

Medical electrical equipment —

Part 2: Particular requirements for safety — Specification for infant radiant warmers

The European Standard EN 60601-2-21:1994 with the incorporation of amendment A1:1996 has the status of a British Standard

ICS 11.040.60

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/91, Incubators, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of Manufacturers of Domestic Electrical Appliances
- British Anaesthetic and Respiratory Equipment Manufacturers Association
- British Surgical Trades Association
- Department of Health
- Institution of Physics and Engineering in Medicine and Biology
- Royal College of Midwives
- Royal College of Paediatrics and Child Health

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 June 1997

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Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Text of EN 60601-2-21	5
List of references	Inside back cover

National foreword

This British Standard has been prepared by Technical Committee CH/91. 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*, including amendment A1:1996 published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-21:1994, including amendment 1:1996, published by the International Electrotechnical Commission (IEC). This British Standard supersedes BS EN 60601-2-21:1995, which is withdrawn.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”.

Cross-references

Publication referred to	Corresponding British Standard
	BS 5724 <i>Medical electrical equipment</i>
EN 60601-1:1990 (IEC 601-1:1988)	Part 1:1989 <i>General requirements for safety</i>
	BS EN 60601 <i>Medical electrical equipment</i> Part 1 <i>General requirements for safety</i>
EN 60601-1-1:1993 (IEC 601-1-1:1992)	Section 1.1:1993 <i>Collateral standard. Safety requirements for medical electrical systems</i>
EN 60601-1-2:1993 (IEC 601-1-2:1993)	Section 1.2:1993 <i>Collateral standard. Electromagnetic compatibility. Requirements and tests</i>
EN 60601-1-3:1994 (IEC 601-1-3:1994)	Section 1.3:1995 <i>Collateral standard. General requirements for radiation protection in diagnostic X-ray equipment</i>
EN 60601-1-4:1996 (IEC 601-1-4:1994)	Section 1.4:1997 <i>Collateral standard. Programmable electrical medical systems</i>
EN 60651:1993 (IEC 651:1979)	BS EN 60651:1994 <i>Specification for sound level meters</i>
ISO 3743:1988	BS ISO 3743:1994 <i>Acoustics. Determination of sound power levels of noise sources. Engineering methods for small, movable sources in reverberant fields</i>

¹⁾ Also numbered BS 5724-1

Publication referred to	Corresponding British Standard
ISO 7767:1988	BS 5724 <i>Medical electrical equipment</i> Part 2 <i>Particular requirements for safety</i> Section 2.27:1993 <i>Specification for oxygen analysers for monitoring patient breathing mixtures</i>

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 22, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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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

(including amendment A1:1996)

(IEC 601-2-21:1994 + A1:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des
incubateurs radiants pour nouveaux-nés
(inclut l'amendement A1:1996)
(CEI 601-2-21:1994 + A1:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von Säuglingswärmestrahler
(enthält Änderung A1:1996)
(IEC 601-2-21:1994 + A1:1996)

This European Standard was approved by CENELEC on 1994-07-05; amendment A1 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.

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CENELEC

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

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Ref. No. EN 60601-2-21:1994 + A1:1996 E

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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, Annex AA and Annex BB are informative and Annex ZA is normative.

Foreword to amendment A1

The text of document 62D/195/FDIS, future amendment 1 to IEC 601-2-21:1994, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-2-21:1994 on 1996-10-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1997-07-01
- latest date by which the national standards conflicting with the amendment 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 Annex AA is informative.

Annex ZA has been added by CENELEC.

Contents

	Page	Page
Foreword	2	Annex BB (informative) Bibliography 21
Section 1. General		Annex ZA (normative) Other international publications quoted in this standard with the references of the relevant European publication 22
1 Scope and object	5	Figure 101 — Test device 14
2 Terminology and definitions	5	Figure 102 — Layout of test devices 15
3 General requirements	6	Figure 103 — Illustration of the main requirements 15
4 General requirements for tests	6	
6 Identification, marking and documents	7	
Section 2. Environmental conditions		
10 Environmental conditions	8	
Section 3. Protection against electric shock hazards		
20 Dielectric strength	8	
Section 4. Protection against mechanical hazards		
21 Mechanical strength	8	
24 Stability in NORMAL USE	8	
Section 5. Protection against hazards from unwanted or excessive radiation		
33 Infra-red radiation	9	
Section 6. Protection against hazards of ignition of flammable anaesthetic mixtures		
Section 7. Protection against excessive temperatures and other safety hazards		
42 Excessive temperatures	9	
43 Fire prevention	9	
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	10	
46 Human errors	10	
49 Interruption of the power supply	11	
Section 8. Accuracy of operating data and protection against hazardous output		
50 Accuracy of operating data	11	
Section 9. Abnormal operation and fault conditions; environmental tests		
Section 10. Constructional requirements		
54 General	12	
56 Components and general assembly	12	
Section 101. Additional requirements		
101 Alarms	13	
102 Sound pressure level	13	
Appendix L References — Publications mentioned in this standard	16	
Annex AA (informative) General guidance and rationale	17	