement to explain why the OPERATOR should use this mode whenever possible.

201.7.9.2.13 * Maintenance

Addition:

If the source of radiation has a limited lifetime, the MANUFACTURER shall state, in the ACCOMPANYING DOCUMENTS, the time after which the source of radiation shall be replaced because of ageing.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall include details of any specified combinations of INFANT RADIANT WARMER with other equipment (see 201.4.1).

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 MANUFACTURER shall specify in the ACCOMPANYING DOCUMENTS the maximum CO₂ 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:

201.9.4.2.1 Instability in transport position

Addition:

The INFANT RADIANT WARMER and the mounting brackets and shelves are provided with the most unfavourable combination of detachable parts and ACCESSORIES and are loaded with the recommended maximum load.

201.9.6.2.1 Audible acoustic energy

Addition:

201.9.6.2.1.101 * Audible alarms sound level

Auditory ALARM SIGNALS shall have a sound level of at least 65 dB(A) at a distance of 3 m from the front of the INFANT RADIANT WARMER in a reflecting room. Other than the AUDIO PAUSED specified in 201.12.3.103, the auditory ALARM SIGNAL may be adjusted by the OPERATOR to a minimum lower level of 50 dB(A).

The sound pressure level of the ALARM SIGNAL shall not exceed 80 dB(A) on the MATTRESS.

If the frequency of the auditory ALARM SIGNAL is adjustable by the OPERATOR, these requirements shall apply to all the individual selectable frequencies.

Compliance is checked with the microphone of a sound level meter complying with the requirements of IEC 61672-1 placed 1,5 m above the floor and 3 m from the front of the INFANT RADIANT WARMER.

Compliance of the maximum level is checked with each alarm sound means activated, the sound level being measured at a point 5 cm above the centre of the MATTRESS.

Ensure that the background sound pressure level is at least 10 dB(A) below the measured levels.

201.9.8 MECHANICAL HAZARDS associated with support systems

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.

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.1 General

Addition:

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

Additional subclause:

201.9.8.3.101 Barriers

For INFANT RADIANT WARMERS with an integral bed area, suitable barriers shall be provided to prevent the PATIENT from falling off the MATTRESS. Such barriers as intended to be opened or removed to allow access to the PATIENT shall latch in their closed positions and shall remain locked under the test conditions.

Compliance is checked by inspection and the following test: Apply to all the barriers (other than those secured with the use of a TOOL) an outward horizontal force of 20 N to the centre of each barrier for 5 s. The barriers shall remain closed.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies except as follows:

201.10.6 * Infrared radiation

Addition:

The maximum irradiance level at any point on the MATTRESS shall not exceed 60 mW/cm² in the total infrared spectrum.

The maximum irradiance level shall not exceed 10 mW/cm² in the near infrared spectrum (760 nm to 1 400 nm).

Compliance is checked by measurements.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

Replacement:

The temperature of surfaces accessible to an INFANT on the MATTRESS shall not exceed 40 °C for metal surfaces and 43 °C for other materials when the INFANT RADIANT WARMER is operating under STEADY TEMPERATURE CONDITION at its maximum CONTROL TEMPERATURE.

Under conditions of warm-up to STEADY TEMPERATURE CONDITION or that of a SINGLE FAULT CONDITION, these surfaces shall not exceed 42 °C for metal or 45 °C for other materials.

These requirements apply under NORMAL CONDITION and SINGLE FAULT CONDITIONS including:

- failure of the heater control circuit;
- failure of a SKIN TEMPERATURE SENSOR;
- disconnection of a SKIN TEMPERATURE SENSOR from the INFANT RADIANT WARMER.

201.11.1.4 * GUARDS

Addition:

If the heater element surface temperature exceeds 85 °C in NORMAL USE, heater GUARDS which cannot exceed 85 °C in NORMAL USE shall be fitted.

Compliance is checked by measurement of the temperature and by performing the rigidity test as described in 15.3.2 of the general standard. The heater GUARD shall not touch the heater element.

201.11.2 *Fire prevention

Subclause 11.2 of the general standard applies.

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Replacement:

The INFANT RADIANT WARMER or ME SYSTEM shall be so constructed that in the event of spillage of water (accidental wetting) on the PATIENT support or SKIN TEMPERATURE SENSOR, no HAZARD shall result from the ingress of water.

Compliance is checked by the following tests: Position the INFANT RADIANT WARMER or ME SYSTEM in the least favourable position of NORMAL USE. In the case of an INFANT RADIANT WARMER or ME SYSTEM with BABY CONTROLLED RADIANT WARMER operation, the SKIN TEMPERATURE SENSOR shall be placed at the centre of the upper surface of the MATTRESS. Pour 200 ml of isotonic water (0,9 % saline) steadily on the centre of the MATTRESS over a period of 15 s.

After this test, the INFANT RADIANT WARMER or ME SYSTEM shall meet the dielectric strength requirements specified in 8.8.3 of the general standard and the INFANT RADIANT WARMER or ME SYSTEM shall function normally.

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

Addition:

The INFANT RADIANT WARMER shall be so designed that an interruption and restoration of the power supply 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 INFANT RADIANT WARMER.

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 * Accuracy of SKIN TEMPERATURE SENSOR

The temperature measured by the SKIN TEMPERATURE SENSOR shall be continuously displayed and clearly visible. The temperature displayed shall have an accuracy of $\pm 0,3$ °C. If the display is used to present any other parameter, this shall only be obtained on demand, using a momentary action switch. The range of displayed temperature shall be at least 30 °C to 40 °C.

Compliance is checked by inspection and the following test:

Immerse the SKIN TEMPERATURE SENSOR in a water bath maintained at $36\text{ °C} \pm 0,1\text{ °C}$. Position a calibrated thermometer, accurate to within $\pm 0,05\text{ °C}$, with its bulb adjacent to the SKIN TEMPERATURE SENSOR. The reading of the standard thermometer shall be compared with the displayed temperature and their difference shall not exceed $0,3\text{ °C}$ less the calibrated thermometer error.

201.12.1.102 * Accuracy of distribution of irradiation to the MATTRESS

The difference between the MID-POINT AVERAGE TEMPERATURE and the TEST DEVICE AVERAGE TEMPERATURE of any of the other devices comprising the TEST LOAD shall not exceed 2 °C .

Compliance is checked by the following test: Prepare five TEST DEVICES consisting of aluminium discs each with a mass of $500\text{ g} \pm 10\text{ g}$ and a diameter of $100\text{ mm} \pm 2\text{ mm}$. Drill 5 mm diameter holes $50\text{ mm} \pm 2\text{ mm}$ deep as shown in Figure 201.102 and coat the entire disc surface with non-reflective black paint.

NOTE The disc thickness will be approximately 23 mm .

Subject the INFANT RADIANT WARMER to the following test in a room in which the maximum air velocity is $0,1\text{ m/s}$ and the ambient temperature is maintained at $23\text{ °C} \pm 2\text{ °C}$.

Place four individually identified TEST DEVICES, marked 1, 2, 3 and 4 on the horizontal MATTRESS at the centres of each of four rectangles formed by bisecting the length and width of the MATTRESS as shown in Figure 201.101. Place a fifth TEST DEVICE marked "M" on the mid-point of the MATTRESS. Insert a temperature sensor in each of the five TEST DEVICE centres and, in the case of an INFANT RADIANT WARMER with BABY CONTROLLED RADIANT WARMER operation, attach the SKIN TEMPERATURE SENSOR to the centre of the upper surface of the TEST DEVICE "M", assuring a good thermal conductive contact (e.g. thermal paste). In the case of an INFANT RADIANT WARMER with a BABY CONTROLLED RADIANT WARMER operation, set the temperature control to a CONTROL TEMPERATURE of $36\text{ °C} \pm 0,1\text{ °C}$ and operate the INFANT RADIANT WARMER until a STEADY TEMPERATURE CONDITION is obtained. In the case of an INFANT RADIANT WARMER with only a MANUAL MODE, set the heater output so that the TEST DEVICE will warm up to approximately 36 °C under STEADY TEMPERATURE CONDITION. Take at least 20 readings of temperature of each TEST DEVICE at regular intervals over a 60 min period.

Calculate the five values of the TEST DEVICE AVERAGE TEMPERATURE for each TEST DEVICE as follows:

$$T_1 = \frac{(t_{11} + t_{12} + t_{13} + t_{14} + \dots + t_{1n})}{n}$$

where

T_1 is the TEST DEVICE AVERAGE TEMPERATURE for TEST DEVICE no. 1;

$t_{11} \dots t_{1n}$ are the individual temperature readings taken of TEST DEVICE no. 1 at regular intervals during the STEADY TEMPERATURE CONDITION;

n is the number of readings during the STEADY TEMPERATURE CONDITION.

Calculate the remaining TEST DEVICE AVERAGE TEMPERATURES T_2 , T_3 , T_4 and T_M in the same way.

Compare TEST DEVICE AVERAGE TEMPERATURES T_1 , T_2 , T_3 , T_4 with T_M and verify the maximum difference does not exceed $2,0\text{ °C}$.

