SLOVENSKI STANDARD
SIST EN IEC 60601-2-20:2020/oprA1:2023

01-januar-2023

Medicinska električna oprema - 2-20. del: Posebne zahteve za osnovno varnost in bistvene lastnosti prenosnih otroških inkubatorjev - Dopolnilo A1

Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators - Amendment 1

Medizinische elektrische Geräte - Teil 2-20: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säglings-Tranportinkubatoren

Appareils électromédicaux - Partie 2-20: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs de transport pour nouveau-nés

Ta slovenski standard je istoveten z: **EN IEC 60601-2-20:2020/prA1:2022**

ICS:

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

SIST EN IEC 60601-2-20:2020/oprA1:2023 **en**

62D/1986/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-20/AMD1 ED3	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2022-11-04	**2023-01-27**
SUPERSEDES DOCUMENTS:	
62D/1874/CD, 62D/1967/CC	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT:	SECRETARY:
United States of America	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 2-20: Particular requirements for the basic safety and essential performance of infant transport 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.

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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/1817/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 an asterisk (*) at the beginning of the subclause title.

*Replace, in the existing second paragraph, "*IEC 60601-1-2:2014*" with "*IEC 60601-1-2:2014 and IEC 60601-1-2/AMD1:2020*" and "*IEC 60601-1-12:2014*" with "*IEC 60601-1-12:2014 and IEC 60601-1-12/AMD1:2020*".*

Add, after the existing second paragraph the following paragraph:

If a BABY CONTROLLED TRANSPORT 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, 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 TRANSPORT INCUBATOR is supplied with dedicated physiological monitoring, then IEC 80601-2-49 [9] applies. Measured parameters related to the inherent function of an INFANT TRANSPORT INCUBATOR i.e. the SKIN TEMPERATURE, are not considered to be a physiological monitoring unit as per IEC 80601-2-49 [9].

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

Addition:

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

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
AVERAGE TRANSPORT INCUBATOR TEMPERATURE
Replace, in the existing first paragraph, "INFANT TRANSPORT INCUBATOR TEMPERATURE" with "TRANSPORT INCUBATOR TEMPERATURE".

201.3.207
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.

201.4.10.102 Capacity of transportable electrical power source

Replace, in the existing third paragraph, "INFANT TRANSPORT INCUBATOR TEMPERATURE" with "TRANSPORT INCUBATOR TEMPERATURE".

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 TRANSPORT INCUBATOR shall be operated at a CONTROL TEMPERATURE of 36°C and at a maximum humidity.*

201.12.1.105 * Accuracy of TRANSPORT INCUBATOR TEMPERATURE indication

Replace the existing third paragraph with:

The AVERAGE TEMPERATURE device reading shall not differ from the AVERAGE TRANSPORT INCUBATOR TEMPERATURE, measured by a standard thermometer, by more than 1.1 °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 TRANSPORT 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.

202 * Electromagnetic disturbances – Requirements and tests

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

Replace the existing first paragraph with

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

202.8.9 IMMUNITY TEST LEVELS

Replace the text of the existing second list item with:

– 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 IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020;

212 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT

*Replace, in the entire clause, the reference "*IEC 60601-1-12:2014*" with "*IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020*"*

Add, after the Clause 212, the following new Subclause:

212.4.1 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

The last paragraph of Subclause 4.1 of IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 does not apply.

Note 1 to entry: The test requirements of the general standard are considered to be appropriate for INFANT TRANSPORT INCUBATORS, but this requirement is under consideration for future application.

Add, after the Clause 212.9, the following new Subclauses:

212.10.1 * Additional requirements for mechanical strength of ME EQUIPMENT intended for the EMS ENVIRONMENT

Subclause 10.1 of IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 does not apply.

Note 1 to entry: The test requirements of this particular standard in Subclause 201.15.3 and of the general standard are considered to be appropriate for INFANT TRANSPORT INCUBATORS, but this Subclause is under consideration for future application.

212.11 *Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

The last paragraph of Clause 11 of IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 does not apply.

Note 1 to entry: The test requirements of the general standard and collateral standard are considered to be appropriate for INFANT TRANSPORT INCUBATORS, but this requirement is under consideration for future application Subclause is under consideration for future mandatory application.

AA.2 Rationale for particular clauses and subclauses

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 TRANSPORT INCUBATOR is not considered to be a physiological closed loop controller.

Provided, however, in future applications the temperature control of an INFANT TRANSPORT 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 201.1.4 – Particular standards

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

See also the rationale for Subclause 201.1.3.

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

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

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 201.9.6.2.1.101, placed 1,5 m above the floor and 3 m from the control unit. For this test, the INFANT TRANSPORT 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.

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 TRANSPORT INCUBATOR TEMPERATURE, is intended to alert personnel to the danger of over-heating the INFANT.

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, after the rationale of Subclause 201.15.4.2.2, the following new rationale:

Subclause 202 – Electromagnetic disturbances – Requirements and test

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

Intended function as specified by the MANUFACTURER means the functional requirements of the ESSENTIAL PERFORMANCE 201.12.1.104 and 201.12.1.106 as provided in Table 201.101.

Subclause 212 – Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT

Replace, in the existing first paragraph, "IEC 60601-1-12:2014" *with* "IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020".

Add, after the existing first paragraph of Subclause 212 the following new rationale:

Subclause 212.4.1 – Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

See rationale to 212.10.1

Add, after the existing Subclause 212.8.1 the following two new rationales:

Subclause 212.10.1 – Additional requirements for mechanical strength of ME EQUIPMENT intended for the EMS ENVIRONMENT

This document deals with INFANT TRANSPORT INCUBATORS, either already available or that will become available in the future. The requirements and test procedures of this document have been developed with the intent to make them applicable to a broad range of present and also future INFANT TRANSPORT INCUBATORS. For new developments application of EUROCAE ED-14G or RTCA DO-160G is strongly recommended. Several years of field application, however, demonstrated that the design requirements stemming from the general standard and the pre-existing version of this particular standard, which were carried over into this standard, were sufficient to provide an acceptable degree of safety and patient treatment.

The flexible approach should ensure that this particular standard is not excessively design restrictive. It is intended not to hinder improved mechanical and electrical safety for use in air ambulances in future development while it requires no extensive redesign for existing products.

Subclause 212.11 – Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

See rationale to 212.10.1

Bibliography

Add the following to the end of the Bibliography:

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

[10] EUROCAE ED-14G, Environmental conditions and test procedures for airborne equipment

[11] RTCA DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment

Index of defined terms used in this particular standard

Add the following new terms:

Replace the following existing terms with: