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

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

Appareils électromédicaux
Partie 2: 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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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of the International Standard IEC 601-2-19:1990, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 395.2.19 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 60601-2-19 on 1996-10-01.

The following date was 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) 1997-09-01

Endorsement notice

The text of the International Standard IEC 601-2-1990 was approved by CENELEC as a European Standard without any modification.

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Appareils électromédicaux

Deuxième partie:
Règles particulières de sécurité des incubateurs pour bébés

Medical electrical equipment

Part 2:
Particular requirements for safety of baby incubators

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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
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 Subclause 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.

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 *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 INCUBATOR TEMPERATURE*

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

2.10 *Operation of EQUIPMENT*

Additional definition:

2.10.101 *STEADY TEMPERATURE CONDITION*

The condition reached when the INCUBATOR TEMPERATURE does not vary by more than 1 °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 26 °C.

4.6 *Other conditions*

Additional item:

aa) If not otherwise specified the CONTROL TEMPERATURE shall be 34 °C ± 1 °C and shall always exceed the ambient temperature by at least 3 °C.

5. Classification

This clause of the General Standard applies.

6. Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 *Addition:*

6.1.101 * 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: "An oxygen analyzer should be used when oxygen is administered".

6.1.102 If a heater is accessible without the use of a tool a notice or marking shall be displayed adjacent to the heater giving warning of high surface temperature.

6.3 *Addition:*

b) * Temperature controls shall be clearly marked with temperature settings on or adjacent to the control. The markings shall be provided at intervals of not greater than 0.5 °C for AIR CONTROLLED INCUBATORS and not greater than 0.25 °C for BABY CONTROLLED INCUBATORS.

Marking of the maximum and the minimum values of controls and indicators shall be such that no confusion can arise with regard to the position of the control and/or the indicated values.

6.7 *Addition:*

a) An INCUBATOR shall be equipped with a yellow light according to Sub-clause 54.101 when applicable.

6.8 *ACCOMPANYING DOCUMENTS*

6.8.2 *Instructions for use*

Addition:

aa) The instructions for use shall additionally contain:

– A recommended preventive maintenance procedure and frequency for verifying conformity with product specifications.

*1. A statement that an INCUBATOR should be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known risks and benefits of INCUBATOR use.

*2. A warning that direct sunlight or other radiant heat sources can cause an increase in INCUBATOR temperature to dangerous levels.

*3. A statement that the use of oxygen increases the danger of fire and that auxiliary equipment producing sparks shall not be placed in the INCUBATOR.

*4. A warning that even small quantities of flammable agents, such as ether and alcohol, left in the INCUBATOR can cause fire in connection with oxygen.

*5. A specification of the warm-up time of the INCUBATOR measured as specified in Sub-clause 50.108.