201.12.1.103 * Accuracy of BABY CONTROLLED RADIANT WARMER operation

With the INFANT RADIANT WARMER working in the BABY CONTROLLED RADIANT WARMER operation with horizontal MATTRESS orientation in NORMAL CONDITION, the temperature as measured by the SKIN TEMPERATURE SENSOR shall not differ from the CONTROL TEMPERATURE by more than 0,5 °C.

Compliance is checked during the tests of 201.12.1.102.

201.12.1.104 * Oxygen control

If an oxygen controller forms an integral part of the INFANT RADIANT WARMER, then there shall be independent sensors for monitoring and control of O₂.

A visual and auditory alarm shall be given if the displayed oxygen concentration deviates from the set level by more than ±5 vol. % O₂.

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. % O₂. 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. %.

201.12.1.105 * Weighing scale

If a weighing scale is supplied as an integral part of the INFANT RADIANT WARMER or as an ACCESSORY specifically for use with the INFANT RADIANT WARMER, 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 RADIANT WARMER with horizontal MATTRESS orientation. Each value measured shall remain latched on the scale display at the conclusion of any individual measurement cycle and be retained until discarded by the OPERATOR. If the scale may be exposed to an OXYGEN RICH ENVIRONMENT in use, it shall comply with 6.5 of the general standard.

NOTE Device calibration can 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 with the ME EQUIPMENT operating at NORMAL CONDITIONS of use.

The accuracy of the measurement test shall be verified with the TEST LOADS positioned in locations M and A through D in Figure 201.101.

201.12.2 USABILITY of ME EQUIPMENT

Addition:

201.12.2.101 USABILITY of 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.

201.12.2.102 Usability of mode of operation

In the case of an INFANT RADIANT WARMER which can be operated in various modes of operation, the mode of operation shall be clearly displayed.

Compliance is checked by inspection.

201.12.2.103 * Time and irradiance limits in the MANUAL MODE

In the case of INFANT RADIANT WARMERS which are operated in the MANUAL MODE, an auditory and visual alarm shall be given at least every 15 min and the heater deactivated if the maximum irradiance at any point of the MATTRESS area exceeds a total irradiance level of 10 mW/cm². The heater can be reactivated and the alarm can be reset in compliance with 201.12.3.103 (see 201.12.3).

Compliance is checked by inspection and measurements at an ambient temperature of 23 °C ± 2 °C.

201.12.2.104 * Heat output level at PREWARM MODE

While operating in PREWARM MODE, it shall not be possible for the OPERATOR to modify the heat output level preset by the MANUFACTURER. The level of heat when operating in the PREWARM MODE shall be displayed.

Compliance is checked by inspection.

201.12.3 ALARM SYSTEMS

Addition:

201.12.3.101 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 RADIANT WARMER.

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

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

201.12.3.102 Open and short circuit of the SKIN TEMPERATURE SENSOR in BABY CONTROLLED RADIANT WARMER operation

The INFANT RADIANT WARMER shall be provided with an auditory and visual ALARM SIGNAL which operates in the event of the SKIN TEMPERATURE SENSOR having open circuit or short circuit leads in the BABY CONTROLLED RADIANT WARMER operation.

Both open and short circuit leads shall disconnect the supply to the heater.

Compliance is checked by simulating both fault conditions and observing the effect.

201.12.3.103 * AUDIO PAUSED of auditory ALARM SIGNALS during MANUAL MODE

If the INFANT RADIANT WARMER incorporates a MANUAL MODE, the auditory and visual ALARM SIGNALS (see 201.12.2.103) shall operate within 15 min of commencement of use in this mode. The auditory ALARM SIGNAL shall be AUDIO PAUSED. Following any AUDIO PAUSED, the auditory ALARM SIGNAL shall operate again within 15 min. This sequence shall continue until the manual control mode is changed.

Compliance is checked by inspection, operating the INFANT RADIANT WARMER and timing the alarm.

201.12.3.104 AUDIO PAUSED

With the exception of the alarm specified in 201.12.3.101, it is allowable for the auditory ALARM SIGNAL to be AUDIO PAUSED or switched to a lower sound pressure level by the OPERATOR, but it shall revert automatically to a full value after not more than 15 min. The visual ALARM SIGNAL shall continue after the auditory ALARM SIGNALS has been AUDIO PAUSED until the alarm conditions have been corrected.

Compliance is checked by inspection, operating the INFANT RADIANT WARMER and timing the alarm.

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 instruction for use.

Compliance is checked by inspection.

201.12.4.2 Indication relevant to safety

Addition:

201.12.4.2.101 * CO₂ concentration

If the INFANT RADIANT WARMER is fitted with a COMPARTMENT that encloses the baby, the MANUFACTURER shall disclose the maximum value of CO₂ concentration which will occur in the COMPARTMENT under NORMAL CONDITIONS.

Compliance is checked by the following test:

A 4 % mixture of CO₂ 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 201.101, middle point) through an 8 mm diameter tube in vertical direction from the MATTRESS to the top. CO₂ concentration at a point 15 cm from the middle point shall be measured after 1 h. 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.

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:

201.15.3.5 Rough handling test

Addition:

Following the above tests, the INFANT RADIANT WARMER shall be suitable for future NORMAL USE. Mechanical and structural integrity of the INFANT RADIANT WARMER shall be verified; for example, latches and barriers shall remain closed and ancillary equipment supplied by or available from the MANUFACTURER shall remain secure.

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

201.15.4.2.1 Application

Addition to item a):

After STEADY TEMPERATURE CONDITIONS have been achieved, any sensed temperature deviation exceeding ± 1 °C compared with the CONTROL TEMPERATURE shall cause an auditory and visual alarm to operate, and the INFANT RADIANT WARMER heater shall switch off when the sensed temperature exceeds the CONTROL TEMPERATURE by 1 °C.

Compliance is checked by inspection and both of the following tests:

Test 1

Set the CONTROL TEMPERATURE to 36 °C and immerse the SKIN TEMPERATURE SENSOR in a water bath maintained at $36 \text{ °C} \pm 0,1 \text{ °C}$. Position a calibrated thermometer accurate to within $\pm 0,05 \text{ °C}$ with its bulb adjacent to the SKIN TEMPERATURE SENSOR. After a steady temperature indication is achieved and maintained for at least 10 min, increase the water bath temperature control setting to 38 °C. Report whether the auditory and visual alarms operate at a water bath temperature not exceeding $37 \text{ °C} \pm 0,3 \text{ °C}$ and whether the INFANT RADIANT WARMER heater switches off.

Test 2

As for test 1, but in this instance the temperature control setting of the water bath is reduced from $36 \text{ °C} \pm 0,1 \text{ °C}$ to $34 \text{ °C} \pm 0,1 \text{ °C}$. Report whether the auditory and visual alarms operate above $35 \text{ °C} \pm 0,3 \text{ °C}$ and the INFANT RADIANT WARMER heater remains in operation.

Addition to item b):

The INFANT RADIANT WARMER shall not permit the SKIN TEMPERATURE of the PATIENT to exceed 40 °C under NORMAL CONDITION and each SINGLE FAULT CONDITION.

Compliance is checked by the following test: Place a TEST DEVICE at the centre of the MATTRESS, with the INFANT RADIANT WARMER operating under STEADY TEMPERATURE CONDITIONS at the maximum CONTROL TEMPERATURE, and under any SINGLE FAULT CONDITION.

The TEST DEVICE shall not exceed 40 °C without the auditory and visual alarms operating and the heater being disconnected.

201.15.4.2.2 Temperature settings

Addition:

201.15.4.2.2.101 Range of CONTROL TEMPERATURE

The range of the CONTROL TEMPERATURE in the BABY CONTROLLED RADIANT WARMER operation of an INFANT RADIANT WARMER shall be from 36 °C or less to not more than 38 °C.

Compliance is checked by inspection.

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 RADIANT WARMER 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 stated in the collateral standard for EMC.

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

Annexes

The annexes of the general standard apply.

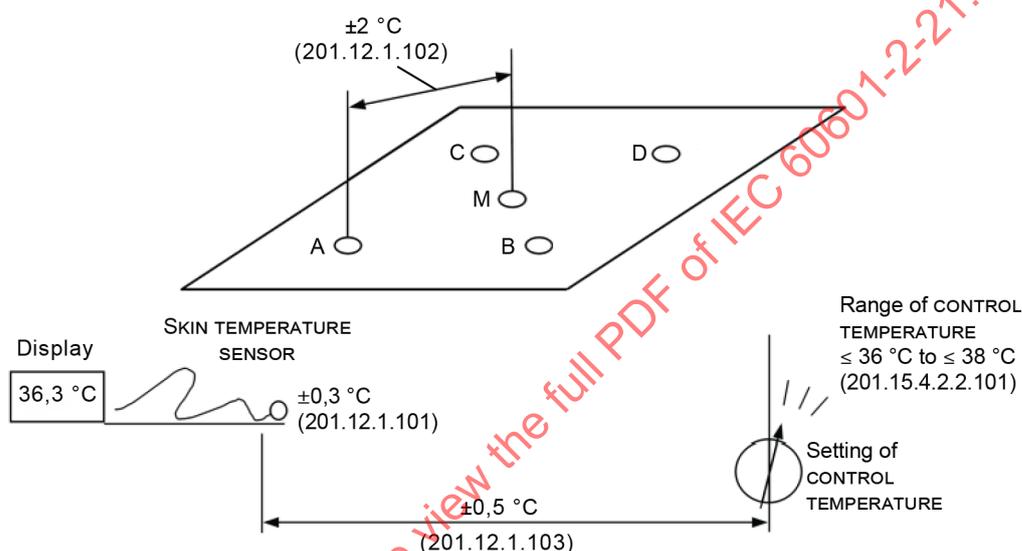
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Annex AA (informative)

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 ± 1 °C	(201.15.4.2.1)
Overtemperature alarm 40 °C	(201.15.4.2.1, Test 2 addition to item b)
Interruption of power supply alarm	(201.12.3.101)
Maximum surface temperature (normal condition) 40 °C (for metals) 43 °C (for other materials) Maximum surface temperature (single fault condition) 42 °C (for metals) 45 °C (for other materials)	(201.11.1.2.2)
Every 15 min alarm in manual mode for irradiance level > 10 mW/cm ²	(201.12.2.103)

IEC

NOTE Number in brackets indicate the relevant subclauses.

