IEC 60601-2-21

Edition 3.0 2023-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

Appareils électromédicaux –
Partie 2-21: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs radiants pour nouveau-nés

IEC 60601-2-21:2020-09/AMD1:2023-11 (en-fr)

IEC Secretariat
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 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

AMENDMENT 1

FOREWORD

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Amendment 1 to IEC 60601-2-21:2020 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

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

Draft	Report on voting
62D/2077/FDIS	62D/2095/RVD

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

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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 or ISO 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 mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1816/RR.

201.1 Scope, object and related standards

Replace the existing footnote 1 with the following new footnote:

The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

201.1.3 Collateral standards

Add an asterisk (*) at the beginning of the subclause title.

*Replace, in the existing second paragraph, "*IEC 60601-1-2:2014 applies" *with: "*IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply*"*.

Add, after the existing second paragraph, the following new paragraph:

If a BABY CONTROLLED RADIANT WARMER is based on a temperature measurement which is substantially influenced by the INFANT'S core or body temperature IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply. Examples for temperature measurements stipulating applicability of IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 are provided in Annex AA.

201.1.4 Particular standards

*Replace, in the existing third paragraph, "*IEC 60601-1 and IEC 60601-1:2005/AMD1:2012*" with "*IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

Add, after the existing last paragraph, the following new paragraph:

If an INFANT RADIANT WARMER is supplied with dedicated physiological monitoring, then IEC 80601-2-49 [34] applies. Measured parameters related to the inherent function of an INFANT RADIANT WARMER i.e. the SKIN TEMPERATURE, are not considered to be a physiological monitoring unit as per IEC 80601-2-49 [34].

201.2 Normative references

Replace the existing references to IEC 60601-1 and IEC 60601-1-2 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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*
IEC 60601-1-2:2014/AMD1:2020

201.3 Terms and definitions

*Replace, in the existing first paragraph, "*IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012" *with "*IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

201.3.203
INFANT

Add, after the existing definition, the following new note to entry:

Note 1 to entry: INFANT includes premature/pre-born baby and neonate baby/newborn baby.

Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements

Replace the existing table with the following new table:

Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
ESSENTIAL PERFORMANCE requirement 1	201.12.1.103, or generation of a visual and audible alarm in compliance with 201.15.4.2.1

201.7.9.2.2 Warning and safety notices

Replace the existing item q) with the following new item:

q) a statement that the INFANT RADIANT WARMER does not adjust for PATIENT temperature in PREWARM MODE and that the mode shall be changed to MANUAL MODE or BABY CONTROLLED RADIANT WARMER (baby mode) immediately when the PATIENT is placed on the device. The MANUFACTURER shall disclose the level of heat in mW/cm^2 or in % of the maximum heater output when operating in PREWARM MODE.

201.9.6.2.1.101 *Audible alarms sound level

Replace the entire text with the following new text:

The audible HIGH PRIORITY and MEDIUM PRIORITY ALARM SIGNALS shall have a sound level of at least 57 dBA. The auditory alarm may be adjusted by the OPERATOR to a minimum lower level of 42 dBA.

Compliance is checked by inspection and measurement of the audible alarm level as specified in 6.3.3.2 of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020.

202 Electromagnetic disturbances – Requirements and tests

Add an asterisk (*) at the beginning of the clause title.

Replace the entire text, including 202.8.9, with the following new text:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply.

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

AA.2 Particular guidance

Subclause 201.1.1 – Scope

Add, after the existing first paragraph, the following new paragraph:

See also the rationale for Subclause 201.1.3.

Add, before the existing subclause 201.3.207, the following new subclause:

Subclause 201.1.3 – Collateral standards

Self-thermoregulation of newborns, especially of preterm newborns, is immature and cannot compensate for thermal changes in their direct vicinity. Hence, the skin temperature of such infants is rather determined by the thermal conditions in the infant's vicinity than by the infant's physiology. Consequently, the skin temperature is only a very weak surrogate for the (clinically relevant) core or body temperature while it is a strong surrogate for the incoming irradiance. Moreover, there are some dedicated physiological situations such as fever or shock that additionally may impair the weak correlation between skin and core temperature. Therefore, such a closed loop controller cannot fulfill the requirements for a reliable physiological closed loop controller. Henceforth, the BABY CONTROLLED RADIANT WARMER is not considered to be a physiological closed loop controller.

Provided, however, in future applications the temperature control of an INFANT RADIANT WARMER is based on temperature measurements being substantially influenced by the core or body temperature of the INFANT the corresponding control is considered to be a physiological closed loop controller. Examples for such temperature measurement are core or body temperature sensors like rectal probes, oral probes or probes measuring the core or body temperature via heat fluxes e.g. on the forehead. Axillary sensors may also be considered substantially influenced by the core or body temperature of the INFANT and henceforth the corresponding control is considered to be a physiological closed loop controller.

Subclause 201.9.6.2.1.101 – Audible alarms sound level

Replace the last three paragraphs with:

Previous editions of this particular standard specified that the alarm sound volume shall be measured in a reflecting room, as such rooms represent a more realistic acoustic situation in an intensive care nursery. Reflecting rooms, however, are not well defined and deliver less reproducible values due to their variable size and geometry. The experts henceforth decided to specify measurements subsequently to be performed in non-reflecting or semi-anechoic rooms. For transfer of the alarm sound volume limits a reflecting room with typical acoustical characteristics was assumed.

For legacy devices it is still permissible to provide objective evidence of compliance with the old test:

Compliance is checked with the microphone of a sound level meter complying with the requirements of IEC 61672-1 placed 1,5 m above the floor and 3 m from the front of the infant radiant warmer.

Compliance of the maximum level is checked with each alarm sound means activated, the sound level being measured at a point 5 cm above the centre of the MATTRESS.

Ensure that the background sound pressure level is at least 10 dBA below the measured levels.

In this case auditory ALARM SIGNALS shall have a sound level of at least 65 dBA at a distance of 3 m perpendicular to the front of the INFANT RADIANT WARMER in a reflecting room. The auditory alarm may be adjusted by the OPERATOR to a minimum lower level of 50 dBA.

Add, after the existing subclause 201.15.4.1.101, the following new clause:

Clause 202 – Electromagnetic disturbances – Requirements and tests

Thermal processes in warming therapy devices are mainly slow and the SKIN TEMPERATURE or the temperature of the TEST DEVICES can be too slow to indicate disturbances that are induced by the EMC IMMUNITY tests in adequate time or at all. Hence, it is recommended to monitor not only the SKIN TEMPERATURE but also other technical signals of the device such as sensor or actuator signals in the tests. Those signals can indicate the consequences of electromagnetic emission on the device during immunity tests much faster.

As an example, during the fast transient/burst IMMUNITY tests the heating actuator of the device can be affected by the disturbance immediately while temperature of a TEST DEVICE as being dampened by heat transfer processes can react only with a delay.

Bibliography

Replace the existing references [31] and [32] with the following new references:

[31] IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

[32] IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

Add the following new reference to the end of the Bibliography:

[34] IEC 80601-2-49:2018, *Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*