IEC 60601-2-20

Edition 2.0 2009-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

Appareils électromédicaux –
Partie 2-20: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs de transport pour nouveau-nés

IEC 60601-2-20:2009

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

FOREWORD

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International standard IEC 60601-2-20 has been prepared by IEC Subcommittee 62D Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-2-20 published in 1990 and its Amendment 1 (1996). This edition constitutes a technical revision. This edition of IEC 60601-2-20 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/731/FDIS	62D/757/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 collateral 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 corrigenda of February 2012 and 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 TRANSPORT INCUBATOR equipment.

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

The requirements are followed by specifications for the relevant tests.

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

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

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT TRANSPORT INCUBATOR equipment, as defined in 201.3.211 of this standard, also referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard specifies safety requirements for INFANT TRANSPORT INCUBATORS but alternate methods of compliance with a specific clause by demonstrating equivalent safety will not be judged as non compliant if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISK presented by the HAZARD has been found to be of an acceptable level when weighed against the benefit of treatment from the device.

This particular standard does not apply to:

– devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information see IEC 80601-2-35 [1][1)];
– INFANT INCUBATORS which are not INFANT TRANSPORT INCUBATOR; for information see IEC 60601-2-19 [2];
– INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [3];
– INFANT PHOTOTHERAPY; for information, see IEC 60601-2-50 [4].

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT TRANSPORT INCUBATORS as defined in 201.3.211, which minimize HAZARDS to the PATIENT and OPERATOR, and to specify tests by which compliance with the requirements can be verified.

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1) Figures between square brackets refer to the Bibliography.

201.1.3 *Collateral standards

Addition:

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

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

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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

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

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

201.2 Normative references

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

NOTE Informative references are listed in the bibliography beginning on page 38.

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*

ISO 32, *Gas cylinders for medical use – Marking for identification of content*

ISO 407, *Small medical gas cylinders – Pin-index yoke-type valve connections*

201.3 Terms and definitions

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

NOTE An index of defined terms is found beginning on page 39.

Addition:

201.3.201
AIR CONTROLLED TRANSPORT INCUBATOR
INCUBATOR in which the air temperature is automatically controlled by an air temperature sensor close to a value set by the OPERATOR

201.3.202
AVERAGE TEMPERATURE
average of temperature readings taken at regular intervals at any specified point in the COMPARTMENT achieved during STEADY TEMPERATURE CONDITION

201.3.203
AVERAGE TRANSPORT INCUBATOR TEMPERATURE
average of the INFANT TRANSPORT INCUBATOR TEMPERATURE readings taken at regular intervals achieved during STEADY TEMPERATURE CONDITION (see Figure 201.102)

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

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

201.3.205
COMPARTMENT
environmentally-controlled enclosure intended to contain an INFANT and with transparent section(s) which allows for viewing of the INFANT

201.3.206
CONTROL TEMPERATURE
temperature selected at the temperature control

201.3.207
INFANT
PATIENT up to the age of three months and a weight less than 10 kg

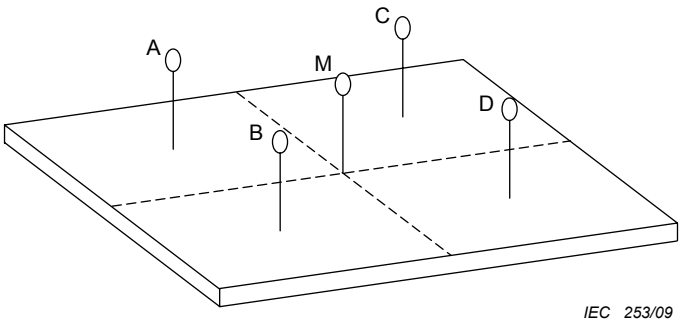
***201.3.208**
INFANT TRANSPORT INCUBATOR
TRANSPORTABLE ME EQUIPMENT that is equipped with a COMPARTMENT and a TRANSPORTABLE electrical power source with the means to control the environment of the INFANT primarily by heated air within the COMPARTMENT

201.3.209
SKIN TEMPERATURE
temperature of the skin of the INFANT at a point on which the SKIN TEMPERATURE SENSOR is placed

201.3.210
SKIN TEMPERATURE SENSOR
sensing device intended to measure the INFANT'S SKIN TEMPERATURE

201.3.211
STEADY TEMPERATURE CONDITION
condition reached when the TRANSPORT INCUBATOR TEMPERATURE does not vary by more than 1 °C over a period of 1 h (see Figure 201.102)

201.3.212
TRANSPORT INCUBATOR TEMPERATURE
temperature of the air at a point 10 cm above the centre of the MATTRESS surface in the COMPARTMENT (see Figure 201.101, point M)



Key

M = INCUBATOR TEMPERATURE sensor

A, B, C, D = Air temperature sensor

The measuring points A to D and M are in a plane parallel to and at a distance of 10 cm from the MATTRESS.

