

# SLOVENSKI STANDARD

## SIST EN IEC 60601-2-20:2020

01-december-2020

### Nadomešča:

SIST EN 60601-2-20:2010

SIST EN 60601-2-20:2010/A1:2017

SIST EN 60601-2-20:2010/A11:2012

---

**Medicinska električna oprema - 2-20. del: Posebne zahteve za osnovno varnost in bistvene lastnosti prenosnih otroških inkubatorjev (IEC 60601-2-20:2020)**

Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators (IEC 60601-2-20:2020)

Medizinische elektrische Geräte - Teil 2-20: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Transportinkubatoren (IEC 60601-2-20:2020)

<https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-4cb94ca87fb5/sist-en-iec-60601-2-20-2020>

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)

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

### **ICS:**

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

**SIST EN IEC 60601-2-20:2020**

**en**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN IEC 60601-2-20:2020

<https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-4cb94ca87fb5/sist-en-iec-60601-2-20-2020>

EUROPEAN STANDARD

**EN IEC 60601-2-20**

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2020

ICS 11.040.10

Supersedes EN 60601-2-20:2009 and all of its  
amendments and corrigenda (if any)

English Version

**Medical electrical equipment - Part 2-20: Particular requirements  
for the basic safety and essential performance of infant transport  
incubators  
(IEC 60601-2-20:2020)**

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)

Medizinische elektrische Geräte - Teil 2-20: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von Transportinkubatoren  
(IEC 60601-2-20:2020)

This European Standard was approved by CENELEC on 2020-10-07. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

**EN IEC 60601-2-20:2020 (E)****European foreword**

The text of document 62D/1763/FDIS, future edition 3 of IEC 60601-2-20, prepared by SC 62D “Electromedical equipment” of IEC/TC 62 “Electrical equipment in medical practice” was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-20:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2021-07-07 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2023-10-07 document have to be withdrawn

This document supersedes EN 60601-2-20:2009 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

**Endorsement notice**

The text of the International Standard IEC 60601-2-20:2020 was approved by CENELEC as a European Standard without any modification.

**(standards.iteh.ai)**

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

[SIST EN IEC 60601-2-20:2020](https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-444f187281a1/iec-60601-2-20-2020)

[https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-](https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-444f187281a1/iec-60601-2-20-2020)

IEC 60601-2-19:2020 NOTE Harmonized as EN IEC 60601-2-19:2020 (not modified)

IEC 60601-2-50 NOTE Harmonized as EN 60601-2-50

IEC 61672-1 NOTE Harmonized as EN 61672-1

ISO 80601-2-56 NOTE Harmonized as EN ISO 80601-2-56

IEC 60601-1-10 NOTE Harmonized as EN 60601-1-10

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cenelec.eu](http://www.cenelec.eu).

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Annex ZA of EN 60601-1:2006 applies, except as follows:</i>				
<i>Addition:</i>				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar. 2010	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
ISO 32	-	Gas cylinders for medical use; Marking for identification of content	-	-
ISO 407	-		-	-
<i>Replace:</i>				
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	EN 60601-1-2	2015

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN IEC 60601-2-20:2020

<https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-4cb94ca87fb5/sist-en-iec-60601-2-20-2020>



IEC 60601-2-20

Edition 3.0 2020-09

# INTERNATIONAL STANDARD

---

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

**STANDARD PREVIEW**  
**(standards.iteh.ai)**  
SIST EN IEC 60601-2-20:2020  
<https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-4cb94ca87fb5/sist-en-iec-60601-2-20-2020>

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

---

ICS 11.040.10

ISBN 978-2-8322-8647-0

**Warning! Make sure that you obtained this publication from an authorized distributor.**

## 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



## 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.

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.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN IEC 60601-2-20:2020](https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-4cb94ca87fb5/sist-en-iec-60601-2-20-2020)

<https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-4cb94ca87fb5/sist-en-iec-60601-2-20-2020>

## 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.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN IEC 60601-2-20:2020](https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-4cb94ca87fb5/sist-en-iec-60601-2-20-2020)

<https://standards.iteh.ai/catalog/standards/sist/cee90a66-a00c-456e-b149-4cb94ca87fb5/sist-en-iec-60601-2-20-2020>

## 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 standard<sup>1</sup> 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]<sup>2</sup>;
- 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.

<sup>1</sup> 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*.

<sup>2</sup> 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*

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

NOTE An index of defined terms is found beginning on page 43.

*Addition:*

### 201.3.201

#### AIR CONTROLLED TRANSPORT INCUBATOR

INCUBATOR in which the air temperature is automatically controlled by an air temperature sensor close to a value set by the OPERATOR

### 201.3.202

#### AVERAGE TEMPERATURE

average of temperature readings taken at regular intervals at any specified point in the COMPARTMENT achieved during STEADY TEMPERATURE CONDITION