IEC 60601-2-19

Edition 3.0 2023-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

Appareils électromédicaux –
Partie 2-19: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs pour nouveau-nés

IEC 60601-2-19:2020-09/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

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 300 terminological entries in English and French, with equivalent terms in 19 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, …). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 300 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 19 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

IEC 60601-2-19

Edition 3.0 2023-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

Appareils électromédicaux –
Partie 2-19: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs pour nouveau-nés

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.10

ISBN 978-2-8322-7660-0

INTERNATIONAL ELECTROTECHNICAL COMMISSION

____

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

AMENDMENT 1

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to IEC 60601-2-19:2020 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/2067/FDIS	62D/2092/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/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 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 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 paragraph:

IEC 80601-2-49 [15] applies to an INFANT INCUBATOR supplied with dedicated physiological monitoring. 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*
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 the following new references under "Addition":

ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process*

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 definition, the following note to entry:

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 last item of the existing list, the following new 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 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 ${}_M\bar{H}$ shall then be calculated as

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

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

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

Given the sensor already provides a scalar value of the magnetic field strength, calculation of the scalar product is skipped. The scalar product ${}_M\bar{H}$ 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 the following new paragraph:

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 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 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

Addition to the first paragraph:

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

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

201.12.1.105 * Accuracy of INCUBATOR TEMPERATURE indication

Replace the existing third paragraph with the following new paragraph:

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.

201.15.4.2.1 Application

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

aa) * An AIR CONTROLLED INCUBATOR shall be equipped with a THERMAL CUT-OUT that 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 that does not exceed 40 °C.

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

202 Electromagnetic disturbances – Requirements and tests

Add an asterisk (*) at the beginning of the clause title, and replace the existing text of this clause, including 202.8.9, with:

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

NOTE 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 201.4.3, 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 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 second and third paragraph, "*warmer*" with "*INFANT RADIANT WARMER*" (2 occurrences).*

Subclause 201.7.9.2.9 – Operating instructions

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

e) LOW FREQUENCY ELECTROMAGNETIC FIELDS can have significant effect on the well-being and the development of an INFANT in an INFANT INCUBATOR. Studies by Bellieni 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^{-3} 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^{-2} 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 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 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.