IEC 60601-2-20

Edition 2.0 2016-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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 60601-2-20:2009-02/AMD1:2016-04(en-fr)

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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/1325/FDIS	62D/1346/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website 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- withdrawn,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.

INTRODUCTION

Replace, in the second paragraph, “IEC 60601-1:2005” *by* “IEC 60601-1”.

201.1 Scope, object and related standards

201.1.3 * Collateral standards

Delete the asterisk (*) from the title.

Replace the second paragraph by the following text:

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Add an asterisk at the beginning of the title, as follows:

201.1.4 * Particular standards

Add the following paragraph at the end of this subclause:

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

201.2 Normative references

Replace "IEC 60601-1-2:2007" *by* "IEC 60601-1".

Remove the reference to IEC 60601-1-10:2007.

201.3 Terms and definitions

Replace, in the first paragraph, "IEC 60601-1:2005*" by* "IEC 60601-1".

201.3.204
BABY CONTROLLED TRANSPORT INCUBATOR

Remove the note at the end of the entry.

201.7.9.2.2 Warning and safety notices

Add, after the existing text, the following new text:

*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.

201.12.1.109 * Accuracy of indication of relative humidity

Replace, in the first paragraph, the phrase "of actual measured value" *by* "relative humidity".

202 Electromagnetic compatibility – Requirements and tests

Replace, in the first paragraph, "IEC 60601-1-2:2007" *by* "IEC 60601-1-2".

202.6.2.3 Radiated RF electromagnetic fields

Replace the number, title and entire text by the following new subclause number, title and text:

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 the collateral standard for EMC;
– for BASIC SAFETY and ESSENTIAL PERFORMANCE, Table 4 for EMERGENCY MEDICAL SERVICES ENVIRONMENT applies (i.e. the system may fail to provide its intended function but shall not create a safety HARM).

210 Requirements for the development of physiologic closed-loop controllers

Delete the entire Clause 210.

Add, before the annexes, the following new clause:

212 * Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

IEC 60601-1-12 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 does not apply.

212.4.2.2.1 Continuous operating conditions

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

NOTE Subclause 201.5.3 of this standard applies instead.

212.4.2.2.2 Transient operating conditions

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

NOTE Subclause 201.12.1.113 of this standard applies instead.

212.5 * Classification of ME EQUIPMENT and ME SYSTEMS

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

212.6.3.5 *Additional requirements for ME EQUIPMENT messages

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

212.7 * Protection against electrical HAZARDS from ME EQUIPMENT

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

212.9 Accuracy of controls and instruments and protection against hazardous outputs

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

NOTE Clause 201.12.1.113 of this standard applies instead

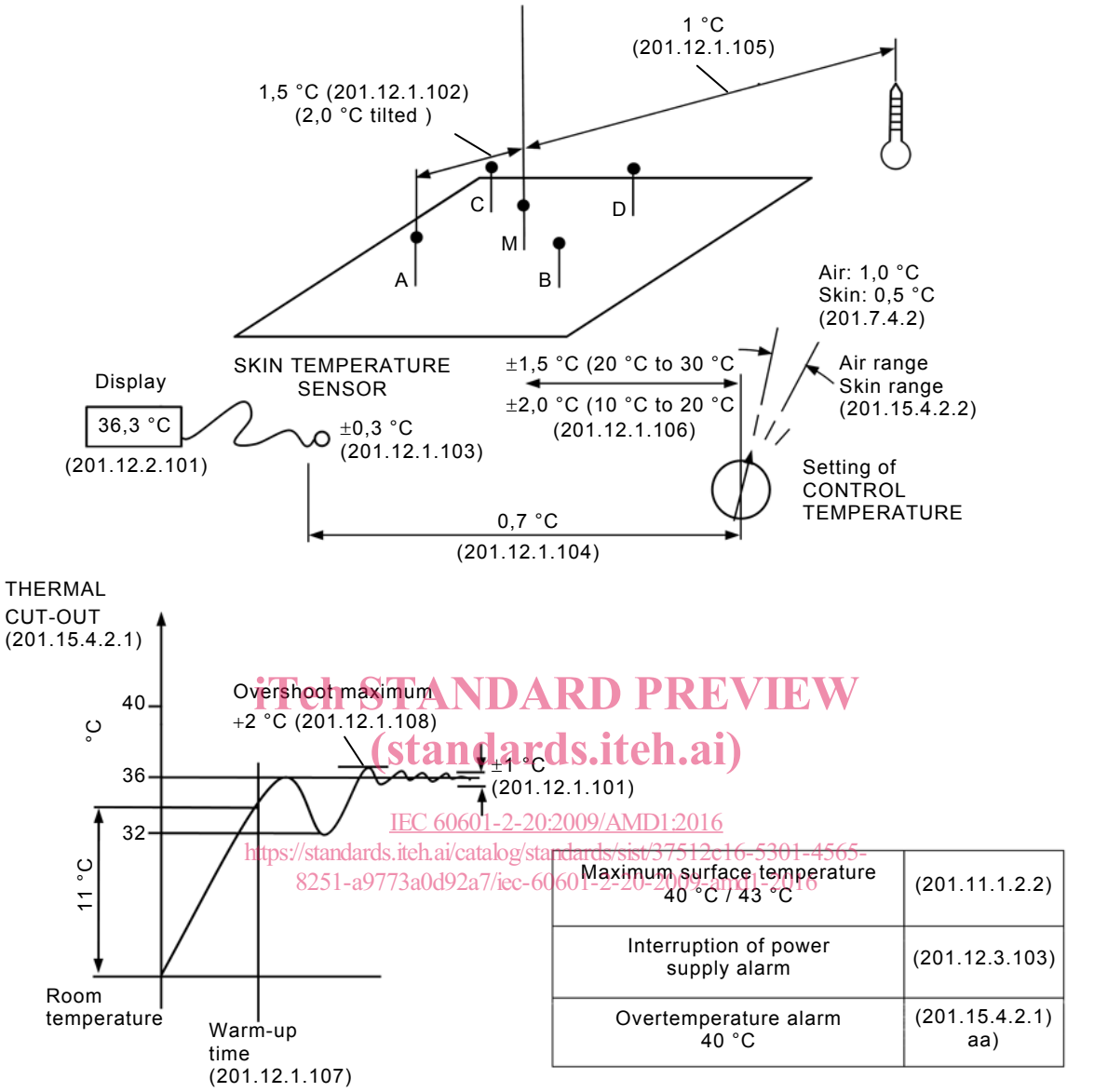
Annex AA
(informative)

