IEC 60601-2-21

Edition 2.0 2009-02

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

IEC 60601-2-21:2009

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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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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 second edition cancels and replaces the first edition published in 1994 and its Amendment 1 (1996). This edition constitutes a technical revision. This edition of IEC 60601-2-21 was revised to structurally align with the 2005 edition of IEC 60601-1.

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

FDIS	Report on voting
62D/735/FDIS	62D/762/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

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

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

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

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of February 2013 have been included in this copy.

INTRODUCTION

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

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 standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard 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 standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard specifies 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;

– 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.

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.

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

201.1.3 *Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

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

201.1.4 Particular standards

Replacement:

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

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

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, 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 standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not

relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

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

Amendment:

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

Addition:

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

NOTE Informative references are listed in the bibliography beginning on page 32.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in the general standard apply, except as follows:

NOTE An index of defined terms is found beginning on page 34.

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.

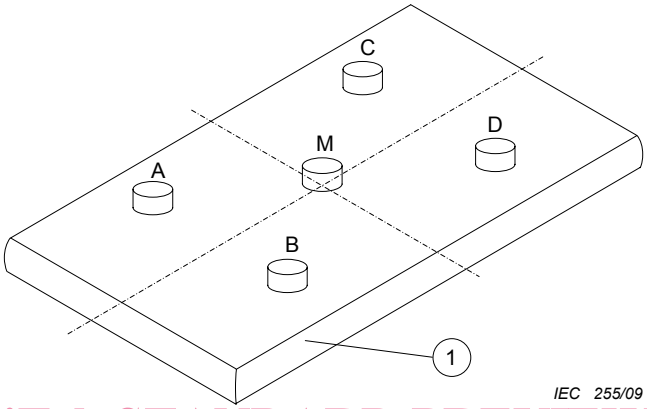
201.3.202
CONTROL TEMPERATURE
temperature selected at the temperature control

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

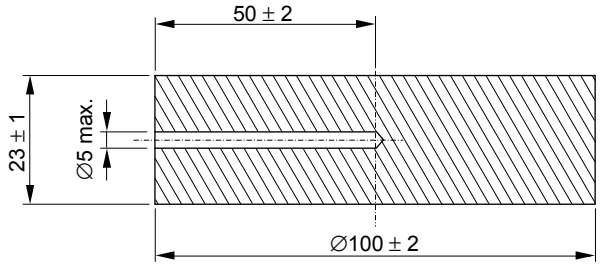
201.3.207
***PREWARM MODE**
mode of operation in which the heater output is maintained at a preset level (set by the MANUFACTURER) for the purpose of pre-warming the INFANT RADIANT WARMER and maintaining the level of warmth of the INFANT RADIANT WARMER prior to an INFANT being placed on the device

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 millimeters



IEC 372/09

Key

1 = Mattress

Surface finish: non-reflective black paint

Disc mass 500 g ± 10 g

Disc material: aluminum of density within the range 2,6 g/cm^3 and 2,9 g/cm^3

Figure 201.102 – TEST DEVICE

201.3.211
TEST DEVICE AVERAGE TEMPERATURE
(T_1, T_2, T_3, T_4 OR T_M)
average temperature reading taken during a STEADY TEMPERATURE CONDITION at regular intervals at the centre of a TEST DEVICE

NOTE T_M is 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 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 particular standard 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 subclause 201.15.4.2.1 of the relevant particular standards (e.g. IEC 60601-2-19 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 standard 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 particular standard, all tests shall be carried out at an ambient temperature within the range of 21 °C to 26 °C.

201.5.4 Other conditions

Addition:

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts
(see also Table C.1 of the general standard)

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 (CO_2): 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 CO_2 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/cm^2 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

201.7.9.3.1 General

Additional item:

– the MANUFACTURER shall specify in the ACCOMPANYING DOCUMENTS the maximum CO_2 concentration (see 201.12.4.2.101)

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

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

201.9.4.2.1 Instability in transport position

Addition: