IEC 60601-2-20

Edition 3.0 2020-09

INTERNATIONAL STANDARD

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

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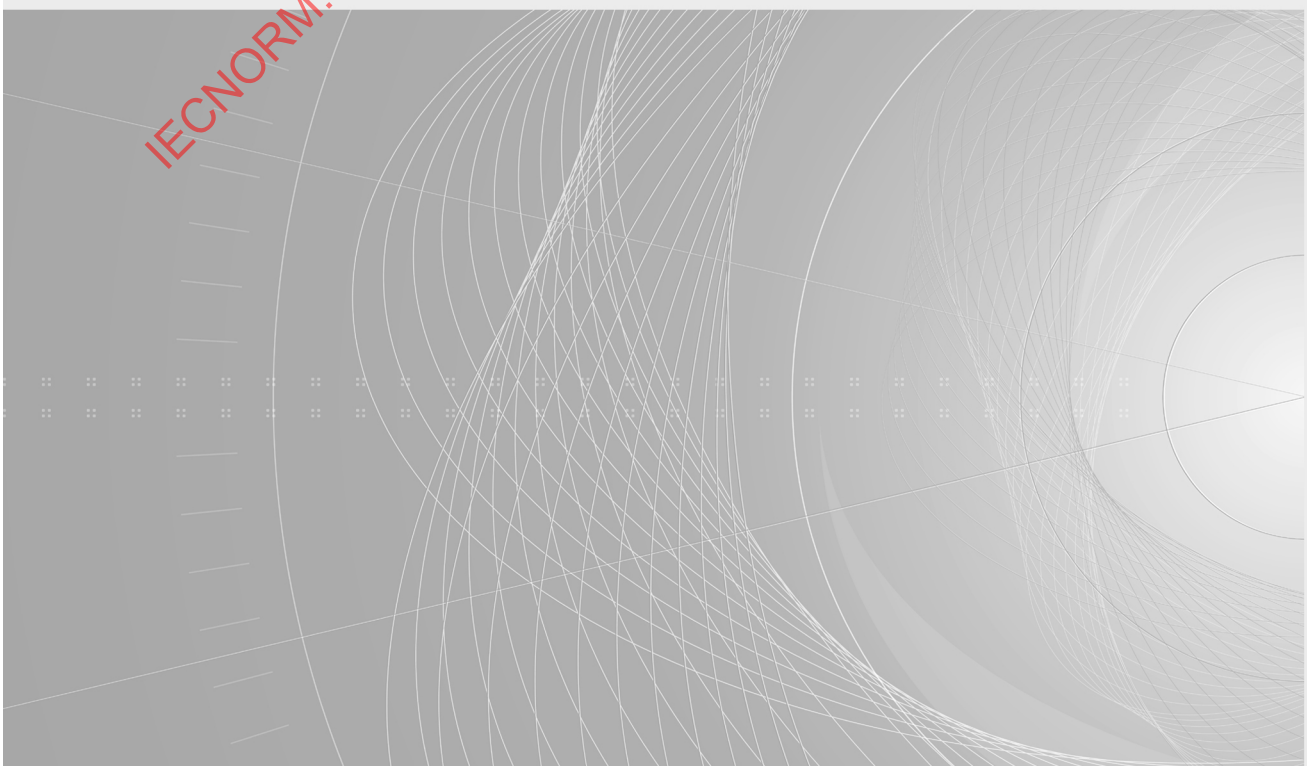

IEC 60601-2-20:2020-09(en)

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-20 has been prepared by IEC Subcommittee 62D Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2009 and Amendment 1:2016. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: re-dating of normative references.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62D/1763/FDIS	62D/1773/RVD

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

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

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type;*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

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

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

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

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

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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 TRANSPORT INCUBATOR 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 2-20: 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[1] applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT TRANSPORT INCUBATOR equipment, as defined in 201.3.208, also referred to as ME EQUIPMENT.

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

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

NOTE See also 4.2 of the general standard.

This particular standard specifies safety requirements for INFANT 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 60601-2-35 [1][2];
– 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 201.3.208, 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 The general standard is IEC 60601-1 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

2 Figures 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 201.2 of this particular standard.

IEC 60601-1-2:2014 and IEC 60601-1-12:2014 apply as modified in Clauses 202 and 212. IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 * Particular standards

Replacement:

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

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

For brevity, IEC 60601-1 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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

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

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

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

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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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.

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

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

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

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

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 43.

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

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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 201.101

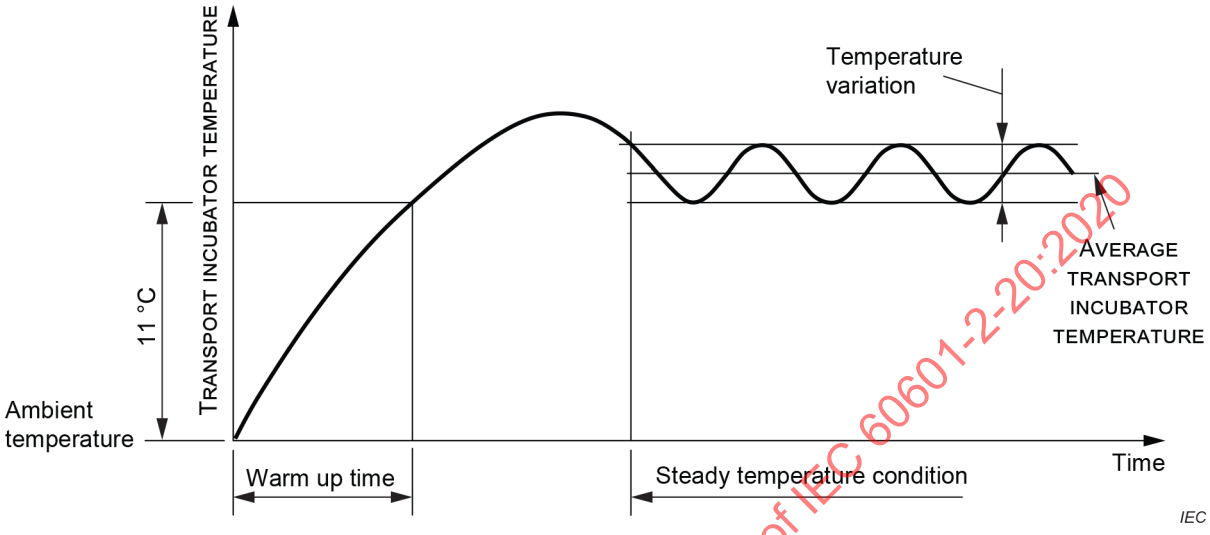

Figure 201.101 – Variation of INCUBATOR TEMPERATURE

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

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

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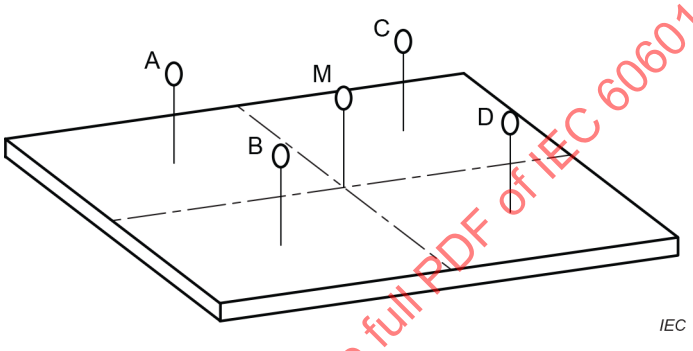
201.3.210
SKIN TEMPERATURE SENSOR
sensing device intended to measure the INFANT's SKIN TEMPERATURE

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 201.101

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 201.102, point M



Key

M TRANSPORT INCUBATOR TEMPERATURE sensor

A, B, C, D air temperature sensor

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

Figure 201.102 – Positioning of air temperature sensors

201.3.213
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 201.15.4.2.1 of the relevant particular standards.

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201.4.3 * ESSENTIAL PERFORMANCE

Addition:

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 201.12.1.101, 201.12.1.102, 201.12.1.104 and 201.12.1.106 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 AC 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.

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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 document when operating within 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 item to the existing list:

aa) 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 of the general standard)

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 of the general standard)

201.7.4.2 * Control devices

Addition:

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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 an 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 shall 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;

   – a statement that an oxygen analyser shall be used when oxygen is delivered to the INFANT.

j) Details of any specified combinations of ME EQUIPMENT (see 201.4.1).

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

201.7.9.2.8 * Start-up PROCEDURE

Addition:

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

201.7.9.2.9 Operating instructions

Addition:

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The instructions for use shall contain the following additional items.

a) * A recommendation of the position and method of use of the SKIN TEMPERATURE SENSOR.

b) * Information about the range of CONTROL TEMPERATURE and relative humidity of the INFANT TRANSPORT INCUBATOR. If the INFANT TRANSPORT INCUBATOR is not supplied with means for control of the degree of humidity, this shall be stated in the instructions for use.

c) * When applicable, a statement of the maximum allowed weight of additional equipment which might be placed on shelves connected to the INFANT TRANSPORT INCUBATOR.

d) Information on the external supply circuits with which the INFANT TRANSPORT INCUBATOR can be operated according to 201.4.10.101. Additionally, the MANUFACTURER shall specify in the ACCOMPANYING DOCUMENTS the polarity of the electrical connections as necessary.

e) A statement:

– of the mass and external dimensions of the INFANT TRANSPORT INCUBATOR including that of the specified external TRANSPORTABLE ELECTRICAL POWER SOURCE and with oxygen delivery system and trolley, if provided;

– with which means and in what way a fixation of the INFANT TRANSPORT INCUBATOR within an emergency vehicle is achieved;

– of the minimum ambient temperature, humidity and atmospheric pressure to which the INFANT TRANSPORT INCUBATOR can be exposed and still meet with the requirements of this document;

– of how the INFANT's movements can be limited within the INFANT TRANSPORT INCUBATOR during transport.

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

201.7.9.3.1 General

Additional item to the first paragraph:

– the maximum CO_2 concentration (see 201.12.4.2.101).