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

AA.2 Particular guidance

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

It is the primary purpose of a BABY CONTROLLED RADIANT WARMER to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR. Hence, SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED RADIANT WARMER, including the displayed value, are considered to be not 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 as defined in IEC 60601-2-19:2020.

Subclause 201.3.207 – PREWARM MODE

INFANT RADIANT WARMERS require significant time for the heater to warm up and, subsequently, for the MATTRESS area to warm up. INFANTS who are placed on INFANT RADIANT WARMERS are often cold stressed from transport or cold stressed and wet from recent birth and cannot tolerate continued cooling while waiting for the warming device to heat up. A MANUAL MODE level of heat below 10 mW/cm² is not sufficient for prewarming the INFANT RADIANT WARMER for these cold stressed INFANTS. These cold stressed INFANTS cannot tolerate the time for the warmers to heat to a level appropriate for their needs without experiencing further cold stress. The PREWARM MODE allows the INFANT RADIANT WARMER to remain warmed to a level suitable for these INFANTS so that the INFANT may immediately begin warming from a cold stressed condition when placed on the INFANT RADIANT WARMER.

Subclause 201.3.212 – TEST LOAD

With respect to irradiation distribution of 201.12.1.102, the aluminium 500 g TEST DEVICES were developed in 1984 on the basis that they were simple to reproduce to specific dimensions, and they respond to temperature changes due to variations in warmer output. Different MANUFACTURERS of INFANT warmers have considered them to be a suitable reference for tests of their products. Other TEST DEVICES of this nature tended to be more complicated to reproduce and more expensive.

This TEST LOAD configuration is not intended to represent a specific INFANT size, but only to test the operation of a radiant warmer.

This TEST LOAD configuration is intended to demonstrate the radiant warmer temperature control mechanism, and indicates the uniformity of heating across the MATTRESS.

A matt black finish of the TEST LOAD should provide a high emissivity value for consistent test data reproduction.

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

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, heated MATTRESS, etc.) shall comply to.

As an example, the intended use of an incubator or warmer is to apply heat to a baby 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 the standard 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 (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, combined with the requirement to define thermal performance, a failure to maintain this state if accompanied by an audible alarm, which would allow a clinician the appropriate mitigating actions, would be the total summation of essential requirements for these type devices.

Subclause 201.5.3 – Ambient temperature, humidity, atmospheric pressure

INFANT RADIANT WARMERS are commonly used in areas where ambient temperatures range from 18 °C to 30 °C.

INFANT RADIANT WARMERS are intended for use in nurseries as well as in labour and delivery rooms; the latter could be cooler than nurseries.

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 201.7.9.2.2 – Warning and safety notices, item g)

It is desirable that the INFANT RADIANT WARMER should be provided with an auditory alarm and visual indication which operates when the SKIN TEMPERATURE SENSOR is detached from the INFANT's skin. Technically this has not been reliably achieved and has therefore not been made a requirement of this document.

Subclause 201.7.9.2.2 – Warning and safety notices, item l)

The INFANT RADIANT WARMER 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 201.7.9.2.2 – Warning and safety notices, item n)

It is inherent in INFANT RADIANT WARMER 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 be responsible for ordering all aspects of INFANT RADIANT WARMER use.

Subclause 201.7.9.2.9 – Operating instructions, item b)

An INFANT RADIANT WARMER in the MANUAL MODE of operation emits a preset amount of energy to the child continuously, regardless of the temperature of the INFANT. If the heater is set at the maximum in order to warm up the INFANT rapidly, the skin of the INFANT can become dangerously hot. It is therefore essential to attend to ME EQUIPMENT operation and INFANT condition at frequent intervals. It is recommended that the PATIENT under the INFANT RADIANT WARMER be supervised.

Subclause 201.7.9.2.13 – Maintenance

There have been reports of hot fragments (e.g. metal oxide particles) from aged warmer heaters falling onto the MATTRESS.

Subclause 201.9.6.2.1.101 – Audible alarms sound level

Temporary threshold shifts of hearing in adults have been associated with 8 h of significantly higher sound levels. While data on INFANTS is not available, a lower value was chosen to provide an added margin of safety.

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 radiant warmer 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 semi-anechoic 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 201.10.6 – Infrared radiation

INFANT RADIANT WARMERS provide thermal support by directing invisible infrared light to the INFANT's body. The source of this infrared light is an overhead heater whose electrical power input is limited by design, thereby limiting the amount of infrared energy output that can be directed at the INFANT.

The limits proposed in this document are based upon a review of literature regarding the effect of infrared radiation upon the eyes and skin of humans [1 to 14]².

Infrared measurements can be made in the 760 nm to 1 400 nm wavelength (IR-A region) as well as the 1 400 nm to 4 500 nm segment of the wavelength IR-B and IR-C regions.

The IR-A region is associated with potential for damage to the crystalline lens of the eye which may lead to a cataract. The IR-B and IR-C regions are almost completely absorbed by the cornea (the outermost layer of the eyes) with a resulting potential for burn.

From a review of the literature, the following statements can be made.

a) There have been no reports from any sources describing any harmful effects of infrared radiant energy on either the eyes or skin in INFANTS nursed under INFANT RADIANT WARMERS. Retrospective examinations specifically looking for any eye effects have produced no evidence of harmful effects for either short-term or long-term evaluations. The long-term evaluations were performed from 30 days to 6 years after the INFANTS were nursed under radiant warmers.

b) Spectral irradiance measurements on several commercially available radiant warmers show the absolute peak irradiance that the INFANT could be exposed to is less than 60 mW/cm² across the entire electromagnetic spectrum, with less than 10 mW/cm² in the IR-A wavelength region. The irradiance the INFANT would normally be exposed to at maintenance heat levels is much less than these levels. Clinical reports have documented that the mean irradiance needed to maintain a stable SKIN TEMPERATURE could be anywhere from 12 mW/cm² to approximately 25 mW/cm² for very small INFANTS. Higher levels would be needed routinely during warming of cold INFANTS and/or warming newly born INFANTS with skin still wet with amniotic fluid. Generally, the smaller premature INFANTS require more irradiance to maintain their SKIN TEMPERATURE because they have a relatively larger surface-area-to-mass ratio that permits larger heat losses per unit weight.

c) Wheldon and Rutter [15] accurately report absolute irradiance levels, observing a maintenance irradiance level of (58 ± 3) mW/cm² for INFANTS averaging 1,6 kg.

Similar levels of irradiance have been used in neonatal intensive care units for at least the last 15 years to provide thermal support to premature INFANTS.

No reports have identified a corneal opacity or skin inflammation caused by the nursing of the INFANT under a radiant warmer.

d) The recommendation of AAMI is 60 mW/cm².

Both cataracts and retinal lesions have been documented as being caused by IR-A wavelengths. Absorption of the infrared energy by the iris, which indirectly heats the lens (and forms opacities), has been identified as the most likely cause of infrared induced cataracts. INFANT RADIANT WARMERS possess very little IR-A energy when compared to sources that have caused cataract formation.

Retinal lesions have been reported to be caused primarily by shorter visible light wavelengths and the actual IR-A component may be a negligible contributor to any retinal damage that could occur.

The proposed radiant warmer threshold values put forth by the Emergency Care Research Institute in 1973 have been observed and maintained by MANUFACTURERS of radiant warmers on the market today. These limits of less than 300 mW/cm² for the IR-B and IR-C regions and less than 40 mW/cm² for the IR-A region are based on data that have since been updated and re-evaluated and confirm their appropriateness.

2 Figures in square brackets refer to the Bibliography.

Photobiologists have not yet determined absolute maximum safe levels of incoherent infrared light in the IR-A, B and C regions. It has been proposed that for IR-A wavelengths, a safe, chronic exposure level probably is in the order of 10 mW/cm² with allowances for incidental exposures for several minutes up to 100 mW/cm². In a 1980 publication from one of these same authors [16, 17, 18], it was concluded that 100 mW/cm² for IR-B and IR-C regions is the safe threshold limit for chronic exposure of the cornea. Since the time these limits were proposed, these authors have documented that more recent investigations indicate that infrared radiation may not be as hazardous as was once thought.

