



SLOVENSKI STANDARD
SIST HD 395.2.19 S1:1995

01-maj-1995

Medical electrical equipment - Part 2: Particular requirements for safety of baby incubators (IEC 601-2-19:1990)

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

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

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

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Ta slovenski standard je istoveten z: HD 395.2.19 S1:1992

ICS:

11.040.60 Terapevtska oprema Therapy equipment

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HARMONIZATION DOCUMENT

HD 395.2.19 S1

DOCUMENT D'HARMONISATION

HARMONISIERUNGSDOKUMENT

April 1992

UDC 615.478.5:618.39:616-053.3:614.8

Descriptors: Medical electrical equipment, incubator, baby 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 BABY INCUBATORS
(IEC 601-2-19:1990)

Appareils électromédicaux
Deuxième partie: Règles
particulières de sécurité des
incubateurs pour bébés

(CEI 601-2-19:1990)

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

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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

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

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Ref. No. HD 395.2.19 S1:1992 E

FOREWORD

At the request of CENELEC Technical Committee TC 62, Electrical equipment in medical practice, the International Standard IEC 601-2-19:1990 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 395.2.19 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.

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ENDORSEMENT NOTICE

The text of the International Standard 601-2-19:1990 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
601-2-20	1990	Part 2: Particular requirements for safety of transport incubators	HD 395.2.20 S1	1992
651	1979	Sound level meters	HD 425 S1	1983

Other publications

- 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

<https://standards.iteh.ai/catalog/standards/sist/4ffc30eb-08dc-444a-bb15-88dd47d2e9bd/sist-hd-395-2-19-s1-1995>

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Appareils électromédicaux

Deuxième partie:
Règles particulières de sécurité des
incubateurs pour bébés

Medical electrical equipment

iTeh STANDARD PREVIEW

Part 2:

Particular requirements for safety of
baby incubators

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for safety of baby 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
62D(CO)38	62D(CO)43

Full information on the voting for the approval of this Standard can be found in the Voting Report 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.
 601-2-20 (1990): Medical electrical equipment. Part 2: Particular requirements for safety of transport incubators.
 651 (1979): Sound level meters.

Other publications:

- 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 baby incubators

INTRODUCTION

This Particular Standard concerns the safety of baby 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 INCUBATORS, as defined in Sub-clause 2.1.101 of this standard.

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

It also does not apply to transport incubators* used for the transportation of infants.

1.2 Object

Addition:

The object of this Particular Standard is to establish requirements for 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 an APPLIED PART.

Additional definitions:

2.1.101 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.

2.1.102 BABY COMPARTMENT

The portion of an INCUBATOR intended to contain a baby.

2.1.103 AIR CONTROLLED INCUBATOR

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 INCUBATOR

An air controlled 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 Controls and limiting devices

Additional definitions:

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.

* For these, see IEC 601-2-20.