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

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

201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.1 General

Addition:

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

201.9.4.2.1 Instability in transport position

Addition:

The INFANT TRANSPORT INCUBATORS shall remain stable when tilted 10° in NORMAL USE and when tilted 20° during transportation.

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Compliance is checked by the following test:

The INFANT TRANSPORT INCUBATOR is placed in any possible position of NORMAL USE on a plane inclined at an angle of 0,18 rad (10°) to the horizontal plane. If wheels are present, they shall be temporarily fixed in their most disadvantageous position. Doors and drawers and the like shall be placed in the most disadvantageous position during NORMAL USE. The MATTRESS tray shall be extended outside the enclosure.

The test shall be repeated at an angle of 0,36 rad (20°), in which case the MATTRESS tray shall not be extended outside the enclosure. Doors and drawers and the like shall be placed in their most disadvantageous position during transportation.

201.9.4.3 Instability from unwanted lateral movement (including sliding)

Additional subclauses:

201.9.4.3.101 Tip-over force

The lateral force to cause the INFANT TRANSPORT INCUBATOR to tip over shall be greater than 100 N.

Compliance is checked by the following test:

With the INFANT TRANSPORT INCUBATOR wheels locked and with the ME EQUIPMENT in the worst-case configuration of parts and ACCESSORIES, a lateral force shall be applied and measured using a force gauge. The point of application shall be at the highest point of the body of the ME EQUIPMENT. The INFANT TRANSPORT INCUBATOR shall not tip over when the force is 100 N or less.

201.9.4.3.102 * Prevention of movements

If the ME EQUIPMENT is mounted on wheels, the MANUFACTURER shall provide a means to prevent movement of the ME EQUIPMENT on a slope of at least 10° to the horizontal.

Compliance is checked by inspection and by the following test:

Place the ME EQUIPMENT with its wheels in a locked position and with all ACCESSORIES fitted, on a plane inclined at an angle of 10° to the horizontal. Report whether the ME EQUIPMENT is in a maintain position.

201.9.4.3.103 Prevention of INFANT's movements

A means shall be provided to limit the INFANT's movement to a defined area within the COMPARTMENT during NORMAL USE.

Compliance is checked by inspection.

201.9.4.3.104 * Prevention of vibration

A means should be provided to limit the INFANT's vibration within the COMPARTMENT during transportation.

201.9.6.2 Acoustic energy

201.9.6.2.1 Audible acoustic energy

Additional subclauses:

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201.9.6.2.1.101 Sound level within the COMPARTMENT

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

Compliance is checked by the following test:

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

201.9.6.2.1.102 * Audible alarms sound level

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

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

201.9.6.2.1.103 * Audible alarms sound level within COMPARTMENT

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

Compliance is checked by the following test:

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

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.1 General

Amendment:

The normal load for an INFANT is reduced to 10 kg (see 201.3.207).

Additional subclauses:

201.9.8.3.101 * Barriers

For devices with an integral bed, suitable barriers such as walls or side panels shall prevent the PATIENT from falling off. Barriers intended to be opened or removed to allow access to the INFANT, such as doors, ports etc., shall close so as not to open under the test conditions specified below. It shall not be possible for barriers to be insecurely closed or latched whilst appearing to be engaged. The mechanical integrity of the INFANT TRANSPORT INCUBATOR shall be maintained under the following test conditions.

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Compliance is checked by inspection and by the following test:

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

201.9.8.3.102 MATTRESS tray

For devices with an integral bed, if the MATTRESS tray can be extended outside the enclosure, it shall be restrained to ensure that the tray remains attached to the INCUBATOR, is supported and does not tip under the weight of the INFANT.

Compliance is checked by the following test:

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

Additional subclause:

201.9.8.101 Supports and mounting brackets for ACCESSORIES

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

Compliance is checked by inspection and by the following test:

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

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Replacement:

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

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

– failure of the air circulation;

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

Compliance is checked by the following test:

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

201.11.2 * Fire prevention

Subclause 11.2 of the general standard applies.

201.11.6.2 * Overflow in ME EQUIPMENT

Replacement of the first paragraph:

If ME EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, including transit between periods of use, liquid overflowing from the reservoir or chamber shall not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor shall an unacceptable RISK be created.

Addition:

201.11.6.2.101 Water level indicator

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

Compliance is checked by inspection.

201.11.6.3 * Spillage on ME EQUIPMENT and ME SYSTEMS

Replacement:

INFANT TRANSPORT INCUBATORS shall be so constructed that spillage does not wet parts which if wetted might cause a HAZARD. Such spillage is considered a SINGLE FAULT CONDITION.

Compliance is checked by the following test:

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

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Addition:

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

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

Addition:

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The ME EQUIPMENT shall be so designed that an interruption and a 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 ME EQUIPMENT.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

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

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 * Stability of TRANSPORT INCUBATOR TEMPERATURE

During STEADY TEMPERATURE CONDITION, the TRANSPORT INCUBATOR TEMPERATURE shall not differ from the AVERAGE TRANSPORT INCUBATOR TEMPERATURE by more than 1 °C.

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

201.12.1.102 * Uniformity of TRANSPORT INCUBATOR TEMPERATURE

With an INFANT TRANSPORT INCUBATOR working as an AIR CONTROLLED TRANSPORT INCUBATOR and the CONTROL TEMPERATURE set at any temperature within its range, the AVERAGE TEMPERATURE in each of the points A, B, C and D as specified in the test instruction shall not differ from the AVERAGE TRANSPORT INCUBATOR TEMPERATURE by more than 1,5 °C in NORMAL USE. In any position of the tilted MATTRESS, it shall not differ by more than 2 °C.

Compliance is checked by the following test:

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

The differences between the five measured values and the measured AVERAGE TRANSPORT INCUBATOR TEMPERATURE shall be compared as specified. The test shall be undertaken with the INCUBATOR MATTRESS tray horizontal and at the two extremes of its tilt angles.

201.12.1.103 * Accuracy of SKIN TEMPERATURE SENSOR

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

Compliance is checked by the following test:

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

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201.12.1.104 * Accuracy between SKIN TEMPERATURE and CONTROL TEMPERATURE

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

Compliance is checked by the following test:

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

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

201.12.1.105 * Accuracy of TRANSPORT INCUBATOR TEMPERATURE indication

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

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

The AVERAGE TEMPERATURE device reading shall not differ from the AVERAGE TRANSPORT INCUBATOR TEMPERATURE, measured by a standard thermometer, by more than 1 °C, less the standard thermometer error. The standard thermometer shall be accurate within ±0,05 °C. It shall have a measuring range of at least 20 °C to 40 °C. If the temperature sensitive component of any device is located at a point where the air temperature consistently differs from the TRANSPORT INCUBATOR TEMPERATURE, the device may be specially calibrated with an offset in order to meet the above requirements. However, in this case, full details of the special calibration shall be specified in the ACCOMPANYING DOCUMENTS.

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

201.12.1.106 * Accuracy of TRANSPORT INCUBATOR TEMPERATURE control

With an INFANT TRANSPORT INCUBATOR operating as an AIR CONTROLLED TRANSPORT INCUBATOR, the AVERAGE TRANSPORT INCUBATOR TEMPERATURE shall not differ from the CONTROL TEMPERATURE by more than ±2 °C at an ambient temperature between 10 °C and 20 °C, and by more than ±1,5 °C at an ambient temperature between 20 °C and 30 °C.

Compliance is checked by measuring the AVERAGE TRANSPORT INCUBATOR TEMPERATURE at a CONTROL TEMPERATURE of 36 °C and in the STEADY TEMPERATURE CONDITION at an ambient temperature of 15 °C ± 1 °C and an ambient temperature of 25 °C ± 1 °C.

201.12.1.107 * Warm-up time

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

Compliance is checked by the following test:

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

201.12.1.108 * Overshoot of TRANSPORT INCUBATOR TEMPERATURE after adjustment

After adjustment of the CONTROL TEMPERATURE in the manner described in the following test, the overshoot in TRANSPORT INCUBATOR TEMPERATURE shall not exceed 2 °C.

Compliance is checked by the following test:

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

201.12.1.109 * Accuracy of indication of relative humidity

For INFANT TRANSPORT INCUBATOR, any indicated value of relative humidity shall have an accuracy of ±15 % relative humidity.

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

201.12.1.110 * Oxygen control

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

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

Compliance is checked by the following test:

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

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

201.12.1.111 * Air velocity

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

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

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201.12.1.112 Change in ambient temperature

Following the changes in ambient temperature described in the following test, the TRANSPORT INCUBATOR TEMPERATURE shall not differ from the CONTROL TEMPERATURE by more than 3 °C.

Compliance is checked by the following test:

The INFANT TRANSPORT INCUBATOR is operated as an AIR CONTROLLED TRANSPORT INCUBATOR connected to an external power source. When the STEADY TEMPERATURE CONDITION is established at an ambient temperature within the range of 21 °C to 25 °C and at a CONTROL TEMPERATURE of 36 °C, it shall be set to operate in accordance with the ACCOMPANYING DOCUMENTS without a SUPPLY MAINS and transferred into an environment where the ambient temperature is being kept at (–5 ± 2) °C and the wind velocity is not more than 1 m/s. After 15 min, it shall be returned into an environment where the ambient temperature lies within the range of 20 °C to 25 °C and reconnected to an external supply and operated for a further 30 min. The TRANSPORT INCUBATOR TEMPERATURE shall be monitored throughout the whole test and at no time shall it go outside the specific limits.

If the ACCOMPANYING DOCUMENTS specify to meet this requirement at a lower ambient temperature than (–5 ± 2) °C or for a longer period than 15 min, the INFANT TRANSPORT INCUBATOR shall be additionally tested for compliance with those claims as indicated.

201.12.1.113 Provision of oxygen

a) There shall be means for the provision of oxygen.

   Compliance is checked by inspection.

b) If the source of oxygen is incorporated in the INFANT TRANSPORT INCUBATOR, it shall be capable of delivering oxygen of such an amount that a concentration of up to 60 vol % can be given to the INFANT during at least 1 h. Where oxygen is supplied from a reservoir, there shall be an indication of the remaining content. This indication shall be on a position which can be easily read. Gas connections to high pressure cylinders shall comply with ISO 32 and ISO 407.

   Compliance is checked by inspection and measurement.

201.12.1.114 Overshoot of TRANSPORT INCUBATOR TEMPERATURE after opening

After opening the access doors of the front side of the INCUBATOR for 10 min, the overshoot in TRANSPORT INCUBATOR TEMPERATURE shall not exceed 2 °C.

Compliance is checked by the following test:

The INFANT TRANSPORT INCUBATOR is operated as an AIR CONTROLLED TRANSPORT INCUBATOR at a CONTROL TEMPERATURE of 36 °C until STEADY TEMPERATURE CONDITION is reached. The access door of the front side of the INFANT TRANSPORT INCUBATOR is then opened for 10 min. After closing of the doors, the overshoot of TRANSPORT INCUBATOR TEMPERATURE shall be measured.

201.12.1.115 * Weighing scale

If a weighing scale is supplied as an integral part of the ME EQUIPMENT or as an ACCESSORY specifically for use with the ME EQUIPMENT, 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 ME EQUIPMENT 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-enriched environment in use, it shall comply with the requirements of 6.5 of the general standard.

NOTE Device calibration can be both verified and updated by the OPERATOR during usage.

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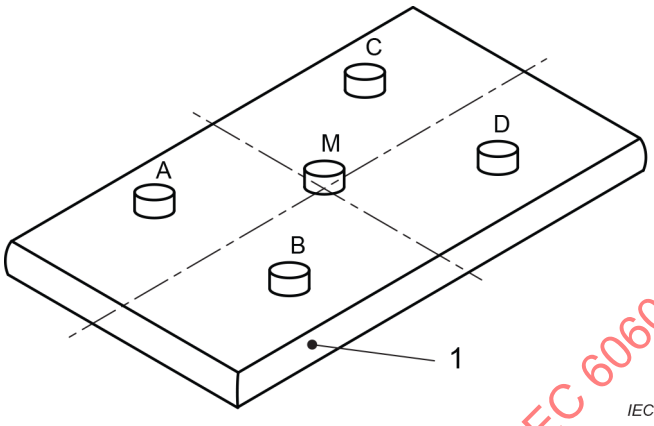
Compliance is checked by the following test:

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



Key

1 MATTRESS

Figure 201.103 – Layout of weight test devices

201.12.2 USABILITY of ME EQUIPMENT

Addition:

201.12.2.101 * Indication of SKIN TEMPERATURE

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

Compliance is checked by inspection.

201.12.2.102 * Indication of the mode of operation

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

Compliance is checked by inspection.

201.12.2.103 Temperature control

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

Compliance is checked by inspection.

201.12.3 ALARM SYSTEMS

Addition:

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201.12.3.101 * Air circulation fan

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

– failure of the fan to rotate, or

– blocking of the air outlets from the INFANT TRANSPORT INCUBATOR COMPARTMENT, and

– when possible, blocking of the air inlet.

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

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

– *the fan is disabled;*

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

– *the air inlet is blocked, when applicable.*

201.12.3.102 * Connector to SKIN TEMPERATURE SENSOR

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

– becoming electrically disconnected,

– having open-circuited leads, or

– having short-circuited leads.

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

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

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

201.12.3.103 Interruption of power supply

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

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

a) operating the INFANT TRANSPORT INCUBATOR from the main supply;

b) operating the INFANT TRANSPORT INCUBATOR from its TRANSPORTABLE ELECTRICAL POWER SOURCE.

In both cases, an audible and visual indication of the failure of power supply shall be provided for a minimum time of 10 min.

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201.12.3.104 AUDIO PAUSED of audible alarm

Deliberately silenced audible alarms shall have a maintained visual indication.

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

The time necessary for warming up the INCUBATOR from COLD CONDITION may be 30 min.

Compliance is verified by functional check and time measurement.

201.12.3.105 Alarm function test

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

Compliance is checked by inspection.

201.12.4.2 Indication relevant to safety

Addition:

201.12.4.2.101 * CO_2 concentration

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

Compliance is checked by the following test:

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

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

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

201.13.2.2 * Electrical SINGLE FAULT CONDITION

Addition:

Applicable SINGLE FAULT CONDITIONS are short and open circuiting of components or wiring, which

– cause sparks to occur, or
– increase the energy of sparks, or
– increase temperatures.

201.13.2.6 * Leakage of liquid

Addition:

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

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Leakage of 200 ml is considered as NORMAL CONDITION.

Compliance is checked by the following tests:

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

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

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

201.15.3 Mechanical strength

Additional subclause:

201.15.3.101 Access to the INFANT

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

201.15.3.4.2 * PORTABLE ME EQUIPMENT

Addition before the first paragraph:

15.3.4.2 also applies to INFANT TRANSPORT INCUBATORS whether or not they are classified as PORTABLE ME EQUIPMENT.

Addition after the last paragraph, including the note:

Following the above tests, the INFANT TRANSPORT INCUBATOR shall be suitable for further NORMAL USE. Mechanical and structural integrity of the INFANT TRANSPORT INCUBATOR shall be verified; for example, latches and doors 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 * Connection of 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.

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201.15.4.2 Temperature and overload control devices

201.15.4.2.1 Application

Addition:

aa) * An INFANT TRANSPORT INCUBATOR shall be equipped with a THERMAL CUT-OUT which operates independently of any THERMOSTAT. It shall be so arranged that the heater is disconnected and an auditory and visual warning is given at a TRANSPORT INCUBATOR TEMPERATURE which does not exceed 40 °C. The THERMAL CUT-OUT(S) shall be

- non-self-resetting but capable of being manually reset, or
- self-resetting at a TRANSPORT INCUBATOR TEMPERATURE between 39°C and 34°C, and the alarm shall operate continuously until manually reset.

Compliance is checked by inspection and the following tests:

With the INFANT TRANSPORT INCUBATOR set to operate as an AIR CONTROLLED TRANSPORT INCUBATOR, the THERMOSTAT is disabled and the INFANT TRANSPORT INCUBATOR is switched on. At the time the alarm operates, the TRANSPORT INCUBATOR TEMPERATURE shall not exceed 40 °C and the supply to the heater shall be disconnected. The heater supply shall not be restored until either:

- *the THERMAL CUT-OUT(S) is (are) manually reset, or*
- *the TRANSPORT INCUBATOR TEMPERATURE falls below 39°C.*

Test:

With the INFANT TRANSPORT INCUBATOR set to operate as a BABY CONTROLLED TRANSPORT INCUBATOR, the THERMOSTAT is disabled and the SKIN TEMPERATURE SENSOR is separately maintained at a temperature below the CONTROL TEMPERATURE. At the time the alarm operates, the TRANSPORT INCUBATOR TEMPERATURE shall not exceed 40 °C and the supply to the heater shall be disconnected. The heater supply shall not be restored until either:

- *the THERMAL CUT-OUT is manually reset, or*
- *the TRANSPORT INCUBATOR TEMPERATURE falls below 39 °C.*

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

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

201.15.4.2.2 * Temperature settings

Addition:

For an AIR CONTROLLED TRANSPORT INCUBATOR, the range of CONTROL TEMPERATURES shall be from 30 °C or less to not more than 39 °C. The maximum setting of the CONTROL TEMPERATURE shall not be less than 36 °C.

Compliance is checked by inspection.

For a BABY CONTROLLED TRANSPORT INCUBATOR, the range of the CONTROL TEMPERATURE shall be from 35 °C or less to not more than 37,5 °C. The CONTROL TEMPERATURE range may be overridden by a special action of the OPERATOR up to 39 °C.

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Compliance is checked by inspection.

201.15.4.6.1 Fixing, prevention of maladjustment

Addition:

Where the relative movement of any control knob and its actuating mechanism can affect the setting of the INFANT TRANSPORT INCUBATOR air temperature, they shall be positively secured together to prevent the possibility of being fixed in the incorrect position.

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 TRANSPORT INCUBATOR and/or system

- shall continue to perform its intended function as specified by the MANUFACTURER at a level up to 3 V/m for the frequency range of IEC 60601-1-2:2014;
- shall, for BASIC SAFETY and ESSENTIAL PERFORMANCE, comply to Table 4 for HOME HEALTHCARE ENVIRONMENT (i.e. the system may fail to provide its intended function but shall not create a safety HARM).

212 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT

IEC 60601-1-12:2014 applies, except as follows:

212.4.2.1 * Environmental conditions of transport and storage between uses

Subclause 4.2.1 of IEC 60601-1-12:2014 does not apply.

212.4.2.2 * Environmental operating conditions

Subclause 4.2.2.2 of IEC 60601-1-12:2014 does not apply.

212.4.2.2.1 Continuous operating conditions

Subclause 4.2.2.1 of IEC 60601-1-12:2014 does not apply.

NOTE Subclause 201.5.3 of this document applies instead.

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212.4.2.2.2 Transient operating conditions

Subclause 4.2.2 of IEC 60601-1-12:2014 does not apply.

NOTE Subclause 201.12.1.112 of this document applies instead.

212.5 * Classification of ME EQUIPMENT and ME SYSTEMS

Clause 5 of IEC 60601-1-12:2014 does not apply.

NOTE See the additional statement in the instructions for use required by 212.6.3.2 of this particular standard.

212.6.3.2 Additional requirements for an electrical power source

Addition:

The instructions for use shall contain a statement that the INFANT TRANSPORT INCUBATOR may only be used with SUPPLY MAINS that is regularly checked for proper PE connection.

212.6.3.4 * Additional requirements for operating instructions

Subclause 6.3.4 of IEC 60601-1-12:2014 does not apply.

212.6.3.5 *Additional requirements for ME EQUIPMENT messages

Subclause 6.3.5 of IEC 60601-1-12:2014 does not apply.

212.7 * Protection against electrical HAZARDS from ME EQUIPMENT

Clause 7 of IEC 60601-1-12:2014 does not apply.

212.8.1 * Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Subclause 8.1 of IEC 60601-1-12:2014 does not apply.

212.9 Accuracy of controls and instruments and protection against hazardous outputs

Clause 9 of IEC 60601-1-12:2014 does not apply.

NOTE Subclause 201.12.1.112 of this document applies instead.

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Annexes

The annexes of the general standard apply.

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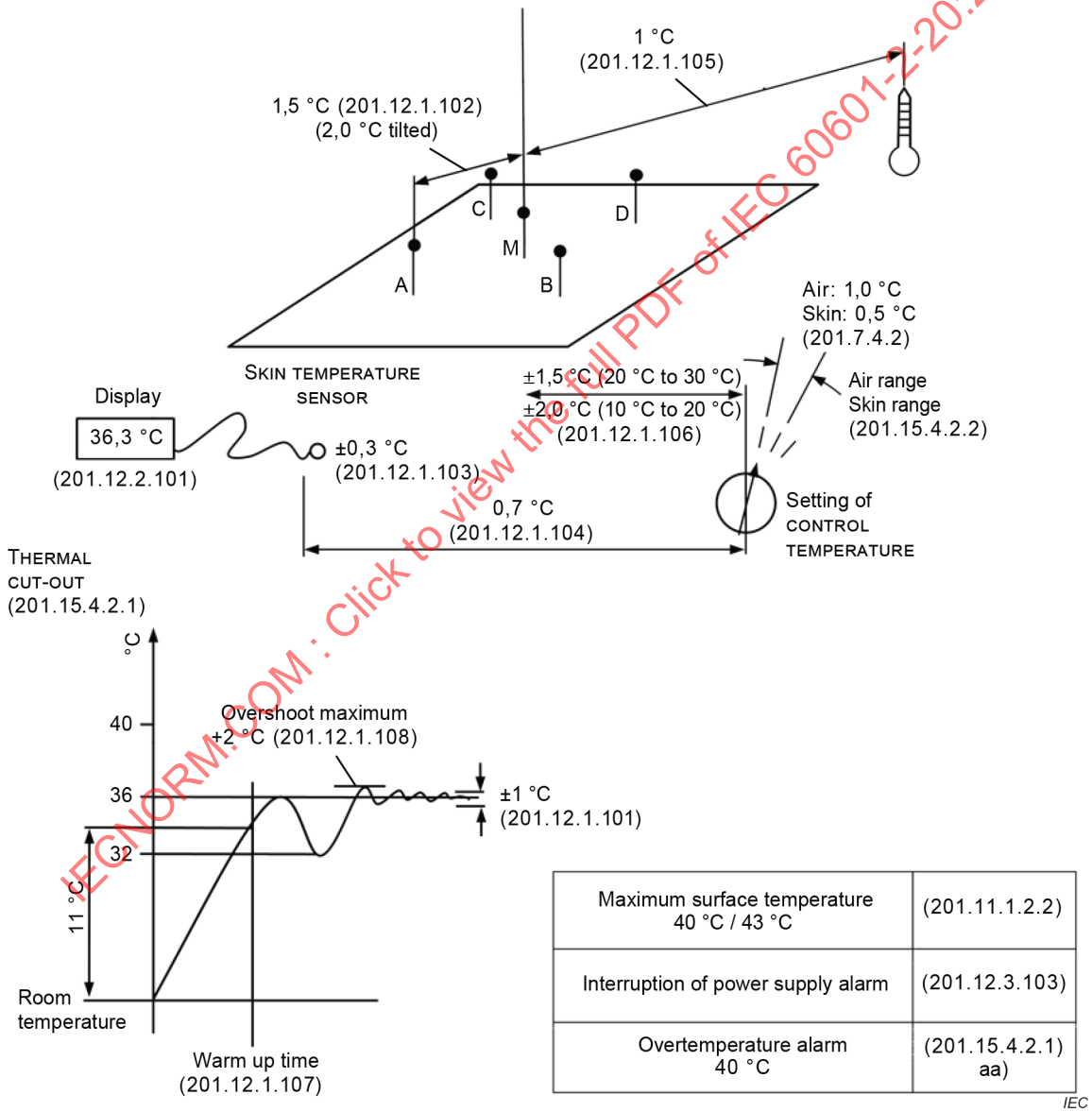
Annex AA
(informative)

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.



Maximum surface temperature 40 °C / 43 °C	(201.11.1.2.2)
Interruption of power supply alarm	(201.12.3.103)
Overtemperature alarm 40 °C	(201.15.4.2.1) aa)

NOTE Numbers in brackets indicate the relevant subclauses.

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

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AA.2 Rationale for particular clauses and subclauses

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

Subclause 201.1.4 – Particular standards

It is the primary purpose of a BABY CONTROLLED TRANSPORT INCUBATOR to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR. Hence, SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED TRANSPORT INCUBATOR, including the displayed value, are not considered to be a CLINICAL THERMOMETER in the sense of the particular standard ISO 80601-2-56, unless they are specifically extended to measure the body temperature.