Since no harmful effects from the irradiance levels now present in radiant warmers have been reported, these levels can serve as a maximum threshold limit until further data are made available.

Although further study of threshold levels could be useful to further define limits, the actual benefits derived from the use of radiant warmers far outweigh the potential, unreported, and theoretical RISKS associated with radiant infrared energy from INFANT RADIANT WARMERS. No reports of any harmful infrared energy induced effects have been documented in the medical literature after nearly 15 years of clinical use.

- e) The spectral characteristics for human eye and skin media have been documented in the literature. No studies of the neonatal eye spectral characteristics have been reported. Only the spectral characteristics of neonatal skin with respect to visible light have been reported.

Although the neonatal eye is not completely developed at birth, the spectral characteristics are believed to be similar to those of an adult. Examinations of neonatal eyes after being nursed in radiant warmers have not shown any harmful effects from the level of IR-A delivered by the radiant warmers.

Neonatal excised skin specimens have been shown to have similar spectral absorption characteristics to adult skin in the visible light regions. However, for the IR-A regions, the skin absorption can vary with the skin thickness.

Since the skin's reflectance is greatest in the IR-A regions, much of the incident light will be reflected away, and only a small portion of the total incident light would actually penetrate the skin.

Most infra-red energy is in the IR-B and IR-C regions and is absorbed by the top 1 mm to 2 mm of skin. No harmful effect from absorption of the radiant energy from a radiant warmer has been reported. Since infrared energy is not energetic enough to enter into photochemical reactions with skin components, the only effect of the absorption of the energy is heating, which is the primary reason the INFANT is under a radiant warmer.

- f) The associated HAZARDS from exposure to infrared energy for humans and animals, using both coherent and incoherent light have been documented in the literature [19 to 23]. The HAZARDS, reported in the literature, from exposure of humans to incoherent infrared light are cutaneous skin burns, corneal opacities and inflammation, lenticular opacities (cataracts), retinal lesions, and skin inflammation. Recent reports have shown that the cutaneous skin burns, corneal opacities and inflammation, and skin inflammation are due entirely to the IR-B and IR-C portions of the infra-red spectrum; because the outermost layer of the skin and eye absorb all of the incident radiation in the wavelength regions, they do not transmit any significant portion of incident energy below this outermost layer. Skin pain thresholds have been documented at approximately 45 °C.

Several commercially available radiant warmers have SKIN TEMPERATURE limits to prevent the SKIN TEMPERATURE from exceeding 40 °C. Corneal opacities have been reported in neonates, but usually are associated with other pathological conditions (in association with congenital glaucoma, or as a result of an infection from either congenital rubella or herpes virus).

Subclause 201.11.1.2.2 – APPLIED PARTS not intended to supply heat to a PATIENT

The requirements of this subclause can be based upon the BSI publication [24], and the drafting committee having noted the potential RISK of babies under warmers coming into contact with hot metallic or other surface; hence the stated limits.

Subclause 201.11.1.4 – GUARDS

Heater GUARDS are intended to prevent the OPERATOR from inadvertently touching the hot heater element surface.

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 subclause.

MATRESSES 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 neonates 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 RADIANT WARMER, 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 enriched environment have been met. No incident has been reported concerning fire ignition inside the bassinet of a warmer for many years. Also, even with warmer MATRESSES, additional concerns were discussed around the toxicity of fumes that can be produced by materials that have been treated with flame retardant additives. Therefore, with the exception of elevating (accelerant) the RISK of fire from the cover material, no specific flammability rating is required of the PAD's cover and the inner filler.

Subclause 201.12.1.101 – Accuracy of SKIN TEMPERATURE SENSOR

The SKIN TEMPERATURE SENSOR indication of temperature error is only a part of the total error associated with skin surface temperature measurement. Other errors can be introduced by variation of the area of sensor contact, contact pressure and heat exchange between the sensor and its environment. The accuracy is most important at 36 °C, which is around the normal PATIENT SKIN TEMPERATURE. Accuracy to this degree is required to establish the best possible function of the SKIN TEMPERATURE SENSOR control system.

Subclause 201.12.1.102 – Accuracy of distribution of irradiation to the MATTRESS

Long experience of both the medical and technical requirements for INFANT RADIANT WARMERS has shown that this level of performance (2 °C) is satisfactory in maintaining the temperature of the baby, and readily achievable technically.

Subclause 201.12.1.103 – Accuracy of BABY CONTROLLED RADIANT WARMER operation

The OPERATOR of the INFANT RADIANT WARMER shall be confident that the temperature that is set will be the actual temperature achieved within $\pm 0,5$ °C.

Subclause 201.12.1.104 – Oxygen control

Relatively low oxygen concentrations for the PATIENT may cause brain damage. Relatively high oxygen concentration for the PATIENT may cause a retinopathy of prematurity. In SINGLE FAULT CONDITION, the use of one sensor may cause a HAZARD for the baby, therefore for this operation the sensors are required to operate independently.

Subclause 201.12.1.105 – Weighing scale

Weight scales used in paediatric medical equipment have unique requirements that differ significantly from those of weight scales used in general commercial or domestic weighing applications. Absolute accuracy is important, however not to the degree of accuracy (1/1 000) required by commercial scales used for monetary transactions. More important from a clinical application is the information provided by weight trends, demonstrating an increase or decrease trend in the weight of the INFANT PATIENT. Absolute accuracy is very difficult at best due to electrical leads, tubing, and other PATIENT care devices that cannot be completely eliminated from the measurement.

Because weighing an INFANT is a difficult process requiring both hands of the OPERATOR in the manipulation of the INFANT PATIENT, it is necessary that the weight reading be held and displayed until such time as the OPERATOR has completed the PROCEDURE. The weight reading should be displayed until the OPERATOR has recorded it or stored it, if electronic storage is an option.

An INFANT PATIENT needs to be contained in a heated, controlled environment for an extended period of time. Moving an INFANT for any reason can be harmful to the INFANT PATIENT's well being. INFANT PATIENTS often remain in their controlled environment, INFANT INCUBATOR or INFANT RADIANT WARMER, for 2 or more weeks. During this time it is necessary for the OPERATOR to assure the calibration of the weight scale. Additionally, it may be necessary for the OPERATOR to be able to adjust the calibration should the weight scale be out of calibration without the necessity to remove the scale or move the INFANT for calibration.

Subclause 201.12.2.103 – Time and irradiance limits in the MANUAL MODE

It is necessary to have in the MANUAL MODE a mode of operation without alarm function on a low heater output level to keep the INFANT RADIANT WARMER previously warmed (as a stand-by function) or to provide only a small proportion of heat to the baby (usually bigger babies). The experts of this working group and the paediatric doctors from the German National Committee are of the opinion that, at a level of 10 mW/cm², there is no RISK to babies under radiant warmers. Long experience with the use of radiant warmers with low output levels confirms this statement. There are no known HAZARDS.

Subclause 201.12.2.104 – Heat output level at PREWARM MODE

The PREWARM MODE is not appropriate for care of an INFANT after the INFANT has been placed on the INFANT RADIANT WARMER. See 201.3.207.

Subclause 201.12.3.103 – AUDIO PAUSED of auditory ALARM SIGNALS during MANUAL CONTROL

An INFANT RADIANT WARMER operating in the MANUAL MODE continuously emits a preset amount of energy to the INFANT regardless of his/her temperature. If this energy is at a maximum in order to rapidly warm up the INFANT, the INFANT's skin can become dangerously hot. A considerable source of RISK is that there is not necessarily an automatic monitoring of the INFANT's temperature. It is therefore essential to have a periodic alarm operation and the condition of the INFANT under the warmer assessed at frequent intervals.

Subclause 201.12.4.2.101 – CO₂ concentration

It is considered that a general test, applicable to all INFANT RADIANT WARMERS, should be prescribed, giving definite performance features. It was recognized that mixing of CO₂ within the air of the COMPARTMENT is not so easy to realize and therefore a mixture of CO₂/air should be administered, instead.

Subclause 201.15.4.1.101 – Temperature sensors

The response of the rectal temperature of the INFANT to environmental temperature changes is slow and is not suitable for controlling the INFANT RADIANT WARMER CONTROL TEMPERATURE. The requirement of this subclause is intended to eliminate wrong applications of the SKIN TEMPERATURE SENSOR.

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-21: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs radiants pour nouveau-nés

AVANT-PROPOS

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Cette troisième édition annule et remplace la deuxième édition parue en 2009 et son Amendement 1 (2016). Cette édition constitue une révision technique.

Cette édition inclut la modification technique majeure suivante par rapport à l'édition précédente: alignement avec l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012.

Le texte de cette norme internationale est issu des documents suivants:

FDIS	Rapport de vote
62D/1766/FDIS	62D/1776/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

La version française de la norme n'a pas été soumise au vote.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

- exigences et définitions: caractères romains;
- *modalités d'essai: caractères italiques;*
- indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;
- TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DE LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme:

- "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
- "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit est vraie.

