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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

FOREWORD	3
INTRODUCTION	6
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions	9
201.4 General requirements	12
201.5 General requirements for testing ME EQUIPMENT	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	14
201.7 ME EQUIPMENT identification, marking and documents	14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	16
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	17
201.10 Protection against unwanted and excessive radiation HAZARDS	20
201.11 Protection against excessive temperatures and other HAZARDS	20
201.12 Accuracy of controls and instruments and protection against hazardous outputs	21
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	28
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	28
201.15 Construction of ME EQUIPMENT	29
201.16 ME SYSTEMS	31
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	31
202 Electromagnetic compatibility disturbances – Requirements and tests	31
210 – Requirements for the development of physiologic closed-loop controllers	31
212 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT	32
Annexes	34
Annex AA (informative) Particular guidance and rationale	35
Bibliography	46
Index of defined terms used in this particular standard	47
Figure 201.101 – Variation of INCUBATOR TEMPERATURE	10
Figure 201.102 – Positioning of air temperature sensors	11
Figure 201.103 – Layout of weight test devices	25
Figure AA.1 – Illustration of the main requirements of this document	35
Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements	13

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators**

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 provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 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) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

International standard IEC 60601-2-20 has been prepared by IEC Subcommittee 62D Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2009 and Amendment 1:2016. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: re-dating of normative references.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62D/1763/FDIS	62D/1773/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type*;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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 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 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

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT TRANSPORT INCUBATOR equipment.

This particular standard amends and supplements IEC 60601-1:~~2005~~, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the "general standard".

The requirements are followed by specifications for the relevant tests.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT TRANSPORT INCUBATOR equipment, as defined in 201.3.244208, also referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document, except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard specifies safety requirements for INFANT TRANSPORT INCUBATORS, but alternate methods of compliance with a specific clause, by demonstrating equivalent safety, will not be judged as non-compliant, if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISK presented by the HAZARD has been found to be of an acceptable level when weighed against the benefit of treatment from the device.

This particular standard does not apply to:

- devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information, see ~~IEC 80601-2-35~~ IEC 60601-2-35 [1]²;
- INFANT INCUBATORS which are not INFANT TRANSPORT INCUBATOR; for information see IEC 60601-2-19 [2];
- INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [3];
- INFANT PHOTOTHERAPY; for information, see IEC 60601-2-50 [4].

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT TRANSPORT INCUBATORS as defined in 201.3.244208,

¹ The general standard is IEC 60601-1 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

² Figures between square brackets refer to the Bibliography.

which minimize HAZARDS to the PATIENT and OPERATOR, and to specify tests by which compliance with the requirements can be verified.

201.1.3—* Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014 and ~~IEC 60601-1-10~~ IEC 60601-1-12:2014 apply as modified in Clauses 202 and ~~210 respectively~~ 212. IEC 60601-1-3 and IEC 60601-1-10 ~~does~~ not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 * Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 and IEC 60601-1:2005/AMD1:2012 ~~is~~ are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through ~~3.139~~ 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED TRANSPORT INCUBATOR including the displayed value are not considered to be a CLINICAL THERMOMETER in the sense of the particular standard ISO 80601-2-56.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows:

Amendment:

~~IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests~~

Addition:

~~IEC 60601-1-10:2007, Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers~~

IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1:2005/AMD1:2012

ISO 32, Gas cylinders for medical use – Marking for identification of content

ISO 407, Small medical gas cylinders – Pin-index yoke-type valve connections

Replacement:

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

INTERNATIONAL STANDARD

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

CONTENTS

FOREWORD	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references.....	9
201.3 Terms and definitions.....	9
201.4 General requirements	11
201.5 General requirements for testing ME EQUIPMENT	13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	13
201.7 ME EQUIPMENT identification, marking and documents	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	15
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	15
201.10 Protection against unwanted and excessive radiation HAZARDS	18
201.11 Protection against excessive temperatures and other HAZARDS	18
201.12 Accuracy of controls and instruments and protection against hazardous outputs	20
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	26
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	27
201.15 Construction of ME EQUIPMENT	27
201.16 ME SYSTEMS	29
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	29
202 Electromagnetic disturbances – Requirements and tests.....	29
212 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT	29
212.5 * Classification of ME EQUIPMENT and ME SYSTEMS.....	30
212.7 * Protection against electrical HAZARDS from ME EQUIPMENT	30
212.9 Accuracy of controls and instruments and protection against hazardous outputs	30
Annexes	31
Annex AA (informative) Particular guidance and rationale	32
Bibliography.....	42
Index of defined terms used in this particular standard.....	43
Figure 201.101 – Variation of INCUBATOR TEMPERATURE	10
Figure 201.102 – Positioning of air temperature sensors.....	11
Figure 201.103 – Layout of weight test devices.....	24
Figure AA.1 – Illustration of the main requirements of this document	32
Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements.....	12

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- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT TRANSPORT INCUBATOR equipment.

