SLOVENSKI STANDARD
SIST HD 395.2.20 S1:1995

01-maj-1995

Medical electrical equipment - Part 2: Particular requirements for safety of transport incubators (IEC 601-2-20:1990)

Medical electrical equipment -- Part 2: Particular requirements for safety of transport incubators

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

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité des incubateurs de transport

Ta slovenski standard je istoveten z: **HD 395.2.20 S1:1992**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

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HARMONIZATION DOCUMENT

DOCUMENT D'HARMONISATION

HARMONISIERUNGSDOKUMENT

HD 395.2.20 S1

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Descriptors: Medical electrical equipment, incubator, transport incubator, safety, protection against electric shocks, protection against radiation, constructional requirements, terminology, tests

ENGLISH VERSION

MEDICAL ELECTRICAL EQUIPMENT
PART 2: PARTICULAR REQUIREMENTS FOR SAFETY OF TRANSPORT INCUBATORS
(IEC 601-2-20:1990)

Appareils électromédicaux
Deuxième partie: Règles particulières de sécurité des incubateurs de transport

(CEI 601-2-20:1990)

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

(IEC 601-2-20:1990)

This Harmonization Document was approved by CENELEC on 1992-03-24. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for implementation of this Harmonization Document on a national level.

Up-to-date lists and bibliographical references concerning national implementation may be obtained on application to the Central Secretariat or to any CENELEC member.

This Harmonization Document exists in three official versions (English, French, German).

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

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FOREWORD

At the request of the CENELEC Technical Committee TC 62, Electrical equipment in medical practice, the International Standard IEC 601-2-20:1990 was submitted to the CENELEC Unique Acceptance Procedure (UAP) in July 1991 for acceptance as a Harmonization Document.

The text of the reference document was approved by CENELEC as HD 395.2.20 S1 on 24 March 1992.

The following dates were fixed:

- latest date of announcement of the HD at national level	(doa)	1992-09-01
- latest date of publication of a harmonized national standard	(dop)	1993-03-01
- latest date of withdrawal of conflicting national standards	(dow)	1993-03-01

For products which have complied with the relevant national standard before 1993-03-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1998-03-01.

ENDORSEMENT NOTICE

The text of the International Standard 601-2-20:1990 was approved by CENELEC as a Harmonization Document without any modification.

ANNEX ZA (normative)

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

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
601-1	1977	Safety of medical electrical equipment Part 1: General requirements	HD 395.1 S1	1979
601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
601-2-19	1990	Part 2: Particular requirements for safety of baby incubators	HD 395.2.19 S1	1992
651	1979	Sound level meters	HD 425 S1	1983

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

NORME INTERNATIONALE
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Première édition
First edition
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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

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Commission Électrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE V

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for safety of transport incubators

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.

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* IEC 601-2-21.

** IEC 601-2-19.