

BRITISH STANDARD

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60601-2-21 :
1995
BS 5724 :
Section 2.121 :
1995
IEC 601-2-21 :
1994**

Medical electrical equipment

Part 2. Particular requirements for safety —

Specification for infant radiant warmers

The European Standard EN 60601-2-21 : 1994 has the status of a British Standard

Cooperating organizations

The European Committee for Electrotechnical Standardization (CENELEC), under whose supervision this European Standard was prepared, comprises the national committees of the following countries:

Austria	Italy
Belgium	Luxembourg
Denmark	Netherlands
Finland	Norway
France	Portugal
Germany	Spain
Greece	Sweden
Iceland	Switzerland
Ireland	United Kingdom

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 April 1995

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National foreword

This British Standard has been prepared under the direction of the Health and Environment Sector Board. It is the English language version of EN 60601-2-21 : 1994 *Medical electrical equipment — Part 2: Particular requirements for the safety of infant radiant warmers*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-21 : 1994, published by the International Electrotechnical Commission (IEC). This British Standard supersedes BS 5724 : Section 2.25 : 1988 which is withdrawn.

This Particular Standard amends and supplements BS EN 60601-1¹⁾ hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of this Particular Standard take precedence over those of the General Standard.

A rationale for the most important requirements is given in annex AA. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This annex does not form part of the requirements of the standard.

Additional information. The following print types are used in this standard.

Requirements, compliance with which can be tested, and definitions: in roman type.

Explanations, advice and general statements: in small roman type.

Test procedures: *in italic type*.

Terms defined in clause 2 of the General Standard: in SMALL CAPITALS.

NOTE. *Typographical error.* In figure 102, 'maltress' should read 'mattress'.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

¹⁾ Also numbered BS 5724 : Part 1.

ICS 11.040.60

Descriptors: Medical electrical equipment, warmer, radiant warmer, safety requirements, equipment specifications, equipment protection, test

English version

Medical electrical equipment Part 2: Particular requirements for the safety of infant radiant warmers

(IEC 601-2-21 : 1994)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des
incubateurs radiants pour nouveaux-nés
(CEI 601-2-21 : 1994)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von Säuglingswärmestrahler
(IEC 601-2-21 : 1994)

This European Standard was approved by CENELEC on 1994-07-05. 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 document 62D(CO)71, as prepared by Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in July 1992.

The reference document was approved by CENELEC as EN 60601-2-21 on 5 July 1994.

The following dates were fixed:

- latest date of publication
of an identical national
standard (dop) 1995-07-01
- latest date of withdrawal
of conflicting national
standards (dow) 1995-07-01

For products which have complied with the relevant national standard before 1995-07-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-07-01.

Annexes designated 'normative' are part of the body of the standard. Annexes designated 'informative' are given only for information. In this standard, annexes AA and BB are informative and annex ZA is normative.

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MEDICAL ELECTRICAL EQUIPMENT
Part 2: Particular requirements for the safety
of infant radiant warmers

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Replacement:

This Particular Standard applies to INFANT RADIANT WARMERS as defined in 2.2.101.

Requirements for INFANT RADIANT WARMERS intended for use outside a hospital baby care environment, INFANT RADIANT WARMERS having a heated mattress, and INFANT RADIANT WARMERS powered by an INTERNAL ELECTRICAL POWER SOURCE are not included in this Particular Standard.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of INFANT RADIANT WARMERS as defined in 2.2.101.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991).

For brevity, Part 1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa*), *bb*), etc.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; 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 requirements of this Particular Standard take priority over those of the General Standard.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Replacement:

All parts of the RADIANT WARMER accessible to the infant.

Additional definitions:

2.1.101 SKIN TEMPERATURE SENSOR

A sensing device including the link with the EQUIPMENT intended to measure the infant's skin temperature.

2.1.102 TEST DEVICE

A totally mat blackened disc used as a reproducible receiver of radiant energy during testing of the INFANT RADIANT WARMER. (See figure 101.)

2.1.103* TEST LOAD

An array of five TEST DEVICES used in a specified configuration (see figure 102) for performance tests of the INFANT RADIANT WARMER.

2.2 EQUIPMENT types (classification)

Additional definition:

2.2.101 INFANT RADIANT WARMER (hereinafter referred to as EQUIPMENT)

An electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant PATIENT by direct radiation of energy in the infra-red region of the electromagnetic spectrum.

* Rationale, see annex AA.

2.10 Operation of EQUIPMENT

Addition:

2.10.101 STEADY TEMPERATURE CONDITION

A condition which is reached when the temperature, measured at the centre of the TEST DEVICE positioned on the mid point of the EQUIPMENT mattress, does not vary by more than 1 °C over a period of 1 h.

2.10.102 TEST DEVICE AVERAGE TEMPERATURE (T_1 , T_2 , T_3 , T_4 or T_M)

The average temperature reading taken during a STEADY TEMPERATURE CONDITION at regular intervals at the centre of a TEST DEVICE.

2.10.103 MID POINT AVERAGE TEMPERATURE (T_M)

The TEST DEVICE AVERAGE TEMPERATURE of the TEST DEVICE positioned at the mid point of the EQUIPMENT mattress. (See figure 102.)

2.10.104 CONTROL TEMPERATURE

The temperature set at the temperature control.

2.10.105 MANUAL MODE

A mode of operation in which the heater output is either at a fixed level or a proportion of its maximum output set by the USER.

2.10.106 BABY CONTROLLED MODE

A mode of operation in which the power output varies automatically in response to the temperature of the baby, to achieve a temperature close to a value set by the USER.

3 General requirements

This clause of the General Standard applies except as follows:

3.6* SINGLE FAULT CONDITIONS

Additional items:

- aa) failure of a SKIN TEMPERATURE SENSOR;
- bb) disconnection of a SKIN TEMPERATURE SENSOR from the EQUIPMENT;
- cc) failure of the heater control circuit.

* Rationale, see annex AA.