SLOVENSKI STANDARD
SIST EN IEC 60601-2-19:2021/oprA1:2023

01-januar-2023

Medicinska električna oprema - 2-19. del: Posebne zahteve za osnovno varnost in bistvene lastnosti otroških inkubatorjev - Dopolnilo A1

Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators - Amendment 1

Medizinische elektrische Geräte - Teil 2-19: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglingsinkubatoren

Ta slovenski standard je istoveten z: **EN IEC 60601-2-19:2021/prA1:2022**

ICS:

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

SIST EN IEC 60601-2-19:2021/oprA1:2023 **en**

62D/1984/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-19/AMD1 ED3**	
DATE OF CIRCULATION: **2022-11-04**	CLOSING DATE FOR VOTING: **2023-01-27**
SUPERSEDES DOCUMENTS: **62D/1875/CD, 62D/1968/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 2-19: Particular requirements for the basic safety and essential performance of infant incubators

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
62D/XX/FDIS	62D/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.

_____

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/1818/RR.

_____

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 INCUBATOR 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 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 INCUBATOR is supplied with dedicated physiological monitoring, then IEC 80601-2-49 [15] applies. Measured parameters related to the inherent function of an INFANT INCUBATOR i.e. the SKIN TEMPERATURE, are not considered to be a physiological monitoring unit as per IEC 80601-2-49 [15].

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".

201.3.208
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.

Add, after the existing definition 201.3.212, the following new term and definition:

201.3.213
LOW FREQUENCY ELECTROMAGNETIC FIELDS
ELECTROMAGNETIC FIELDS with a frequency below 400 kHz

201.7.9.2.9 Operating instructions

Add, after the final paragraph of existing list item d), the following text:

e) * a specification of the LOW FREQUENCY ELECTROMAGNETIC FIELD strength of the INFANT INCUBATOR measured as specified below

The LOW FREQUENCY ELECTROMAGNETIC FIELD strength of the INFANT INCUBATOR is measured according to the following procedure:

Calibrated sensors for the electromagnetic magnetic field strength in the range of 10 Hz to 400 kHz shall be placed at the point M (see Figure 201.102) in a plane parallel to and 5 cm above the MATTRESS surface.

The INFANT INCUBATOR is operated as an AIR CONTROLLED INCUBATOR at a CONTROL TEMPERATURE of 36 °C until STEADY TEMPERATURE CONDITION is reached. The LOW FREQUENCY ELECTROMAGNETIC FIELD strength components in the vertical (z) and two perpendicular directions (x and y) are then measured as a temporal average value for ΔT = 10 min for the point M. The scalar product ${}_M\overline{H}$ shall then be calculated as

$$ {}_M\overline{H} = \sqrt{{}_M\overline{H}_x^2 + {}_M\overline{H}_y^2 + {}_M\overline{H}_z^2} $$

from the time-averaged components $\overline{H}_x, \overline{H}_y, \overline{H}_z$

$$ {}_M\overline{H}_n = \frac{1}{\Delta T}\int_{t=0}^{\Delta T} {}_M H'_n \, dt \quad (with\ n = x, y, z) $$

Given the sensor already provides a scalar value of the magnetic field strength calculation of the scalar product is skipped. The scalar product ${}_M\overline{H}$ shall be disclosed in the instructions for use.

201.9.6.2.1.101 * Sound level within the COMPARTMENT

Replace the existing first paragraph with:

In NORMAL USE, the sound level within the COMPARTMENT shall not exceed a sound pressure level of $L_{eq,1h}$ = 55 dB A and $L_{F,max}$ = 75 dB A except as specified in 201.9.6.2.1.103.

201.9.6.2.1.102 * Audible alarm sound level

Replace the existing text of this subclause with:

The auditory 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. For this test, the INFANT INCUBATOR shall be operated at a CONTROL TEMPERATURE of 36°C and at a maximum humidity.*

Add, at the end of the existing subclause 201.11.6.6, the following new subclause:

201.11.7 *Biocompatibility of ME equipment and ME systems

Add after the existing first paragraph the following text:

aa) The COMPARTMENT of an INFANT INCUBATOR shall be evaluated for biocompatibility according to ISO 18562-1:2017.

bb) Those parts of COMPARTMENT which are in direct contact with the INFANT'S skin shall be evaluated for biocompatibility according to ISO 10993-1:2018.