Les formes verbales utilisées dans la présente norme sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

- "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est impérative pour la conformité au présent document
- "il convient" signifie que la satisfaction à une exigence ou à un essai est recommandée, mais n'est pas obligatoire pour la conformité au présent document;
- "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d'un titre d'alinéa ou de tableau, il indique l'existence d'une recommandation ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général: *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu du présent document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "<http://webstore.iec.ch>" dans les données relatives au document recherchée. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

NOTE L'attention des utilisateurs du présent document est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Les comités recommandent que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

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INTRODUCTION

Les exigences minimales de sécurité spécifiées dans la présente norme particulière sont considérées comme assurant un degré pratique de sécurité dans le fonctionnement des INCUBATEURS RADIANTS POUR NOUVEAU-NES.

La présente norme particulière modifie et complète l'IEC 60601-1, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*, appelée "norme générale" dans la suite du texte.

Les exigences sont suivies de spécifications relatives aux essais correspondants.

Une recommandation générale et une justification relatives aux exigences de la présente norme particulière sont indiquées à l'Annexe AA.

Il est admis que la connaissance des raisons qui ont conduit à énoncer ces exigences non seulement facilite l'application correcte de la présente norme particulière, mais accélérera en son temps toute révision rendue nécessaire du fait de modifications dans la pratique clinique ou d'évolutions technologiques. Cependant, l'Annexe AA ne fait pas partie des exigences du présent document.

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-21: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs radiants pour nouveau-nés

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale¹ s'applique, avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des INCUBATEURS RADIANTS POUR NOUVEAU-NES, tels que définis au 201.3.204, également désignés sous le terme APPAREILS EM.

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des APPAREILS EM ou des SYSTEMES EM dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception de 7.2.13 et de 8.4.1 de la norme générale.

NOTE Voir aussi 4.2 de la norme générale.

La présente norme particulière spécifie les exigences de sécurité relatives aux INCUBATEURS RADIANTS POUR NOUVEAU-NES, mais des méthodes alternatives de conformité à un article spécifique, en démontrant un niveau équivalent de sécurité, ne sont pas considérées comme non conformes, si le FABRICANT a démontré dans son DOSSIER DE GESTION DES RISQUES que le RISQUE présenté par le DANGER s'est révélé avoir un niveau acceptable, lorsqu'il a été évalué par rapport aux avantages du traitement présentés par le dispositif.

La présente norme particulière ne s'applique pas aux:

- dispositifs délivrant de la chaleur par l'intermédiaire de COUVERTURES, COUSSINS ou MATELAS en usage médical; voir l'IEC 60601-2-35 à titre informatif;
- INCUBATEURS POUR NOUVEAU-NES, voir l'IEC 60601-2-19 à titre informatif;
- INCUBATEURS DE TRANSPORT POUR NOUVEAU-NES; voir l'IEC 60601-2-20 à titre informatif;
- APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES, voir l'IEC 60601-2-50 à titre informatif.

Les CAPTEURS DE TEMPERATURE CUTANEE appliqués au fonctionnement d'un INCUBATEUR RADIANT A REGULATION CUTANEE incluant la valeur affichée ne sont pas considérés comme un THERMOMETRE MEDICAL au sens de la norme particulière ISO 80601-2-56.

¹ La norme générale est constituée de l'IEC 60601-1:2005 et de l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles.*

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des INCUBATEURS RADIANTS POUR NOUVEAU-NES définis au 201.3.204, qui réduisent le plus possible les DANGERS vis-à-vis du PATIENT et de l'OPERATEUR, et de spécifier des essais pour démontrer la conformité à ces exigences.

201.1.3 Normes collatérales

Addition:

La présente norme particulière se rapporte aux normes collatérales applicables répertoriées à l'Article 2 de la norme générale et à l'Article 2 de la présente norme particulière.

L'IEC 60601-1-2:2014 s'applique telle que modifiée dans l'Article 202. L'IEC 60601-1-3 et l'IEC 60601-1-10 ne s'appliquent pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales en fonction de ce qui est approprié à l'APPAREIL EM particulier à l'étude, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, dans la présente norme particulière, l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012 sont désignées par le terme "norme générale". Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple, 201.1 dans la présente norme traite du contenu de l'Article 1 de la norme générale) ou à celle de la norme collatérale applicable avec le préfixe "20x", où x est le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, 202.4 dans la présente norme particulière traite du contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière traite du contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale et des normes collatérales applicables sont spécifiées en utilisant les termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"*Addition*" signifie que le texte de la présente norme particulière vient s'ajouter aux exigences de la norme générale ou de la norme collatérale applicable.

"*Modification*" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme cela est indiqué par le texte de la présente norme particulière.

Les paragraphes, figures ou tableaux ajoutés à la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées 3.1 à 3.147, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes complémentaires sont nommées AA, BB, etc., et les points complémentaires aa), bb), etc.

Les paragraphes, figures ou tableaux ajoutés à une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière, examinées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la Bibliographie.

L'Article 2 de la norme générale s'applique avec les exceptions suivantes:

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, ainsi que les suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse <http://www.electropedia.org/>
- ISO Online browsing platform: disponible à l'adresse <http://www.iso.org/obp>

NOTE Un index des termes définis est donné à partir de la page 76.

Addition:

201.3.201

INCUBATEUR RADIANT A REGULATION CUTANEE

mode de fonctionnement dans lequel la puissance de sortie varie automatiquement afin de maintenir la température mesurée par un CAPTEUR DE TEMPERATURE CUTANEE en fonction de la TEMPERATURE DE COMMANDE attribuée par l'OPERATEUR

201.3.202

TEMPERATURE DE COMMANDE

température choisie à l'aide de la commande de température

201.3.203

NOUVEAU-NE

PATIENT âgé de trois mois au maximum et pesant moins de 10 kg

201.3.204

INCUBATEUR RADIANT POUR NOUVEAU-NES

dispositif à énergie électrique avec une source de chauffage par rayonnement, destiné à maintenir l'équilibre thermique d'un NOUVEAU-NE par rayonnement direct d'énergie dans le domaine infrarouge du spectre électromagnétique

201.3.205

MODE MANUEL

mode de fonctionnement dans lequel l'énergie produite par le corps chauffant est soit à un niveau fixe, soit une proportion de son énergie produite maximale réglée par l'OPERATEUR

201.3.206

TEMPERATURE MOYENNE AU CENTRE

T_M

TEMPERATURE MOYENNE DU DISPOSITIF D'ESSAI, ce dernier étant placé au centre du MATELAS de l'INCUBATEUR RADIANT POUR NOUVEAU-NES (voir Figure 201.101)

