SLOVENSKI STANDARD

SIST EN 60601-2-21:1995/A1:1998

prva izdaja
september 1998

Medical electrical equipment - Part 2: Particular requirements for the safety of infant radiant warmers - Amendment A1 (IEC 60601-2-21:1994/A1:1996)

ICS 11.040.60

Referenčna številka
SIST EN 60601-2-21:1995/A1:1998(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-21/A1

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UDC 615.84:615.478.5:614.8
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Descriptors: Medical electrical equipment, warmer, radiant warmer, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of infant radiant warmers
(IEC 601-2-21:1994/A1:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des incubateurs radiants pour nouveaux-nés
(CEI 601-2-21:1994/A1:1996)

Medische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Säuglingswärmestrahler
(IEC 601-2-21:1994/A1:1996)

This amendment A1 modifies the European Standard EN 60601-2-21:1994; it was approved by CENELEC on 1996-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/195/FDIS, future amendment 1 to IEC 601-2-21:1994, 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 amendment A1 to EN 60601-2-21:1994 on 1996-10-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1997-07-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1998-06-13

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annex AA is informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of amendment 1:1996 to the International Standard IEC 601-2-21:1994 was approved by CENELEC as an amendment to the European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Addition to (replacement in) annex ZA of EN 60601-1:1990/A2:1995:				
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2 A13	1995 1996
IEC 601-1-1	1992	1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 601-1-3	1994	3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	EN 60601-1-3	1994
IEC 601-1-4	1996	4. Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
IEC 651	1979	Sound level meters	EN 60651	1994
ISO 3743	1988	Acoustics - Determination of sound power levels of noise sources - Engineering methods for special reverberation test rooms	-	-
ISO 7767	1988	Oxygen analysers for monitoring patient breathing mixtures - Safety requirements	-	-

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
601-2-21

1994

AMENDEMENT 1
AMENDMENT 1

1996-10

Amendement 1

Appareils électromédicaux –

Partie 2:
Règles particulières de sécurité pour les incubateurs radiants pour nouveaux-nés

Amendment 1

Medical electrical equipment –

Part 2:
Particular requirements for the safety of infant radiant warmers

Bureau central de la Commission Electrotechnique Internationale 3, rue de Varembé Genève Suisse

IEC
Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/195/FDIS	62D/219/RVD

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

Page 9

INTRODUCTION

Replace the first paragraph by the following:

This Particular Standard concerns the safety of INFANT RADIANT WARMERS. It amends and supplements IEC 601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements of safety*, with its amendments 1 (1991) and 2 (1995).

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SECTION ONE

1 Scope and object

1.1 *Scope*

Replace the text of this subclause by the following:

Addition:

This Particular Standard applies to INFANT RADIANT WARMERS as defined in 2.2.101.

1.3 *Particular Standards*

Replace the first paragraph by the following:

With this amendment to the Particular Standard for INFANT RADIANT WARMERS the following documents are to be taken into consideration

IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, with its amendments 1 (1991) and 2 (1995).

1.5 *Collateral Standards*

Add the following new text:

The following Collateral Standards apply:

IEC 601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral standard: Safety requirements for medical electrical systems*

IEC 601-1-2: 1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 601-1-3: 1994, *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 601-1-4: 1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

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2 Terminology and definitions

2.1.5 *APPLIED PART*

Replace the text of this subclause by the following:

The definition of IEC 601-1 (see amendment 2) applies.

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3 General requirements

Add the following new subclause:

3.101 For EQUIPMENT which combines alternative heat sources, for instance incubators with integrated radiant warmers, heated mattresses, etc., the safety requirements of the Particular Standards for these alternative heat sources, if any, shall be met. The safety requirements of this Particular Standard shall not be altered by such additional heat sources specified by the manufacturer, details of which are provided in the instruction for use.

Compliance is checked by the test of clauses 42 and 56.6 of the relevant standards.

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6 Identification, marking and documents

6.8 *ACCOMPANYING DOCUMENTS*

6.8.2 *Instructions for use*

aa) Add, on page 19, a new item as follows:

20. details of any specified combinations of EQUIPMENT (see 3.101)