This particular standard amends and supplements IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the "general standard".

The requirements are followed by specifications for the relevant tests.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT TRANSPORT INCUBATOR equipment, as defined in 201.3.208, also referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document, except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard specifies safety requirements for INFANT TRANSPORT INCUBATORS, but alternate methods of compliance with a specific clause, by demonstrating equivalent safety, will not be judged as non-compliant, if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISK presented by the HAZARD has been found to be of an acceptable level when weighed against the benefit of treatment from the device.

This particular standard does not apply to:

- devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information, see IEC 60601-2-35 [1]²;
- INFANT INCUBATORS which are not INFANT TRANSPORT INCUBATOR; for information see IEC 60601-2-19 [2];
- INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [3];
- INFANT PHOTOTHERAPY; for information, see IEC 60601-2-50 [4].

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT TRANSPORT INCUBATORS as defined in 201.3.208, which minimize HAZARDS to the PATIENT and OPERATOR, and to specify tests by which compliance with the requirements can be verified.

¹ The general standard is IEC 60601-1 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

² Figures between square brackets refer to the Bibliography.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014 and IEC 60601-1-12:2014 apply as modified in Clauses 202 and 212. IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 * Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

SKIN TEMPERATURE SENSORS which are applied to operate a BABY CONTROLLED TRANSPORT INCUBATOR including the displayed value are not considered to be a CLINICAL THERMOMETER in the sense of the particular standard ISO 80601-2-56.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

ISO 32, *Gas cylinders for medical use – Marking for identification of content*

ISO 407, *Small medical gas cylinders – Pin-index yoke-type valve connections*

Replacement:

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*

SOMMAIRE

AVANT-PROPOS	47
INTRODUCTION.....	50
201.1 Domaine d'application, objet et normes connexes	51
201.2 Références normatives	53
201.3 Termes et définitions	53
201.4 Exigences générales.....	56
201.5 Exigences générales relatives aux essais des APPAREILS EM	57
201.6 Classification des APPAREILS EM et des SYSTEMES EM	58
201.7 Identification, marquage et documentation des APPAREILS EM	58
201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM	60
201.9 Protection contre les DANGERS MECANQUES des APPAREILS EM et des SYSTEMES EM.....	60
201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs.....	64
201.11 Protection contre les températures excessives et les autres DANGERS.....	64
201.12 Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques.....	65
201.13 SITUATIONS DANGEREUSES et conditions de défaut pour l'EQUIPEMENT EM	73
201.14 SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP).....	73
201.15 Construction de l'APPAREIL EM	73
201.16 SYSTEMES EM	76
201.17 Compatibilité électromagnétique des appareils EM et des SYSTEMES EM.....	76
202 Perturbations électromagnétiques – Exigences et essai	76
212 * Exigences pour les appareils électromédicaux et les systèmes électromédicaux destinés à être utilisés dans l'environnement des services médicaux d'urgence	76
212.5 * Classification des APPAREILS EM et des SYSTEMES EM	76
212.7 * Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM	77
212.9 Précision des commandes et des instruments et protection contre les sorties dangereuses	77
Annexes	78
Annexe AA (informative) Guide particulier et justifications	79
Bibliographie.....	90
Index des termes définis utilisés dans la présente norme particulière	91
Figure 201.101 – Variation de la TEMPERATURE DE L'INCUBATEUR.....	54
Figure 201.102 – Position des capteurs de la température de l'air	55
Figure 201.103 – Implantation des dispositifs d'essai de poids	70
Figure AA.1 – Représentation graphique des principales exigences du présent document.....	79
Tableau 201.101 – Exigences de PERFORMANCES ESSENTIELLES supplémentaires	56

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

APPAREILS ÉLECTROMÉDICAUX –

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

AVANT-PROPOS

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- 8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
- 9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

La Norme internationale IEC 60601-2-20 a été établie par le sous-comité 62D: Appareils électromédicaux, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale.

Cette troisième édition annule et remplace la deuxième édition parue en 2009 et l'Amendement 1:2016. Cette édition constitue une révision technique.

Cette édition inclut la modification technique majeure suivante par rapport à l'édition précédente: nouvelle datation des références normatives.

La présente version bilingue (2021-07) correspond à la version anglaise monolingue publiée en 2020-09.

La version française de cette norme n'a pas été soumise au vote.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

- exigences et définitions: caractères romains;
- *modalités d'essais: caractères italiques*;
- indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;
- TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DE LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme:

- "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
- "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot " Article " suivi du numéro de l'article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

- "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité au présent document;
- "il convient" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité au présent document;
- "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d'un alinéa ou d'un titre de tableau, il indique l'existence d'un guide ou d'une justification applicable à cet élément à consulter à l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général: *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "<http://webstore.iec.ch>" dans les données relatives du document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

NOTE L'attention des utilisateurs du présent document est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

INTRODUCTION

Les exigences minimales de sécurité spécifiées dans la présente norme particulière sont considérées comme assurant un degré pratique de sécurité dans le fonctionnement des INCUBATEURS DE TRANSPORT POUR NOUVEAU-NÉS.

La présente norme particulière modifie et complète l'IEC 60601-1, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*, appelée "norme générale" dans la suite du texte.

Les exigences sont suivies de spécifications relatives aux essais correspondants.

Une recommandation générale et une justification relatives aux exigences de la présente norme particulière sont indiquées à l'Annexe AA. Il est considéré que la connaissance des raisons qui ont conduit à énoncer ces exigences non seulement facilite l'application correcte de la présente norme particulière, mais accélérera en son temps toute révision rendue nécessaire du fait de modifications dans la pratique clinique ou d'évolutions technologiques. Cependant, l'Annexe AA ne fait pas partie des exigences du présent document.

APPAREILS ÉLECTROMÉDICAUX –

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

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale¹ s'applique, avec les exceptions suivantes:

201.1.1 Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des INCUBATEURS DE TRANSPORT POUR NOUVEAU-NES, tels que définis au 201.3.208, également désignés sous le terme APPAREILS EM.

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des APPAREILS EM ou des SYSTEMES EM dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception de 7.2.13 et de 8.4.1 de la norme générale.

NOTE Voir aussi 4.2 de la norme générale.

La présente norme particulière spécifie les exigences de sécurité relatives aux INCUBATEURS DE TRANSPORT POUR NOUVEAU-NES, mais des méthodes alternatives de conformité à un article spécifique, en démontrant un niveau équivalent de sécurité, ne sont pas considérées comme non conformes, si le FABRICANT a démontré dans son DOSSIER DE GESTION DES RISQUES que le RISQUE présenté par le DANGER s'est révélé avoir un niveau acceptable, lorsqu'il a été évalué par rapport aux avantages du traitement présentés par le dispositif.

La présente norme particulière ne s'applique pas aux:

- dispositifs délivrant de la chaleur par l'intermédiaire de COUVERTURES, COUSSINS ou MATELAS en usage médical; voir l'IEC 60601-2-35 [1]² à titre informatif;
- INCUBATEURS POUR NOUVEAU-NES qui ne sont pas des INCUBATEURS DE TRANSPORT POUR NOUVEAU-NES; voir l'IEC 60601-2-19 [2] à titre informatif;
- INCUBATEURS RADIANTS POUR NOUVEAU-NES, voir l'IEC 60601-2-21 [3] à titre informatif;
- APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES, voir l'IEC 60601-2-50 [4] à titre informatif.

¹ La norme générale est l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*.

² Les chiffres entre crochets se réfèrent à la Bibliographie.

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des INCUBATEURS DE TRANSPORT POUR NOUVEAU-NES définis au 201.3.208, qui réduisent le plus possible les dangers vis-à-vis du PATIENT et de l'OPERATEUR, et de spécifier des essais qui permettent de vérifier la conformité aux exigences.

201.1.3 Normes collatérales

Addition:

La présente norme particulière fait référence aux normes collatérales applicables énumérées à l'Article 2 de la norme générale et à l'Article 201.2 de la présente norme particulière.

L'IEC 60601-1-2:2014 et l'IEC 60601-1-12:2014 s'appliquent telles que modifiées dans les Articles 202 et 212. L'IEC 60601-1-3 et l'IEC 60601-1-10 ne s'appliquent pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles que publiées.

201.1.4 * Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales en fonction de ce qui est approprié à l'APPAREIL EM considéré, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, dans la présente norme particulière, le terme "norme générale" désigne l'IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012. Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple 201.1 dans le présent document aborde le contenu de l'Article 1 de la norme générale) ou à celle de la norme collatérale applicable avec le préfixe "20x", où x est le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale et des normes collatérales applicables sont spécifiées en utilisant les termes suivants:

"Remplacement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"Addition" signifie que le texte de la présente norme particulière vient s'ajouter aux exigences de la norme générale ou de la norme collatérale applicable.

"Amendement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme cela est indiqué par le texte de la présente norme particulière.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées 3.1 à 3.147, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires sont nommées AA, BB, etc., et les points supplémentaires aa), bb), etc.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière, considérées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

Les CAPTEURS DE TEMPERATURE CUTANEE appliqués au fonctionnement d'un INCUBATEUR DE TRANSPORT A REGULATION CUTANEE incluant la valeur affichée ne sont pas considérés comme un THERMOMETRE MEDICAL au sens de la norme particulière ISO 80601-2-56.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la Bibliographie.

L'Article 2 de la norme générale s'applique, avec les exceptions suivantes:

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012

ISO 32, *Bouteilles à gaz pour usages médicaux – Marquage pour l'identification du contenu*

ISO 407, *Petites bouteilles à gaz médicaux – Raccords de robinets du type à étrier avec ergots de sécurité*

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-20: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*