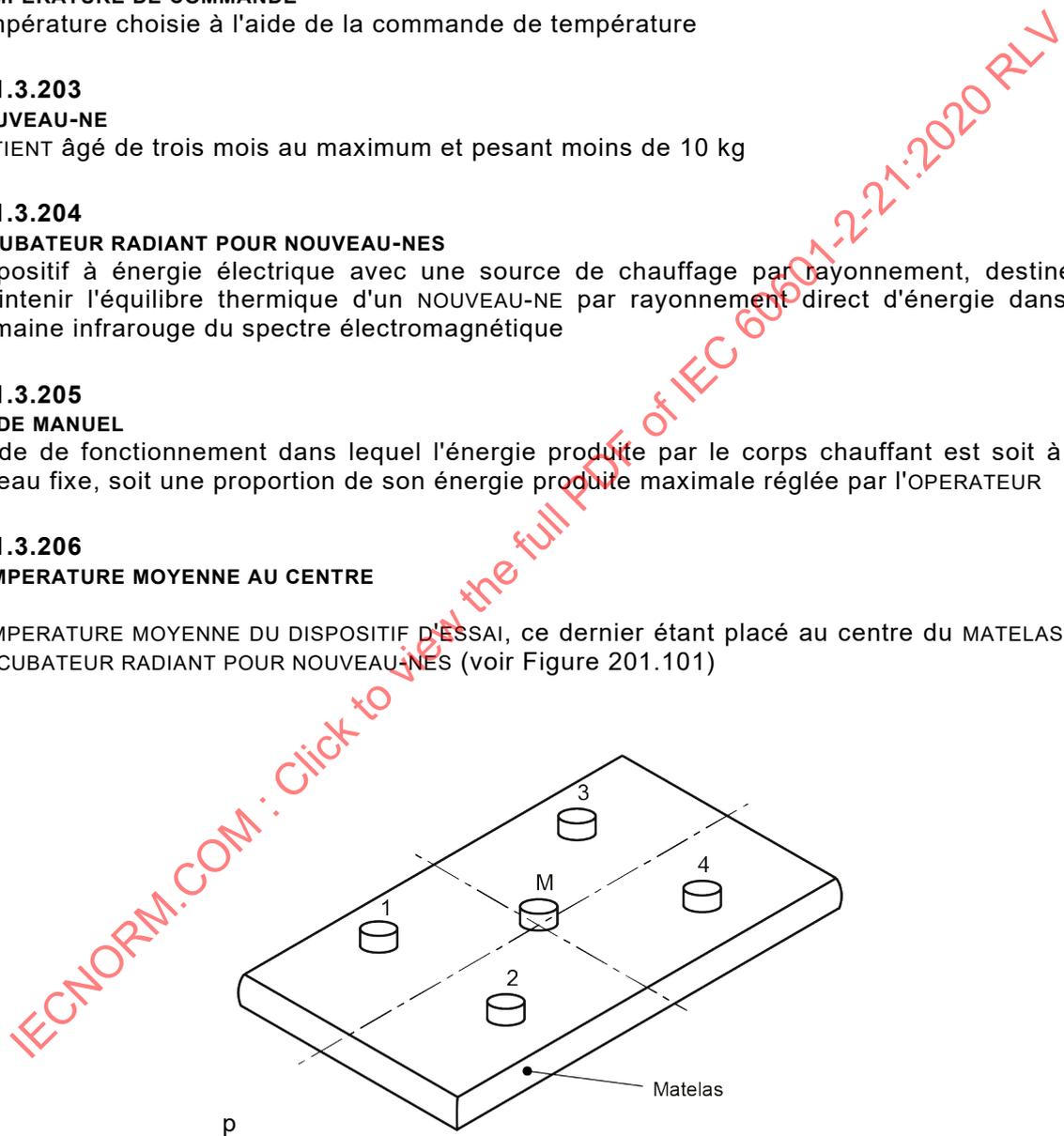


Figure 201.101 – Implantation des DISPOSITIFS D'ESSAI

201.3.207***MODE DE PRECHAUFFAGE**

mode de fonctionnement dans lequel l'énergie produite par le corps chauffant est maintenue à un niveau préréglé (fixé par le FABRICANT) pour préchauffer l'INCUBATEUR RADIANT POUR NOUVEAU-NES et maintenir son niveau de chaleur avant qu'un NOUVEAU-NE ne soit placé dans le dispositif

201.3.208**CAPTEUR DE TEMPERATURE CUTANEE**

dispositif sensible destiné à mesurer la TEMPERATURE CUTANEE DU NOUVEAU-NE

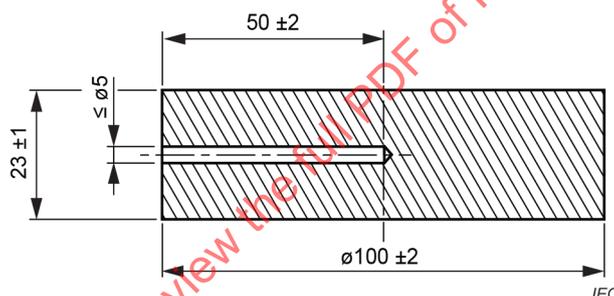
201.3.209**CONDITION DE TEMPERATURE STABILISEE**

condition atteinte lorsque la température mesurée au centre du DISPOSITIF D'ESSAI, placé au milieu du MATELAS de l'INCUBATEUR RADIANT POUR NOUVEAU-NES, ne varie pas de plus de 1 °C pendant 1 h

201.3.210**DISPOSITIF D'ESSAI**

disque entièrement mat et noirci utilisé en tant que récepteur reproductible de l'énergie rayonnante lors des essais de l'INCUBATEUR RADIANT POUR NOUVEAU-NES (voir Figure 201.102)

Dimensions en millimètres



Finition de surface:	peinture noire non réfléchissante
Masse du disque:	500 g ± 10 g
Matériau du disque:	aluminium de densité comprise dans la plage de 2,6 g/cm ³ à 2,9 g/cm ³

Figure 201.102 – DISPOSITIF D'ESSAI

201.3.211**TEMPERATURE MOYENNE DU DISPOSITIF D'ESSAI**

(T_1 , T_2 , T_3 , T_4 OU T_M)

valeur moyenne de la température relevée à intervalles de temps réguliers au centre du DISPOSITIF D'ESSAI, en CONDITION DE TEMPERATURE STABILISEE

Note 1 à l'article: T_M , T_1 , T_2 , T_3 , T_4 , sont exprimées en °C.

201.3.212***CHARGE D'ESSAI**

ensemble de cinq DISPOSITIFS D'ESSAI utilisés dans une configuration spécifiée (voir Figure 201.101) pour les essais de performances de l'INCUBATEUR RADIANT POUR NOUVEAU-NES

201.4 Exigences générales

L'Article 4 de la norme générale s'applique avec les exceptions suivantes:

201.4.1 Conditions d'application aux APPAREILS EM ou aux SYSTEMES EM

Addition:

Pour les APPAREILS EM ou les SYSTEMES EM qui combinent des sources de chaleur alternatives, par exemple les couveuses avec DISPOSITIFS DE CHAUFFAGE RADIANTS incorporés, les dispositifs délivrant de la chaleur par l'intermédiaire de COUVERTURES, COUSSINS ou MATELAS, etc., les exigences de sécurité des autres normes particulières applicables doivent être prises en considération. De plus, les exigences de sécurité du présent document doivent être satisfaites en combinaison avec l'autre appareil, agréé par le FABRICANT, comme cela est indiqué dans les DOCUMENTS D'ACCOMPAGNEMENT, selon l'Article 16.

La vérification est effectuée par l'essai de l'Article 201.11 et de 201.15.4.2.1 des normes particulières correspondantes (par exemple, l'IEC 60601-2-19:2020, etc.).

201.4.3 PERFORMANCE ESSENTIELLE

Addition:

201.4.3.101 *Exigences de PERFORMANCES ESSENTIELLES supplémentaires

Des exigences de PERFORMANCES ESSENTIELLES supplémentaires sont données dans les paragraphes répertoriés dans le Tableau 201.101.

Tableau 201.101 – Exigences de PERFORMANCES ESSENTIELLES supplémentaires

Exigence	Paragraphe
Exigence 1 de PERFORMANCES ESSENTIELLES	201.12.1.103 et génération d'une alarme visuelle et sonore conforme à 201.15.4.2.1

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique avec les exceptions suivantes:

201.5.3 * Température ambiante, humidité, pression atmosphérique

Addition au point a):

L'APPAREIL EM doit être conforme aux exigences du présent document lorsqu'il fonctionne dans les conditions suivantes:

- une température ambiante dans une plage comprise entre 18 °C et 30 °C;
- une vitesse de l'air ambiant inférieure à 0,3 m/s.

Sauf spécification contraire dans le présent document, tous les essais doivent être effectués à une température ambiante dans une plage comprise entre 21 °C et 26 °C.

201.5.4 Autres conditions

Point complémentaire à la liste existante:

aa) Sauf spécification contraire, la TEMPERATURE DE COMMANDE doit être de 36 °C ± 1 °C et doit toujours être supérieure d'au moins 3 °C à la température ambiante.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique avec les exceptions suivantes:

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM (voir aussi le Tableau C.1 de la norme générale)

Paragraphes complémentaires:

201.7.2.101 * Dispositif de surveillance de l'oxygène

Un INCUBATEUR RADIANT POUR NOUVEAU-NES qui n'est pas équipé d'un dispositif incorporé de surveillance de l'oxygène et qui comporte des moyens pour l'administration d'oxygène doit porter à un endroit bien visible un texte indiquant: "Utiliser un dispositif de surveillance de l'oxygène en cas d'administration d'oxygène".

201.7.2.102 Marquages de distance

L'INCUBATEUR RADIANT POUR NOUVEAU-NES ne possédant pas de surface de couchage intégrée doit porter de façon permanente et claire une indication sur les distances acceptables entre les systèmes de chauffage des INCUBATEURS RADIANTS POUR NOUVEAU-NES et tout MATELAS.

201.7.4.2 Dispositifs de commande

Addition:

Des moyens doivent être prévus pour réaliser une sélection et une indication claires de la TEMPERATURE DE COMMANDE, sur ou à proximité des organes de commande. Les moyens prévus doivent permettre une résolution à intervalles ne dépassant pas 0,2 °C.

201.7.9.2.2 Avertissements et consignes de sécurité

Addition:

Les instructions d'utilisation doivent également contenir:

- a) un énoncé stipulant que le contrôle indépendant de la température du NOUVEAU-NE par l'OPERATEUR est indispensable et qu'il est imprudent de laisser un NOUVEAU-NE sans surveillance dans l'INCUBATEUR RADIANT POUR NOUVEAU-NES;
- b) des recommandations sur les distances acceptables entre le système de chauffage de l'INCUBATEUR RADIANT POUR NOUVEAU-NES et tout matelas l'équipant, ainsi qu'un énoncé relatif aux conséquences que toute modification de cette distance peut entraîner;
- c) des instructions relatives aux positions et aux méthodes recommandées d'utilisation et de fixation des capteurs de température prévus pour l'INCUBATEUR RADIANT POUR NOUVEAU-NES;
- d) pour un INCUBATEUR RADIANT POUR NOUVEAU-NES avec une PARTIE APPLIQUEE DE TYPE B, dans lequel le NOUVEAU-NE peut ne pas être isolé de la terre, une mise en garde signalant que des précautions particulières doivent être prises pour vérifier que tout appareil supplémentaire relié au NOUVEAU-NE est électriquement sûr;
- e) le cas échéant, une recommandation à l'OPERATEUR sur l'inspection régulière des loquets et des systèmes de fermeture des barrières, dans le but de prévenir la chute du NOUVEAU-NE;

- f) une indication relative aux charges maximales qui peuvent être appliquées à tous les supports et arceaux de montage pour ACCESSOIRES et matériel annexe.
- g) * des informations sur les conséquences entraînées par le décollement d'un CAPTEUR DE TEMPERATURE CUTANEE de la peau du PATIENT sur le fonctionnement de l'INCUBATEUR RADIANT POUR NOUVEAU-NES;
- h) le cas échéant, un énoncé stipulant que l'inclinaison du matelas de sa position horizontale par rapport au corps chauffant de l'INCUBATEUR RADIANT POUR NOUVEAU-NES peut altérer les performances de ce dernier (voir 201.12.1.102);
- i) un énoncé stipulant que des ACCESSOIRES, par exemple pour photothérapie ou matelas chauffants, ou bien la lumière solaire peuvent élever la température du NOUVEAU-NE à des niveaux dangereux;
- j) un énoncé stipulant que l'INCUBATEUR RADIANT POUR NOUVEAU-NES ne convient pas à une utilisation en présence de gaz anesthésiques inflammables ou d'autres matériaux inflammables, tels que certains types de liquides de nettoyage;
- k) un énoncé stipulant que les températures rectales ne sont pas appropriées pour le réglage de l'énergie produite par le corps chauffant de l'INCUBATEUR RADIANT POUR NOUVEAU-NES;
- l) * un énoncé selon lequel l'INCUBATEUR RADIANT POUR NOUVEAU-NES n'est pas en mesure de faire la distinction entre une augmentation de la température interne accompagnée d'une TEMPERATURE CUTANEE basse (fièvre) et une température interne basse accompagnée d'une TEMPERATURE CUTANEE basse (hypothermie), ainsi qu'une recommandation visant à surveiller la température du PATIENT;
- m) un énoncé stipulant que les conditions ambiantes (par exemple, un courant d'air) sont susceptibles d'affecter l'équilibre thermique du NOUVEAU-NE;
- n) * un énoncé stipulant qu'un INCUBATEUR RADIANT POUR NOUVEAU-NES ne doit être utilisé que par du personnel formé spécialement et sous la direction du personnel médical qualifié, qui connaît très bien les RISQUES et les avantages liés à l'utilisation d'un incubateur radiant pour nouveau-nés;
- o) un énoncé stipulant qu'un INCUBATEUR RADIANT POUR NOUVEAU-NES peut augmenter la perte d'eau imperceptible du PATIENT;
- p) concentration en dioxyde de carbone (CO₂): Si le matelas de l'INCUBATEUR RADIANT POUR NOUVEAU-NES est équipé d'un COMPARTIMENT clos qui héberge le bébé, le FABRICANT doit spécifier (voir 201.12.4.2.101) dans les DOCUMENTS D'ACCOMPAGNEMENT la concentration maximale de CO₂ qui apparaît dans le COMPARTIMENT dans des CONDITIONS NORMALES;
- q) un énoncé stipulant que l'INCUBATEUR RADIANT POUR NOUVEAU-NES ne se règle pas à la température du PATIENT en MODE DE PRECHAUFFAGE et que le mode doit passer en MODE MANUEL ou en INCUBATEUR RADIANT A REGULATION CUTANEE (mode cutané) immédiatement lorsque le PATIENT est placé sur le dispositif. Le fabricant doit indiquer le niveau de chaleur en mW/cm² lors d'un fonctionnement en MODE DE PRECHAUFFAGE.

201.7.9.2.9 Instructions de fonctionnement

Addition:

Les instructions d'utilisation doivent contenir en plus

- a) pour chaque mode de commande, un énoncé détaillé décrivant la méthode au moyen de laquelle la quantité de rayonnement est régulée et la température du nouveau-né est maintenue;
- b) * si le fonctionnement en INCUBATEUR RADIANT A REGULATION CUTANEE est disponible, un énoncé expliquant pour quelle raison il convient que l'OPERATEUR utilise ce mode dans toute la mesure du possible.

201.7.9.2.13 * Maintenance

Addition:

Si la source de rayonnement a une durée de vie limitée, le FABRICANT doit indiquer, dans les DOCUMENTS D'ACCOMPAGNEMENT, la durée au terme de laquelle la source de rayonnement doit être remplacée du fait de son vieillissement.

201.7.9.2.14 ACCESSOIRES, équipements supplémentaires, fournitures utilisées

Addition:

Les instructions d'utilisation doivent inclure les informations détaillées concernant chaque combinaison spécifiée de l'INCUBATEUR RADIANT POUR NOUVEAU-NES avec un autre appareil (voir 201.4.1).

201.7.9.3 Description technique (voir aussi le Tableau C.6 de la norme générale)

201.7.9.3.1 Généralités

Point complémentaire au premier alinéa:

- le FABRICANT doit spécifier dans les DOCUMENTS D'ACCOMPAGNEMENT la concentration maximale en CO₂ (voir 201.12.4.2.101).

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de la norme générale s'applique.

201.9 Protection contre les DANGERS MECANQUES des APPAREILS EM et des SYSTEMES EM

L'Article 9 de la norme générale s'applique avec les exceptions suivantes:

201.9.4.2.1 Instabilité en position de transport

Addition:

L'INCUBATEUR RADIANT POUR NOUVEAU-NES et les arceaux et consoles de montage sont équipés de la combinaison la plus défavorable de parties amovibles et d'ACCESSOIRES, et sont chargés avec la charge maximale recommandée.

201.9.6.2.1 Énergie acoustique audible

Addition:

201.9.6.2.1.101 * Niveau de pression acoustique des alarmes sonores

Les SIGNAUX D'ALARME sonore doivent avoir un niveau de pression acoustique d'au moins 65 dB(A) à une distance de 3 m de l'avant de l'INCUBATEUR RADIANT POUR NOUVEAU-NES dans un local réfléchissant. Hormis la PAUSE DE L'ALARME SONORE spécifiée au 201.12.3.103, le SIGNAL D'ALARME sonore peut être réglé par l'OPERATEUR à un niveau bas minimal de 50 dB(A).

Le niveau de pression acoustique du SIGNAL D'ALARME ne doit pas dépasser 80 dB(A) sur le MATELAS.

Si la fréquence du SIGNAL D'ALARME sonore est réglable par l'OPERATEUR, ces exigences doivent s'appliquer à toutes les fréquences individuelles qui peuvent être choisies.

La vérification est effectuée avec le microphone d'un sonomètre conforme aux exigences de l'IEC 61672-1, placé à 1,5 m au-dessus du sol et à 3 m de l'avant de l'INCUBATEUR RADIANT POUR NOUVEAU-NES.

La vérification du niveau maximal est effectuée avec chaque dispositif d'alarme sonore activé, le niveau sonore étant mesuré en un point situé à 5 cm au-dessus du centre du MATELAS.

Vérifier que le niveau de pression acoustique du bruit de fond est inférieur d'au moins 10 dB(A) aux niveaux mesurés.

201.9.8 DANGERS MECANIQUES associés aux systèmes de support

Paragraphe complémentaire:

201.9.8.101 Supports et arceaux de montage des ACCESSOIRES

Les supports et arceaux de montage des ACCESSOIRES doivent être adaptés et avoir une résistance suffisante pour leur fonction.

La vérification est effectuée par examen et par l'essai suivant:

Une force verticale progressivement croissante est appliquée au centre des supports et des arceaux de montage, par exemple une tablette d'ACCESSOIRE en position étendue avec une charge recommandée par le FABRICANT. La force est augmentée, à partir de zéro, dans un intervalle de temps compris entre 5 s et 10 s, jusqu'à trois fois la charge recommandée, et est maintenue pendant 1 min. Les éléments en essai ne doivent pas présenter de signes de détérioration.

201.9.8.3 Résistance des supports PATIENT ou OPERATEUR ou des systèmes de suspension

201.9.8.3.1 Généralités

Addition:

La charge normale pour un NOUVEAU-NE est abaissée à 10 kg.

Paragraphe complémentaire:

201.9.8.3.101 Barrières

En ce qui concerne les INCUBATEURS RADIANTS POUR NOUVEAU-NES équipés d'une surface de couchage intégrée, des barrières appropriées doivent être prévues pour prévenir la chute du PATIENT hors du MATELAS. Les barrières destinées à être ouvertes ou enlevées pour pouvoir accéder au PATIENT doivent se verrouiller en position de fermeture et doivent rester fermées dans les conditions d'essai.

La vérification est effectuée par examen et par l'essai suivant: appliquer à toutes les barrières (autres que celles fixées à l'aide d'un OUTIL) une force horizontale de 20 N, dirigée vers le centre de chaque barrière, et maintenue pendant 5 s. Les barrières doivent rester fermées.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs

L'Article 10 de la norme générale s'applique avec l'exception suivante:

201.10.6 * Rayonnements infrarouges

Addition:

Le niveau maximal d'éclairement énergétique, en tout point du MATELAS, ne doit pas dépasser 60 mW/cm² dans tout le spectre infrarouge.

Le niveau maximal d'éclairement énergétique ne doit pas dépasser 10 mW/cm² dans le spectre infrarouge proche (760 nm à 1 400 nm).

La vérification est effectuée par des mesurages.