Particular guidance and rationale

Add, immediately after the annex title, the following new text and figure:

AA.1 Requirements and the safety concept of this standard

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 standard considered it helpful to provide a synopsis of the requirements of this standard. 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)

IEC

NOTE Numbers in brackets indicate the relevant subclauses.

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

AA.2 Particular guidance

Subclause 201.1.3 – Collateral standards

Delete the title and entire text.

Add the following new text:

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 considered to be not a CLINICAL THERMOMETER in the sense of the particular standard ISO 80601-2-56 unless they are specifically extended to measure the body temperature.

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

Subclause 201.7.9.2.2 – Warnings and safety notices

Add, after the existing text, the following new text:

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 201.9.6.2.1.102 – Audible alarms sound level

Add the following text:

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

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

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

Subclause 202.6.2.3.1 – Requirements

Delete the title and entire text.

Subclause 210.5.1 – Instructions for use

Delete the title and entire text.

Subclause 210.6.3 – PCLS VARIABLE logging

Delete the title and entire text.

Subclause 210.8.2.2.6 – * Responses of the PCLS

Delete the title and entire text.

Add the following new rationales at the end of Annex AA:

Subclause 212 – Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

Some of the requirements demanded by IEC 60601-1-12 for emergency medical service environment had to a suitably limited extent already been included in this particular standard for many years. For INFANT TRANSPORT INCUBATORS designed according to this standard, no severe incidents were reported for decades. Thus, the experts of the working group considered including some of the requirements of IEC 60601-1-12 but excluding those that are aimed specifically at users who are untrained or operate INFANT TRANSPORT INCUBATORS only occasionally. Furthermore, such requirements are excluded that specifically account for only emergency situations including mass casualty situations. With respect to rough environmental conditions, only those requirements are included that reflect the mechanical stress during transport such as stress that occurs during road or airborne transport.

Subclause 212.4.2.1 – Environmental conditions of transport and storage between uses

Between transport situations the INFANT TRANSPORT INCUBATORS are mostly kept running in a standby mode within the hospital or ambulance. Subsequently, cold start from very low temperatures is not a likely use scenario.

Subclause 212.4.2.2 – Environmental operating conditions

Regarding ambient temperatures during storage and operation, this particular standard already demanded special requirements which represent the use of transport incubators more specifically than the collateral standard. Thus, the corresponding collateral requirements are excluded.

Subclause 212.5 – Classification of ME EQUIPMENT and ME SYSTEMS

INFANT TRANSPORT INCUBATORS are connected to mains supply most of the time in professional healthcare facilities where proper PE connectors can be assumed. During transport PE connectors in vehicles may undergo rough handling and are in danger of becoming unsecure. Henceforth, regular check for proper PE connectors has to be performed.

Subclause 212.6.3.4 – Additional requirements for operating instructions

Extremely rough environmental conditions like dust or lint are unlikely to occur as transport is scheduled and can avoid such conditions.

Subclause 212.6.3.5 – Additional requirements for ME EQUIPMENT messages

INFANT TRANSPORT INCUBATORS have been used for scheduled transport of infants between professional healthcare facilities for several decades. Such transport is usually accompanied by professional medical staff like neonatologists or neonatal nurses who are familiar with the use of INFANT TRANSPORT INCUBATORS.

Subclause 212.7 – Protection against electrical HAZARDS from ME EQUIPMENT

Pollution caused by dust is unlikely to occur. See rationale of Subclause 212.6.3.4.

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

During transport, the INFANT TRANSPORT INCUBATOR experiences outdoor conditions, such as low temperatures or precipitation, only for a limited time, namely for the short transfer from the professional healthcare facility to the vehicle and vice versa.

Bibliography

Delete the following reference:

[7] ISO 21647:2004, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors*

Add the following reference:

[7] ISO 80601-2-56, *Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

Index of defined terms used in this particular standard

Replace all instances of "IEC 60601-1:2005" *by* "IEC 60601-1".

Replace all instances of "IEC 60601-1-6:2006" *by* "IEC 60601-1-6".

Replace all instances of "IEC 60601-1-8:2007" *by* "IEC 60601-1-8".

Replace all instances of "IEC 60601-2-19:2009" *by* "IEC 60601-2-19".

Replace all instances of "IEC 60601-2-21:2009" *by* "IEC 60601-2-21".

Replace all instances of "IEC 60601-2-50:2009" *by* "IEC 60601-2-50".

Replace all instances of "IEC 80601-2-35:2009" *by* "IEC 80601-2-35".

Delete all terms referenced from IEC 60601-1-10:2007.