SLOVENSKI STANDARD
SIST EN IEC 60601-2-21:2021/oprA1:2023

01-januar-2023

Medicinska električna oprema - 2-21. del: Posebne zahteve za osnovno varnost in bistvene lastnosti otroških sevalnih ogrevalnikov - Dopolnilo A1

Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers - Amendment 1

Medizinische elektrische Geräte - Teil 2-21: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglingswärmestrahlern

Amendement 1 - Appareils électromédicaux - Partie 2-21: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs radiants pour nouveau-nés

Ta slovenski standard je istoveten z: **EN IEC 60601-2-21:2021/prA1:2022**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN IEC 60601-2-21:2021/oprA1:2023 **en**

62D/1983/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-21/AMD1 ED3	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2022-11-04	**2023-01-27**
SUPERSEDES DOCUMENTS:	
62D/1873/CD, 62D/1966/CC	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Amendment 1 - Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

PROPOSED STABILITY DATE: 2028

NOTE FROM TC/SC OFFICERS:

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:

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

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 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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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 may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D1808/INF. The review report for this amendment is 62D/1816/RR.

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201.1 Scope, object and related standards

Replace the existing footnote 1 with the following text:

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 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 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 6060-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply. Examples for temperature measurements stipulating applicability of IEC 60601-1-10:2007, IEC 6060-1-10:2007/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 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*
Amendment 1:2012
Amendment 2:2020

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*
Amendment 1:2020

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 first paragraph, the following note:

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

Replace the existing Table 201.101 with:

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 list item q) with:

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 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 test

Replace the entire text with:

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.

A.1 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 the new subclause before the existing subclause 201.1.4:

Subclause 201.1.3 – Collateral standards

Thermoregulation of newborns especially 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:

Former editions of this particular standard specified the alarm sound volume to be measured in a reflecting room as such rooms represent the acoustic situation in an intensive care nursery realistically. 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 prove 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 the new subclause after the existing subclause 201.15.4.1.101:

Subclause 202 – Electromagnetic disturbances – Requirements and test

Thermal processes in warming therapy devices are mainly slow. Therefore, the SKIN TEMPERATURE or the temperature of the TEST DEVICES might 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 consider not only the SKIN TEMPERATURE but also other technical signals of the device such as sensor or actuator signals. Those signals may indicate the impact 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 may be affected by the disturbance immediately while temperature of a TEST DEVICE as being dampened by heat transfer processes may react only with a delay.

Bibliography

Replace the existing list item 32 with:

[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*
Amendment 1:2012
Amendment 2:2020