SLOVENSKI STANDARD
SIST EN 60601-2-21:1995

01-maj-1995

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

Medical electrical equipment -- Part 2: Particular requirements for the safety of infant radiant warmers

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von Säuglingswärmestrahlern

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité des incubateurs radiants pour nouveaux-nés

Ta slovenski standard je istoveten z: **EN 60601-2-21:1994**

ICS:

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

SIST EN 60601-2-21:1995 **en**

EUROPEAN STANDARD

NORME EUROPEENNE

EUROPÄISCHE NORM

EN 60601-2-21

August 1994

ICS 11.040.60

Descriptors: Medical electrical equipment, warmer, radiant warmer, safety requirements, equipment specifications, equipment protection, test

ENGLISH VERSION

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

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des incubateurs radiants pour nouveaux-nés

(CEI 601-2-21:1994)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Säuglingswärmestrahler
(IEC 601-2-21:1994)

This European Standard was approved by CENELEC on 1994-07-05. 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, 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(CO)71, as prepared by Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in July 1992.

The reference document was approved by CENELEC as EN 60601-2-21 on 5 July 1994.

The following dates were fixed:

- latest date of publication of an identical national standard	(dop)	1995-07-01
- latest date of withdrawal of conflicting national standards	(dow)	1995-07-01

For products which have complied with the relevant national standard before 1995-07-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-07-01.

Annexes designated "normative" are part of the body of the standard. Annexes designated "informative" are given only for information. In this standard, annexes AA and BB are informative and annex ZA is normative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-2-21:1994 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT 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.

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

IEC Publication	Date	Title	EN/HD	Date
Addition to annex ZA of EN 60601-1:1990/A11:1993:				
651	1979	Sound level meters	EN 60651	1994

Other publication:

ISO 3743:1988 - Acoustics - Determination of sound power levels of noise sources Engineering methods for special reverberation test rooms

NORME INTERNATIONALE
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601-2-21

Première édition
First edition
1994-02

Appareils électromédicaux

Partie 2:
Règles particulières de sécurité des incubateurs radiants pour nouveau-nés

Medical electrical equipment

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

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. 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. The 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 the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

International Standard IEC 601-2-21 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

DIS	Report on voting
62D(CO)71	62D(CO)74

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.

Annexes AA and BB are for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– notes, explanations, advice, instructions, general statements, exceptions and references: in smaller type;

– *test specifications: in italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 601-1: SMALL CAPITALS.

INTRODUCTION

This Particular International Standard amends and supplements IEC 601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety,* as amended by its amendment 1 (1991), hereinafter referred to as the General Standard (see 1.3).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the 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.

MEDICAL ELECTRICAL EQUIPMENT

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

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 *Scope*

Replacement:

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

Requirements for INFANT RADIANT WARMERS intended for use outside a hospital baby care environment, INFANT RADIANT WARMERS having a heated mattress, and INFANT RADIANT WARMERS powered by an INTERNAL ELECTRICAL POWER SOURCE are not included in this Particular Standard.

1.2 *Object*

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of INFANT RADIANT WARMERS as defined in 2.2.101.

1.3 *Particular Standards*

Addition:

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991).

For brevity, Part 1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General 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.