If testing is required compliance is checked by testing under the following conditions:

The INFANT INCUBATOR is operated as an AIR CONTROLLED INCUBATOR at a CONTROL TEMPERATURE of 37 °C and if provided at a humidity level of 80 % relative humidity in STEADY TEMPERATURE CONDITION for 30 days. During this time reprocessing is performed according to and in intervals as specified in the instructions for use.

201.12.1.105 * Accuracy of INCUBATOR TEMPERATURE indication

Replace the existing third paragraph with:

The AVERAGE TEMPERATURE device reading shall not differ from the AVERAGE INCUBATOR TEMPERATURE, measured by a standard thermometer, by more than 0.9 °C, less the standard thermometer error. The standard thermometer shall be accurate within ±0,15 °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 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.

201.12.3.101 * Air circulation fan

Replace, in the second dash of the existing first paragraph, "INCUBATOR COMPARTMENT" with "INFANT INCUBATOR COMPARTMENT".

201.15.4.2.1 Application

Replace the existing first and second paragraph of list item aa) with:

aa) * An AIR CONTROLLED 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 an INCUBATOR TEMPERATURE which does not exceed 40 °C.

Add an asterisk in the first paragraph of item bb):

202 * Electromagnetic disturbances – Requirements and test

Add an asterisk (*) at the beginning of the clause title, and replace the existing text of this clause with:

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

Note 1 to entry: An INFANT INCUBATOR is not considered to be used in a HOME HEALTHCARE ENVIRONMENT.

AA.2 Rationale for particular clauses and subclauses

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 rationale of Subclause 201.1.4, the following new rationale:*

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 surrounding air temperature. 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 INCUBATOR is not considered to be a physiological closed loop controller.

Provided, however, in future applications the temperature control of an INFANT INCUBATOR 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 201.4.3 – ESSENTIAL PERFORMANCE

Replace, in the existing text, "shall" with "needs to".

Replace, in the existing second and third paragraph, "warmer" with "INFANT RADIANT WARMER".

Subclause 201.7.9.2.2 – Warning and safety notices

*Replace, in the existing list item e), "*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*".*

Subclause 201.7.9.2.9 – Operating instructions

Add, after the existing list item d), the following text:

e) LOW FREQUENCY ELECTROMAGNETIC FIELDS may have significant impact on the well-behaviour and the development of an INFANT in an INFANT INCUBATOR. Studies by Belleni et al. suggest that LOW FREQUENCY ELECTROMAGNETIC FIELDS exceeding a certain level can impair the heart frequency variability [16] and melatonin production [17] of INFANTS. The studies reveal that heart frequency variability is noticeably decreased for a field strength higher than 800 nT ($8*10^{-7}$ Tesla = $8*10^{-6}$ Gauss). A sharp threshold where impairment starts, however, cannot be derived from the results of the study. In order to give users of INFANT INCUBATORS a guideline the experts of the working group recommend a value of 1 µT ($1*10^{-6}$ Tesla = $10*10^{-6}$ Gauss) as a threshold for an average LOW FREQUENCY ELECTROMAGNETIC FIELD strength that should not be exceeded for a longer period of time.

A measuring height of 5 cm above the MATTRESS surface instead of 10 cm above it was chosen assuming that LOW FREQUENCY ELECTROMAGNETIC FIELDS rather affects the INFANT's body while INCUBATOR TEMPERATURE (201.12.1.102, 201.12.1.104) or air velocity (201.12.1.111) affect the INFANT's (upper) surface.

Subclause 201.9.6.2.1.102 – Audible alarm sound level

Replace the existing 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 by inspection and measurement of the audible alarm level using a sound level meter, as required in subclause 201.9.6.2.1.101 of this particular standard, placed 1,5 m above the floor and 3 m from the control unit. For this test, the INFANT 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 dBA below that which is measured during the test.

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 control unit in a reflecting room. The auditory alarm may be adjusted by the OPERATOR to a minimum lower level of 50 dBA.