Figure 201.101 – Positioning of air temperature sensors

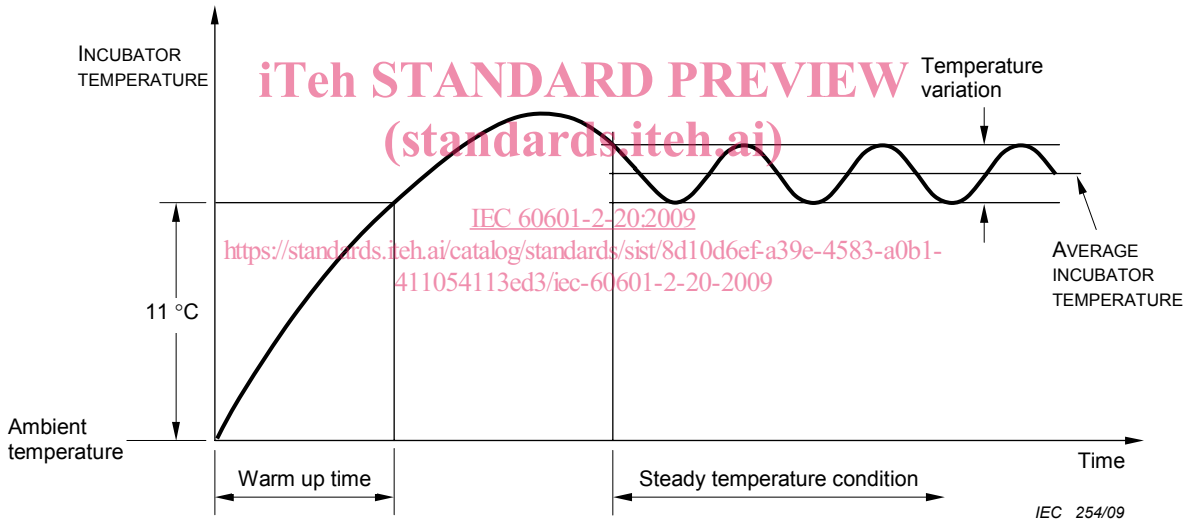


Figure 201.102 – Variation of INCUBATOR TEMPERATURE

201.3.213
TRANSPORTABLE ELECTRICAL POWER SOURCE
rechargeable battery and battery charger intended to provide the electrical power necessary to operate the INFANT TRANSPORT INCUBATOR

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 which combines alternative heat sources, for instance INCUBATORS with integrated INFANT RADIANT WARMERS, devices supplying heat via BLANKETS, PADS or MATTRESSES, etc., the safety requirements of the particular standards for these alternative heat sources, if any, shall be met. The safety requirements of this particular standard shall not be altered by such additional heat sources specified by the MANUFACTURER, details of which are provided in the instruction for use.

Compliance is checked by the tests of clause 201.11 and subclause 201.15.4.2.1 of the relevant particular standards.

201.4.3 *ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 ESSENTIAL PERFORMANCE of INFANT TRANSPORT INCUBATORS

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	201.12.1.104 or generation of a visual and audible alarm in compliance with 201.9.6.2.1.102
ESSENTIAL PERFORMANCE requirement 2	201.12.1.106 or generation of a visual and audible alarm in compliance with 201.9.6.2.1.102

201.4.10 Power supply

Additional subclauses:

201.4.10.101 *Ability to operate with different power supply sources

The INFANT TRANSPORT INCUBATOR shall have a TRANSPORTABLE ELECTRICAL POWER SOURCE consisting of a rechargeable battery and battery charger designed to operate from an alternating current supply voltage. It shall also be designed to operate from at least one external direct and one external alternating current SUPPLY MAINS as specified in the instructions for use. All requirements of the general standard and this particular standard shall continue to be met.

Compliance is checked by repeating the tests in subclauses 201.12.1.101, 201.12.1.102, 201.12.1.105 and 201.12.1.107 with the INFANT TRANSPORT INCUBATOR operating at an ambient temperature of 15 °C ± 1 °C when supplied from each of its SUPPLY MAINS in turn. This also includes the TRANSPORTABLE ELECTRICAL POWER SOURCE.

201.4.10.102 Capacity of TRANSPORTABLE ELECTRICAL POWER SOURCE

The capacity of any TRANSPORTABLE ELECTRICAL POWER SOURCE shall be sufficient to maintain the INFANT TRANSPORT INCUBATOR at a temperature in accordance with the following test during at least 90 min.

Compliance is checked by inspection and the following test:

The INFANT TRANSPORT INCUBATOR with a fully charged battery shall be placed in an environment with an ambient temperature of 15 °C ± 1 °C. It shall be operated from the SUPPLY MAINS until a STEADY TEMPERATURE CONDITION has been established at a CONTROL TEMPERATURE of 36 °C and then set to operate from any TRANSPORTABLE ELECTRICAL POWER

SOURCE. The INFANT TRANSPORT INCUBATOR TEMPERATURE shall be maintained within 2 °C of the CONTROL TEMPERATURE.

This test shall be conducted while all the electrical powered ACCESSORIES, as specified by the MANUFACTURER, are in operation and making the maximum demand upon the external TRANSPORTABLE ELECTRICAL POWER SOURCE.

201.4.10.103 Overcharge of TRANSPORTABLE ELECTRICAL POWER SOURCE

It shall not be possible to overcharge and damage the TRANSPORTABLE ELECTRICAL POWER SOURCE even if the ME EQUIPMENT is left connected to the a.c. electrical power source for an indefinite period. Controls which affect the rate of recharge or the final battery voltage level shall not be accessible to the OPERATOR without the aid of a TOOL.

Compliance is checked by inspection.

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 a):

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

– an ambient temperature between +10 °C and +30 °C.

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 and an ambient air velocity less than 1,0 m/s and greater than 0,3 m/s.

201.5.4 Other conditions

Addition:

If not otherwise specified, the CONTROL TEMPERATURE shall be 36 °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)

Additional subclauses:

201.7.2.101 *Oxygen monitor

An INFANT TRANSPORT INCUBATOR not equipped with an integral oxygen monitor and which provides means for oxygen administration shall be marked in a prominent position with a text which states: "Use an oxygen monitor when oxygen is administered".

NOTE See also 7.5 of the general standard.

201.7.2.102 Heater surface temperature

If a heater is accessible without the use of a TOOL a notice, symbol (see 7.5 of the general standard) or marking shall be displayed adjacent to the heater giving warning of high surface temperature.

201.7.4 Marking of controls and instruments (see also Table C.3)

201.7.4.2 *Control devices

Addition:

Temperature controls shall be clearly marked with temperature settings on or adjacent to the control. The markings shall be provided at intervals of not greater than 1 °C for AIR CONTROLLED TRANSPORT INCUBATORS and not greater than 0,5 °C for BABY CONTROLLED TRANSPORT INCUBATORS.

Marking of the maximum and the minimum values of controls and indicators shall be such that no confusion can arise with regard to the position of the control and/or the indicated values.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall contain the following additional items:

* a) A statement that a INFANT TRANSPORT INCUBATOR should be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known RISKS and benefits of INFANT TRANSPORT INCUBATOR use.

* b) A warning that direct sunlight or other radiant heat sources can cause an increase in TRANSPORT INCUBATOR TEMPERATURE to dangerous levels.

* c) A statement that the use of oxygen increases the danger of fire and that auxiliary equipment producing sparks shall not be placed in the INFANT TRANSPORT INCUBATOR.

* d) A warning that even small quantities of flammable agents, such as ether and alcohol, left in the INFANT TRANSPORT INCUBATOR can cause fire in connection with oxygen.

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

f) A statement of the maximum loads which can be applied to all supports and mounting brackets for ACCESSORIES and ancillary equipment.

g) For TYPE B APPLIED PARTS, where the INFANT may not be isolated from earth, a warning that particular care must be taken to ensure that additional ME EQUIPMENT connected to the INFANT is electrically safe.

h) An information on how and when to verify the functionality of the ALARM SYSTEM.

i) For oxygen administration into the COMPARTMENT:

   – a warning stating that administration of oxygen may increase the noise level for the INFANT within the INFANT TRANSPORT INCUBATOR;

   – an explanation of the operation of supplementary oxygen equipment supplied for use with the INFANT TRANSPORT INCUBATOR or as specified in the ACCOMPANYING DOCUMENTS;