IEC 60601-2-20

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

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

IEC 60601-2-20:2020-09/AMD1:2023-11(en-fr)

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

AMENDMENT 1

FOREWORD

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Amendment 1 to IEC 60601-2-20:2020 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/2068/FDIS	62D/2086/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- withdrawn, or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.

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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 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/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 60601-1-2:2014/AMD1:2020*" and "*IEC 60601-1-12:2014*" with "*IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020*".*

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

If a BABY CONTROLLED TRANSPORT INCUBATOR is based on a temperature measurement that 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:

IEC 80601-2-49 [9] applies to an INFANT TRANSPORT INCUBATOR supplied with dedicated physiological monitoring. 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*
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

Add, under "Addition:", the following new references:

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

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/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
AVERAGE TRANSPORT INCUBATOR TEMPERATURE

*Replace, in the existing definition, "*INFANT TRANSPORT INCUBATOR TEMPERATURE*" with "*TRANSPORT INCUBATOR TEMPERATURE*".*

201.3.207
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.

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 alarms sound level

Replace the existing text of this subclause with the following new text:

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 following new paragraph:

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 first item of the list with the following:

– 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 first sentence "*IEC 60601-1-12:2014 applies*" with "*IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 apply*".*

Add, after 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 does not apply.

NOTE The test requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are considered to be appropriate for INFANT TRANSPORT INCUBATORS, but this requirement is under consideration for future application.

Add, at the end of 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 does not apply.

NOTE The test requirements of this particular standard in 201.15.3 and of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 does not apply.

NOTE The test requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 are considered to be appropriate for INFANT TRANSPORT INCUBATORS, but this requirement 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

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 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 201.9.6.2.1.102 – Audible alarm sound level

Replace the existing last three paragraphs with the following new text:

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 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 entire text of item aa) with the following new text:

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:

Clause 202 – Electromagnetic disturbances – Requirements and tests

Thermal processes in warming therapy devices are mainly slow and the TRANSPORT INCUBATOR TEMPERATURE or the SKIN TEMPERATURE 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 TRANSPORT INCUBATOR 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 the TRANSPORT INCUBATOR TEMPERATURE or the SKIN TEMPERATURE as being dampened by heat transfer processes can 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 title of this rationale, "Subclause 212" *with* "Clause 212".

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" (2 occurrences).

Add, at the end of the existing text of Subclause 212, the following new rationale:

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

See rationale for 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 document, 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 for 212.10.1.