SLOVENSKI STANDARD

SIST EN 60601-2-19:1998/A1:1998

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Medical electrical equipment - Part 2: Particular requirements for the safety of baby incubators - Amendment A1 (IEC 60601-2-19:1990/A1:1996)

ICS 11.040.10

Referenčna številka
SIST EN 60601-2-19:1998/A1:1998(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 60601-2-19/A1

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Descriptors: Medical electrical equipment, incubator, baby incubator, 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 baby incubators
(IEC 601-2-19:1990/A1:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des incubateurs pour bébés
(CEI 601-2-19:1990/A1:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Säuglingsinkubatoren
(IEC 601-2-19:1990/A1:1996)

This amendment A1 modifies the European Standard EN 60601-2-19:1996; 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/193/FDIS, future amendment 1 to IEC 601-2-19:1990, 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 60601-2-19:1996 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) 1997-09-01
- 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 annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of amendment 1:1996 to the International Standard IEC 601-2-19:1990 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 601-2-20	1990	Part 2: Particular requirements for safety of transport incubators	EN 60601-2-20	1996
IEC 651	1979	Sound level meters	EN 60651	1994
ISO 7767	1988	Oxygen analysers for monitoring patient breathing mixtures - Safety requirements	-	-

Annex ZB (informative)

Normative references to international publications with their corresponding European publications

Publication	Année	Titre	EN/HD	Année
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
ISO 3743	1988	Acoustics - Determination of sound power levels of noise sources - Engineering methods for special reverberation test rooms	-	-

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
601-2-19

1990

AMENDEMENT 1
AMENDMENT 1

1996-10

Amendement 1

Appareils électromédicaux –

Partie 2: Règles particulières de sécurité des incubateurs pour bébés

Amendment 1

Medical electrical equipment –

Part 2: Particular requirements for safety of baby incubators

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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/193/FDIS	62D/216/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 baby incubators. It amends and supplements IEC 601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety.*

SECTION ONE

1 Scope and object

1.1 *Scope*

Replace the text of this subclause by the following:

Addition:

This Particular Standard specifies safety requirements for INCUBATORS, as defined in 2.1.101 of this standard.

This standard does not apply to transport incubators used for the transportation of babies (see IEC 601-2-20).

Page 11

1.3 *Particular Standards*

Add the following new text:

With this amendment to the Particular Standard for baby INCUBATORS the following documents are to be taken into consideration:

IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

The requirements of this Particular Standard take priority over the above-mentioned standard and its amendments, hereinafter referred to as the General Standard.

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: 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*

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.

2.1.101 *INCUBATOR*

Replace the text of this subclause by the following:

An EQUIPMENT having a BABY COMPARTMENT which is provided with the means to control the environment of the baby primarily by heated air within the BABY COMPARTMENT.

2.1.102 *BABY COMPARTMENT*

Replace the text of this subclause by the following:

An environmentally-controlled enclosure intended to contain a baby and with transparent section(s) which allows for viewing of the baby.

2.1.104 *BABY CONTROLLED INCUBATOR*

Replace "air controlled" by "AIR CONTROLLED".

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2.9.103 *AVERAGE TEMPERATURE*

Replace the text of this subclause by the following:

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

2.9.105 *INCUBATOR TEMPERATURE*

Replace "baby compartment" by "BABY COMPARTMENT"

2.9.106 *AVERAGE INCUBATOR TEMPERATURE*

Replace the text of this subclause by the following:

The average of the INCUBATOR TEMPERATURE readings taken at regular intervals achieved during STEADY TEMPERATURE CONDITION (see figure 101).

3 General requirements

Add the 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.

Page 15

6 Identification, marking and documents

6.1 *Marking on the outside of EQUIPMENT or EQUIPMENT parts*

6.1.101* *Replace the existing text of this subclause by the following:*

An INCUBATOR not equipped with an integral oxygen analyzer and which provides means for oxygen administration shall be marked in a prominent position with a text which states: "Use an oxygen monitor when oxygen is administered".

6.8 *ACCOMPANYING DOCUMENTS*

6.8.2 *Instructions for use*

aa) Add, on page 17, the new items as follows:

10 The manufacturer shall provide details of any specified combinations of EQUIPMENT (see 3.101).

11 The manufacturer shall state the maximum CO_2 level measured under the conditions of 105.1.

Page 17

SECTION TWO

10 Special environmental conditions

10.2.1 *Environment*

Add the following new text:

Addition:

aa) An ambient air velocity less than 0,3 m/s.

Page 19

SECTION THREE

20 Dielectric strength

20.2 *Requirements for EQUIPMENT with an APPLIED PART*

Replace the text of this subclause by the following:

Item B-b

Amendment:

This is not applicable to INCUBATORS.

20.3 *Values of test voltages*

Addition:

The reference voltage for the insulation B-d shall be a minimum of 250 V.

The test voltage for the insulation B-e shall be a minimum of 1500 V.

SECTION FOUR

21 Mechanical strength

21.6* *Add, to item b), the following paragraph:*

Following the above tests, the INCUBATOR shall be suitable for further NORMAL USE. Mechanical and structural integrity of the INCUBATOR shall be verified; for example latches and doors shall remain closed and ancillary equipment supplied by or available from the manufacturer shall remain secure.