Add, after the rationale of Subclause 201.11.6.6, the following new rationale:

Subclause 201.11.7 – Biocompatibility of ME EQUIPMENT and ME SYSTEMS

Within an INFANT INCUBATOR the parts forming the COMPARTMENT provide a plurality of functions. Besides the main function of warming the INFANT there are several mainly mechanical functions. Among them are safely bearing the INFANT on a MATTRESS that can be tilted and drawn out of the INFANT INCUBATOR. Very often a weighing scale is integrated. In order to provide such mechanical functions, the parts forming the COMPARTMENT need to be mechanically robust. Finally, these parts need to be easily reprocessed. Considering all these requirements restricts the selection of possible materials considerably. As mentioned in ISO 18562-1 during the selection of materials the first consideration should be fitness for purpose which among others comprises their thermal and mechanical properties. In view of the above mentioned limited number of possible materials the RISK MANAGEMENT process may have to conduct a RISK benefit analysis that outweighs the RISK posed by a material in relation to the benefit provided by warming therapy and the related functions.

Following the above a RISK benefit ratio that describes an extension of TOLERABLE EXPOSURE levels in favor of the benefit of warming therapy may be considered. Based on experiences in the design and manufacture of INFANT INCUBATORS the experts consider a RISK benefit ratio of up to 10 as adequate for the application in INFANT INCUBATORS. It must, however, be stated that only very few experiences exist that show to what extent potentially harmful substances are emitted by materials usually used in INFANT INCUBATOR COMPARTMENTS into the breathing gas. The test conditions specified reflect a prolonged exposure time and worst case conditions that can be expected for an INFANT INCUBATOR.

Subclause 201.15.4.2.1 – Application

Replace the existing text of list item aa) with:

aa) Tracheal inspired air with temperatures above 40 °C appear to increase the work of breathing and the incidence of laryngeal spasm. Therefore, the experts consider 40°C an appropriate temperature limit for the air an infant breathes.

An audible alarm for the event of failure of the primary THERMOSTAT and subsequent rise of INCUBATOR TEMPERATURE, is intended to alert personnel to the danger of over-heating the INFANT.

aa), bb) If the thermal cut-out shares resources with the thermostat, such as both being partly implemented in software the independence as required in this subclause yet applies.

Add the new subclause after the existing subclause 201.15.4.2.2.102:

Subclause 202 – Electromagnetic disturbances – Requirements and test

Thermal processes in warming therapy devices are mainly slow. Therefore, the INCUBATOR TEMPERATURE or the SKIN TEMPERATURE 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 INCUBATOR 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 electrical fast transient/burst IMMUNITY tests the heating actuator of the device may be affected by the disturbance immediately while the INCUBATOR TEMPERATURE or the SKIN TEMPERATURE as being dampened by heat transfer processes may react only with a delay.

Bibliography

Add the following to the end of the Bibliography:

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

[16] BELLIENI, CV, ACAMPA, M, MAFFEI, M, MAFFEI, S, PERRONE, S, PINTO, I, STACCHINI, N, BUONOCORE, G. Electromagnetic fields produced by incubators influence heart rate variability in newborns. *Arch Dis Child Fetal Neonatal Ed,* 2008, 93: p.298-301

[17] BELLIENI, CV, TEI, M, IACOPONI, F, TATRANNO, M L, NEGRO, S, PROIETTI, F, LONGINI, M, PERRONE, S, BUONOCORE, G. Is newborn melatonin production influenced by electromagnetic fields produced by incubators? *Early Human Development,* 2012, 88, p. 707-710

Index of defined terms used in this particular standard

Add the following new terms:

ELECTROMAGNETIC COMPATIBILITY (EMC) ..... IEC 60601-1-2:2014, 3.2

HIGH PRIORITY ..... IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 3.22

IMMUNITY ..... IEC 60601-1-2:2014, 3.8

MEDIUM PRIORITY ..... IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 3.28

TOLERABLE EXPOSURE ..... ISO 18562-1:2017, 3.13

Replace the following existing terms with:

BLANKET ..... IEC 60601-2-35:2020, 201.3.201.1 and 201.3.201.2

TOOL ..... IEC 60601-1:2005, 3.127