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 de la norme générale s'applique avec les exceptions suivantes:

201.11.1.2.2 * PARTIES APPLIQUEES non destinées à fournir de la chaleur à un PATIENT

Remplacement:

La température des surfaces accessibles au NOUVEAU-NE sur le MATELAS ne doit pas dépasser 40 °C pour les surfaces métalliques et 43 °C pour les autres matériaux, lorsque l'INCUBATEUR RADIANT POUR NOUVEAU-NES fonctionne en CONDITION DE TEMPERATURE STABILISEE à sa TEMPERATURE DE COMMANDE maximale.

Dans des conditions d'échauffement jusqu'à obtention de la CONDITION DE TEMPERATURE STABILISEE ou en CONDITION DE PREMIER DEFAT, ces températures ne doivent pas dépasser 42 °C pour des surfaces métalliques ou 45 °C pour les autres matériaux.

Ces exigences s'appliquent dans des CONDITIONS NORMALES et dans des CONDITIONS DE PREMIER DEFAT telles que:

- défaillance du circuit de commande du corps chauffant;
- défaillance d'un CAPTEUR DE TEMPERATURE CUTANEE;
- déconnexion du CAPTEUR DE TEMPERATURE CUTANEE de l'INCUBATEUR RADIANT POUR NOUVEAU-NES.

201.11.1.4 * PROTECTIONS

Addition:

Si la température de surface du corps chauffant dépasse 85 °C en UTILISATION NORMALE, des protections de ce corps chauffant, dont la température en UTILISATION NORMALE ne peut dépasser 85 °C, doivent être prévues.

La vérification est effectuée par mesurage de la température et en effectuant l'essai de rigidité spécifié au 15.3.2 de la norme générale. La PROTECTION du corps chauffant ne doit pas être en contact avec ce dernier.

201.11.2 * Prévention du feu

Le paragraphe 11.2 de la norme générale s'applique.

201.11.6.3 Renversement sur des APPAREILS EM et des SYSTEMES EM

Remplacement:

L'INCUBATEUR RADIANT POUR NOUVEAU-NES ou le SYSTEME EM doit être construit de façon qu'en cas de renversement d'eau (mouillage accidentel) sur le support du PATIENT ou sur le CAPTEUR DE TEMPERATURE CUTANEE, aucun DANGER ne doit résulter de la pénétration d'eau.

La vérification est effectuée par les essais suivants: positionner l'INCUBATEUR RADIANT POUR NOUVEAU-NES ou le SYSTEME EM dans la position d'UTILISATION NORMALE la moins favorable. Dans le cas d'un INCUBATEUR RADIANT POUR NOUVEAU-NES ou d'un SYSTEME EM avec fonctionnement en INCUBATEUR RADIANT A REGULATION CUTANEE, le CAPTEUR DE TEMPERATURE CUTANEE doit être placé au centre de la surface supérieure du MATELAS. Verser 200 ml d'eau isotonique (solution saline à 0,9 %) de façon continue sur le centre du MATELAS pendant 15 s.

Après cet essai, l'INCUBATEUR RADIANT POUR NOUVEAU-NES ou le SYSTEME EM doit satisfaire aux exigences relatives à la rigidité diélectrique spécifiées au 8.8.3 de la norme générale et l'INCUBATEUR RADIANT POUR NOUVEAU-NES ou le SYSTEME EM doit fonctionner normalement.

201.11.8 COUPURE DE L'ALIMENTATION / DU RESEAU D'ALIMENTATION VERS L'APPAREIL EM

Addition:

L'INCUBATEUR RADIANT POUR NOUVEAU-NES doit être conçu de sorte que la coupure et le rétablissement de l'alimentation électrique, jusqu'à 10 min, ne modifient pas la TEMPERATURE DE COMMANDE ou d'autres valeurs préétablies.

La vérification est effectuée en coupant le RESEAU D'ALIMENTATION, en le rétablissant ensuite et en examinant l'INCUBATEUR RADIANT POUR NOUVEAU-NES.

201.12 Précision des commandes et des instruments et protection contre les caractéristiques de sortie dangereuses

L'Article 12 de la norme générale s'applique avec les exceptions suivantes:

201.12.1 Précision des commandes et des instruments

Addition:

201.12.1.101 * Précision du CAPTEUR DE TEMPERATURE CUTANEE

La température mesurée par le CAPTEUR DE TEMPERATURE CUTANEE doit être continuellement affichée et clairement visible. La température affichée doit avoir une précision de $\pm 0,3$ °C. Si l'affichage permet d'indiquer d'autres paramètres, cette indication ne doit être obtenue que de façon volontaire en utilisant un interrupteur à rappel. La température affichée doit être au moins comprise entre 30 °C et 40 °C.

La vérification est effectuée par examen et par l'essai suivant:

Immerger le CAPTEUR DE TEMPERATURE CUTANEE dans un bain d'eau dont la température est maintenue à 36 °C $\pm 0,1$ °C. Placer le bulbe d'un thermomètre d'étalonnage, dont la précision de lecture est de $\pm 0,05$ °C, à proximité du CAPTEUR DE TEMPERATURE CUTANEE. La température lue sur le thermomètre étalon doit être comparée à la température affichée, et la différence entre elles ne doit pas dépasser $0,3$ °C moins l'erreur du thermomètre d'étalonnage.

201.12.1.102 * Précision de répartition de l'irradiation au MATELAS

La différence entre la TEMPERATURE MOYENNE AU CENTRE et la TEMPERATURE MOYENNE DU DISPOSITIF D'ESSAI de tout autre dispositif comprenant la CHARGE D'ESSAI ne doit pas dépasser 2 °C.

La vérification est effectuée par l'essai suivant: Préparer cinq DISPOSITIFS D'ESSAI se composant de disques en aluminium, ayant chacun une masse de 500 g ±10 g et un diamètre de 100 mm ±2 mm. Percer des trous de 5 mm de diamètre et de 50 mm ±2 mm de profondeur, comme cela est indiqué à la Figure 201.102, et recouvrir la surface entière du disque d'une peinture noire non réfléchissante.

NOTE L'épaisseur d'un disque est d'environ 23 mm.

Soumettre l'INCUBATEUR RADIANT POUR NOUVEAU-NES à l'essai suivant dans un local dans lequel la vitesse maximale de l'air est de 0,1 m/s et la température ambiante est maintenue à 23 °C ±2 °C.

Placer quatre DISPOSITIFS D'ESSAI identifiés individuellement et marqués 1, 2, 3 et 4 sur le MATELAS horizontal, au centre de chacun des quatre rectangles obtenus en divisant, en deux parties égales, la longueur et la largeur du MATELAS, comme cela est indiqué à la Figure 201.101. Placer un cinquième DISPOSITIF D'ESSAI, marqué "M", au centre du MATELAS. Insérer un capteur de température au centre de chacun des cinq DISPOSITIFS D'ESSAI et, dans le cas d'un INCUBATEUR RADIANT POUR NOUVEAU-NES avec fonctionnement en INCUBATEUR RADIANT A REGULATION CUTANEE, fixer le CAPTEUR DE TEMPERATURE CUTANEE au centre de la surface supérieure du DISPOSITIF D'ESSAI "M", en assurant une bonne conductivité thermique (par exemple, pâte thermique). Dans le cas d'un INCUBATEUR RADIANT POUR NOUVEAU-NES avec fonctionnement en INCUBATEUR RADIANT A REGULATION CUTANEE, régler la commande de température à une TEMPERATURE DE COMMANDE de 36 °C ±0,1 °C et faire fonctionner l'INCUBATEUR RADIANT POUR NOUVEAU-NES jusqu'à ce qu'une CONDITION DE TEMPERATURE STABILISEE soit obtenue. Dans le cas d'un INCUBATEUR RADIANT POUR NOUVEAU-NES fonctionnant seulement en MODE MANUEL, régler la sortie du corps chauffant de manière que la température du DISPOSITIF D'ESSAI s'élève jusqu'à environ 36 °C en CONDITION DE TEMPERATURE STABILISEE. Effectuer au moins 20 lectures des températures de chaque DISPOSITIF D'ESSAI, à intervalles de temps réguliers, pendant 60 min.

Calculer les cinq valeurs de la TEMPERATURE MOYENNE DU DISPOSITIF D'ESSAI pour chaque DISPOSITIF D'ESSAI, comme suit:

$$T_1 = \frac{(t_{11} + t_{12} + t_{13} + t_{14} + \dots + t_{1n})}{n}$$

où

T_1 est la TEMPERATURE MOYENNE DU DISPOSITIF D'ESSAI pour le DISPOSITIF D'ESSAI n° 1;

t_{11}, \dots, t_{1n} sont les lectures individuelles de température effectuées au niveau du DISPOSITIF D'ESSAI n° 1, à intervalles de temps réguliers et en CONDITION DE TEMPERATURE STABILISEE;

n est le nombre de lectures effectuées en CONDITION DE TEMPERATURE STABILISEE.

Calculer, de la même manière, les autres TEMPERATURES MOYENNES DES DISPOSITIFS D'ESSAI T_2 , T_3 , T_4 et T_M .

Comparer les TEMPERATURES MOYENNES DES DISPOSITIFS D'ESSAI T_1 , T_2 , T_3 , T_4 avec T_M et vérifier que la différence maximale ne dépasse pas 2,0 °C.