IEC 60601-2-19

Edition 2.0 2016-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

Appareils électromédicaux –
Partie 2-19: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs pour nouveau-nés

IEC 60601-2-19:2009-02/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/1324/FDIS	62D/1345/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- withdrawn,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

Replace, in footnote 1), “IEC 60601-1:2005” *by* “IEC 60601-1”.

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 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 60601-1-2".

Delete the IEC 60601-1-10:2007 reference.

201.3 Terms and definitions

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

201.3.204
BABY CONTROLLED 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:

*l) a statement that the INFANT 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, "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 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.

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

210 Requirements for the development of physiologic closed-loop controllers

Delete the entire Clause 210.

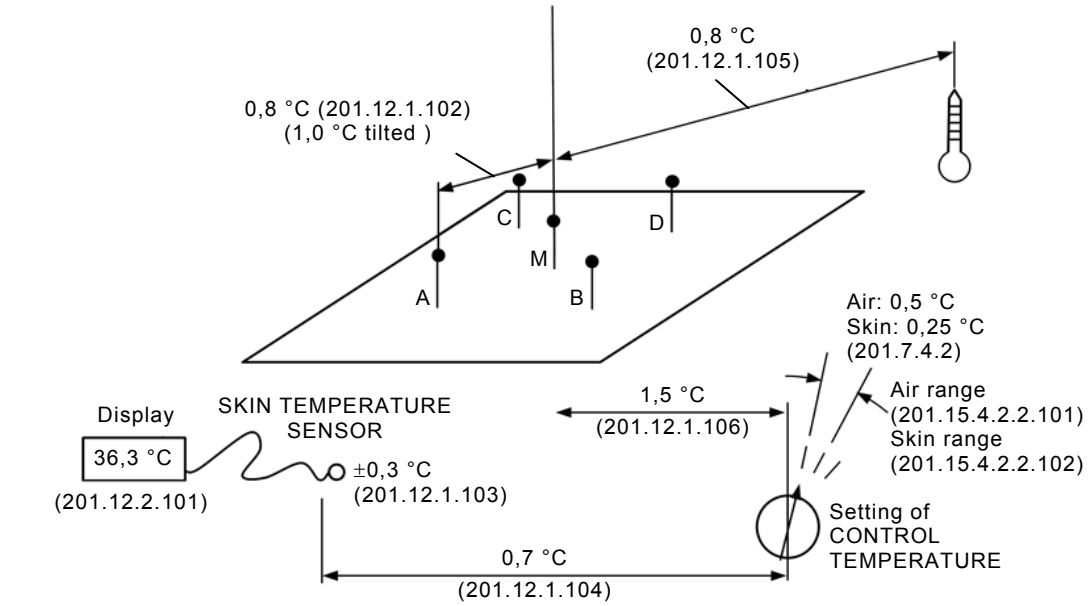
Annex AA
(informative)

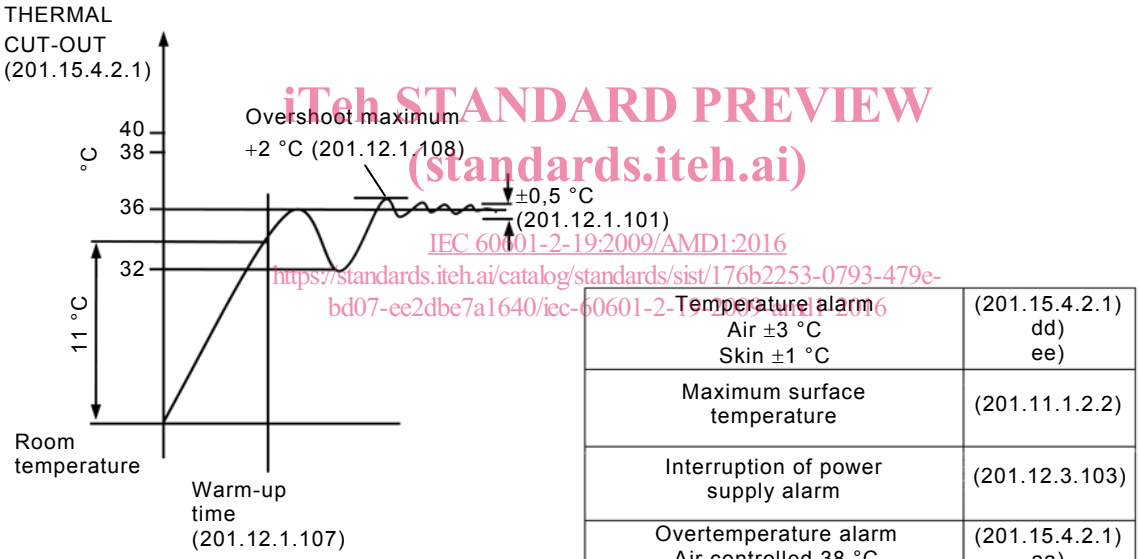
Particular guidance and rationale

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.





Temperature alarm Air ±3 °C Skin ±1 °C	(201.15.4.2.1) dd) ee)
Maximum surface temperature	(201.11.1.2.2)
Interruption of power supply alarm	(201.12.3.103)
Overtemperature alarm Air controlled 38 °C Baby controlled 40 °C	(201.15.4.2.1) aa) bb)

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 INCUBATOR to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR. Hence, SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED 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

Replace the text in e) by the following new text:

e) The overloading of shelves could result in the INFANT INCUBATOR tipping over or mechanical damage which could result in a HAZARD. Subclause 9.4.2.2 of IEC 60601-1 meets the test requirement necessary for INFANT INCUBATORS.

Add, after the existing text in k), the following new text:

l) The INFANT 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 alarm sound level

Add, after the existing text, the following new 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 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.

Bibliography

Add the following reference:

[12] 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 60601-2-20:2009" *by* "IEC 60601-2-20".

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.

Add the following new term:

HOME HEALTHCARE ENVIRONMENT ..... IEC 60601-1-11, 3.2

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