SLOVENSKI STANDARD
SIST EN 60601-2-20:2010

01-januar-2010

Nadomeġļ a:
SIST EN 60601-2-20:1998

Medicinska elektriļ na oprema - 2-20. del: Posebne zahteve za osnovno varnost in bistvene lastnosti prenosnih inkubatorjev (IEC 60601-2-20:2009)

Medical electrical equipment - Part 2-20: Particular requirements for basic safety and essential performance of transport incubators (IEC 60601-2-20:2009)

Medizinische elektrische Geräte - Teil 2-20: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Transportinkubatoren (IEC 60601 -2-20:2009)

Appareils électromédicaux - Partie 2-20: Règles particulières de sécurité de base et de performances essentielles des incubateurs de transport (CEI 60601-2-20:2009)

Ta slovenski standard je istoveten z: **EN 60601-2-20:2009**

ICS:

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

SIST EN 60601-2-20:2010 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-20

November 2009

ICS 11.040.10

Supersedes EN 60601-2-20:1996

English version

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

(IEC 60601-2-20:2009)

Appareils électromédicaux - Partie 2-20: Exigences particulières pour la sécurité de base et les performances essentielles des incubateurs de transport pour nouveau-nés (CEI 60601-2-20:2009)

Medizinische elektrische Geräte - Teil 2-20: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Tranportinkubatoren (IEC 60601-2-20:2009)

This European Standard was approved by CENELEC on 2009-09-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-20:2009 E

Foreword

The text of document 62D/731/FDIS, future edition 2 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 was approved by CENELEC as EN 60601-2-20 on 2009-09-01.

This European Standard supersedes EN 60601-2-20:1996.

EN 60601-2-20:1996 was revised to structurally align with EN 60601-1:2006.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2010-06-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-09-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, 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 standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

− “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

− “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

− “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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-20:2009 was approved by CENELEC as a European Standard without any modification.

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

IEC 80601-2-35	NOTE	Harmonized as EN 80601-2-35:2009 (not modified).
IEC 60601-2-19	NOTE	Harmonized as EN 60601-2-19:2009 (not modified).
IEC 60601-2-21	NOTE	Harmonized as EN 60601-2-21:2009 (not modified).
IEC 60601-2-50	NOTE	Harmonized as EN 60601-2-50:2009 (not modified).
IEC 61672-1	NOTE	Harmonized as EN 61672-1:2003 (not modified).
ISO 21647	NOTE	Harmonized as EN ISO 21647:2009 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace *the reference to IEC 60601-1-2 by:*				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
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	EN 60601-1-10	2008
ISO 32	-[1)]	Gas cylinders for medical use - Marking for identification of content	-	-
ISO 407	-[1)]	Small medical gas cylinders - Pin-index yoke-type valve connections	-	-

[1)] Undated reference.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

_____

IEC 60601-2-20

Edition 2.0 2009-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX X

ICS 11.040.10

ISBN 2-8318-1030-0

CONTENTS

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 second edition cancels and replaces the first edition of IEC 60601-2-20 published in 1990 and its Amendment 1 (1996). This edition constitutes a technical revision. This edition of IEC 60601-2-20 was revised to structurally align with the 2005 edition of IEC 60601-1.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/731/FDIS	62D/757/RVD

Full information on the voting for the approval of this particular 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 standard, 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 standard, 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 standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– "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 publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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, this annex does not form part of the requirements of this standard.