SLOVENSKI STANDARD

SIST EN 60601-2-20:1998

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Medical electrical equipment - Part 2: Particular requirements for the safety of transport incubators (IEC 60601-2-20:1990 + A1:1996)

ICS 11.040.10

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Descriptors: Medical electrical equipment, incubator, transport 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 transport incubators
(IEC 601-2-20:1990 + A1:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des incubateurs de transport
(CEI 601-2-20:1990 + A1:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Transportinkubatoren
(IEC 601-2-20:1990 + A1:1996)

This European Standard 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 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 the International Standard IEC 601-2-20:1990, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 395.2.20 S1 on 1992-03-24.

This Harmonization Document was submitted to the formal vote for conversion into a European Standard and was approved by CENELEC as EN 60601-2-20 on 1996-10-01.

The text of document 62D/194/FDIS, future amendment 1 to IEC 60601-2-20:1990, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC for inclusion in EN 60601-2-20 on 1996-10-01.

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) 1997-06-01
- latest date by which the national standards conflicting with the EN 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 the International Standard IEC 601-2-20:1990 + A1:1996 was approved by CENELEC as a 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 601-2-19	1990	Part 2: Particular requirements for the safety of baby incubators	EN 60601-2-19	1996
IEC 651	1979	Sound level meters	EN 60651	1994
ISO 32	1977	Gas cylinders for medical use - Marking for identification of content	-	-
ISO 407	1991	Small medical gas cylinders - Pin-index yoke-type valve connections	-	-
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	Year	Title	EN/HD	Year
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 601-2-20

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Appareils électromédicaux

Deuxième partie:
Règles particulières de sécurité des incubateurs de transport

Medical electrical equipment

Part 2:
Particular requirements for safety of transport incubators

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

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
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FOREWORD

1) 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.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This Particular Standard has been prepared by Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

The text of this Standard is based upon the following documents:

Six Months' Rule	Report on Voting	Two Months' Procedure	Report on Voting
62D(CO)44	62D(CO)53	62D(CO)55	62D(CO)62

Full information on the voting for the approval of this Standard can be found in the Voting Reports indicated in the above table.

The following IEC publications are quoted in this Standard:

Publications Nos. 601-1 (1977): Safety of medical electrical equipment. Part 1: General requirements.
601-1 (1988): Medical electrical equipment. Part 1: General requirements for safety.
601-2-19 (1990): Medical electrical equipment. Part 2: Particular requirements for safety of baby incubators.

651 (1979): Sound level meters.

Other publications:

ISO 32 (1977): Gas cylinders for medical use – Marking for identification of content.
ISO 407 (1983): Small medical gas cylinders – Yoke-type valve connections – Amendment 1986.

ISO 3743 (1988): Acoustics – Determination of sound power levels of noise sources – Engineering methods for special reverberation test rooms.
ISO 7767 (1988): Oxygen analyzers for monitoring patient breathing mixtures – Safety requirements.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for safety of transport incubators

INTRODUCTION

This Particular Standard concerns the safety of transport incubators. It amends and supplements IEC Publication 601-1 (first edition 1977): Safety of medical electrical equipment, Part 1: General requirements, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard. The title of the General Standard has been changed in the second edition (1988) to read: "Medical electrical equipment, Part 1: General requirements for safety". This change is anticipated in the title of this Particular Standard.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The numbering of sections, clauses and sub-clauses of this Particular Standard corresponds with that of the General Standard.

Sub-clauses or figures which are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc., and additional items *aa), bb),* etc.

In this standard, the following print types are used:

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

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

– *test specifications: in italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Appendix AA. 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 appendix does not form part of the requirements of this standard. The sub-clauses which have corresponding rationale statements are marked with an * after their number.

SECTION ONE – GENERAL

1. **Scope and object**

This clause of the General Standard applies except as follows:

1.1 *Scope*

Addition:

This Particular Standard specifies safety requirements for TRANSPORT INCUBATORS, as defined in Sub-clauses 2.1.101, 2.1.103 and 2.1.104 of this standard.

This standard does not apply to EQUIPMENT which uses radiant heaters.*

See also requirements concerning BABY INCUBATORS.**

1.2 *Object*

Addition:

The object of this Particular Standard is to establish requirements for TRANSPORT INCUBATORS, which minimize hazards to PATIENT and USER, and to specify tests by which compliance with the requirements can be verified.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Replacement:

All parts within the BABY COMPARTMENT, which can intentionally or unintentionally come into contact with the baby shall be considered as APPLIED PARTS.

Additional definitions:

2.1.101 *TRANSPORT INCUBATOR*

An enclosure intended to contain a baby and having transparent section(s) which allow(s) for viewing of the baby, provided with means to control the environment of the baby primarily by heated air within the enclosure, and suitable for the safe conveyance of a baby.

2.1.102 *BABY COMPARTMENT*

The portion of a TRANSPORT INCUBATOR intended to contain a baby.

2.1.103 *AIR CONTROLLED TRANSPORT INCUBATOR*

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

2.1.104 *BABY CONTROLLED TRANSPORT INCUBATOR*

An air controlled TRANSPORT INCUBATOR which has the additional capability of automatically controlling the INCUBATOR air temperature in order to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR close to a value set by the USER.

2.9.101 *SKIN TEMPERATURE SENSOR*

A sensing device intended to measure the baby's skin temperature.

2.9.102 *SKIN TEMPERATURE*

The temperature of the skin of the baby at a point on which the SKIN TEMPERATURE SENSOR is placed.

* IEC 601-2-21.

** IEC 601-2-19.

2.9.103 *AVERAGE TEMPERATURE*

The average of the maximum and minimum temperatures at any specified point in the BABY COMPARTMENT achieved during STEADY TEMPERATURE CONDITION.

2.9.104 *CONTROL TEMPERATURE*

Temperature selected at the temperature control.

2.9.105 *TRANSPORT INCUBATOR TEMPERATURE*

Temperature of the air at a point 10 cm above the centre of the mattress surface in the BABY COMPARTMENT (see figure 102, point A).

2.9.106 *AVERAGE TRANSPORT INCUBATOR TEMPERATURE*

The average of the maximum and minimum TRANSPORT INCUBATOR TEMPERATURES achieved during STEADY TEMPERATURE CONDITION (see figure 101).

2.10.101 *STEADY TEMPERATURE CONDITION*

The condition reached when the TRANSPORT INCUBATOR TEMPERATURE does not vary by more than 2 °C over a period of one hour (see figure 101).

3. General requirements

This clause of the General Standard applies except as follows:

3.6* *Addition:*

Applicable SINGLE FAULT CONDITIONS are short and open circuiting of components or wiring, which

- cause sparks to occur, or
- increase the energy of sparks, or
- increase temperatures.

4. General requirements for tests

This clause of the General Standard applies except as follows:

4.5 *Ambient temperature, humidity and atmospheric pressure*

Replacement:

a) * If not otherwise specified in this Particular Standard, all tests shall be carried out at an ambient temperature within the range of 21 °C to 25 °C.

4.6 *Other conditions*

Additional item:

aa) If not otherwise specified, the CONTROL TEMPERATURE shall be 36 °C and shall always exceed the ambient temperature by at least 3 °C.

5. Classification

This clause of the General Standard applies.