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

Subclause 201.3.208 – INFANT TRANSPORT INCUBATOR

An INFANT TRANSPORT INCUBATOR can be a complete system with an integrated stand and wheels or just the INFANT TRANSPORT INCUBATOR alone.

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

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

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

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

Subclause 201.4.10.101 – Ability to operate with different power sources

It is the basic object of this subclause that an INFANT TRANSPORT INCUBATOR which is fitted with an external TRANSPORTABLE ELECTRICAL POWER SOURCE shall meet with all requirements of the general standard and of this particular standard. In this particular standard, special requirements are given concerning the use of the INFANT TRANSPORT INCUBATOR in conjunction with an external TRANSPORTABLE ELECTRICAL POWER SOURCE or with any other RATED SUPPLY MAINS. These are for instance: 201.4.10.102, 201.4.10.103, but also 201.12.1.112.

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It is considered that these subclauses are sufficient to test the safe design of an INFANT TRANSPORT INCUBATOR together with an external TRANSPORTABLE ELECTRICAL POWER SOURCE. Yet the requirement of 201.4.10.101 ensures that the MANUFACTURER has to realize that any requirement of both the general standard and the particular standard shall be met. Therefore, the test house may choose any other requirement, especially one of those under 201.12.1, in order to check whether the INFANT TRANSPORT INCUBATOR meets this requirement when operated with an external TRANSPORTABLE ELECTRICAL POWER SOURCE.

Subclause 201.5.3 – Ambient temperature, humidity, atmospheric pressure

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

The temperature range of between +10 °C and +30 °C has been considered as a standard range within an emergency vehicle and hospital. Ambient temperatures up to 40 °C would inhibit the required performance and safety characteristics concerning exact temperature control.

Subclause 201.7.2.101 – Oxygen monitor

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

Subclause 201.7.4.2 – Control devices

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

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

Subclause 201.7.9.2.2 – Warning and safety notices

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

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

c), d) Several oxygen fire accidents in INFANT TRANSPORT INCUBATORS have been reported [6]. Alcohol left in the enclosure after a cleaning PROCEDURE is suspected to be the primary ignited material. Arcs from contacts in the THERMOSTAT are thought to be the source of ignition.

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

Subclause 201.7.9.2.8 – Start-up PROCEDURE

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

Subclause 201.7.9.2.9 – Operating instructions

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

b) See rationale to 201.12.1.109.

c) The overloading of shelves could result in the INFANT TRANSPORT INCUBATOR tipping over or mechanical damage which could result in a HAZARD.

Subclause 201.9.4.3.102 – Prevention of movements

The ability to lock wheels eliminates unintentional movement of the ME EQUIPMENT, which could constitute a HAZARD for the PATIENT.

Subclause 201.9.4.3.104 – Prevention of vibration

During transportation, for example in an ambulance, there can be a high level of vibration. To reduce possible RISK to the INFANT, there should be means to lower this vibration, for example shock absorbers or spring/damping elements. As long as there is no test equipment created for this purpose, this is information for MANUFACTURERS of INFANT TRANSPORT INCUBATORS and ambulances.

Subclause 201.9.6.2.1.102 – Audible alarms sound level

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

Despite transport environment is very noisy, the committee decided to keep the 65 dB(A) limit for transport, because the PATIENT is continuously under observation of a medical professional.

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.

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

Subclause 201.9.6.2.1.103 – Audible alarms sound level within COMPARTMENT

It is recognized that hearing loss can result from continuous exposure to high sound levels. While there is no scientific evidence or specific incident to show that exposure to noise levels normally encountered in INFANT TRANSPORT INCUBATORS currently used results in hearing impairment, a conservative value based on current expert opinion on human tolerance to high sound levels was selected.

Subclause 201.9.8.3.101 – Barriers

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

Subclause 201.11.2 – Fire prevention

Reports of fires in oxygen rich atmosphere in medical ME EQUIPMENT are relatively unusual. However, when such fires do occur, they can be severe and very dangerous. See also the rationale of 201.7.9.2.2, c) and d).

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 neonate's skin. The primary requirements of the filler material are to provide a comfortable surface for the long-term stay of the PATIENT.

Since there is no source of ignition inside the canopy of an INFANT TRANSPORT INCUBATOR, the RISK of fire ignition in the area of the MATTRESS is limited since the requirements of 6.5 of the general standard for an OXYGEN RICH ENVIRONMENT have been complied. No incident has been reported concerning fire ignition inside the canopy of an INFANT TRANSPORT INCUBATOR for many years. Also, even with INFANT TRANSPORT INCUBATOR MATTRESSES, additional concerns were discussed around the toxicity of fumes that can be produced by materials that have been treated with flame retardant additives. Therefore, with the exception of elevating (accelerant) the RISK of fire from the cover material, no specific flammability rating is required of the PAD cover and the inner filler.

Subclause 201.11.6.2 – Overflow in ME EQUIPMENT

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

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