

BS 5724 :
Section 2.119 :
1991
IEC 601-2-19 :
1990

Medical electrical equipment

Part 2. Particular requirements for safety

**Section 2.119 Specification for baby
incubators**

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/91, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of British Paediatric Nurses
- Biological Engineering Society
- British Anaesthetic and Respiratory Equipment Manufacturer's Association
- British Paediatric Association
- Department of Health
- Electromedical Trade Association Limited
- Institute of Physical Sciences in Medicine (IPSM)
- Ministry of Defence
- Royal College of Midwives

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 28 June 1991

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Amd. No.	Date	Text affected

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Medical electrical equipment
Part 2. Particular requirements for safety
Section 2.119 Specification for baby incubators

NOTE. This amendment implements CENELEC HD 395.2.19.S1.

Revised text

AMD 7319
December 1992

Front cover

Immediately below the title of Section 2.119, insert the following.

'(Implementation of CENELEC HD 395.2.19.S1)'.

AMD 7319
December 1992

Contents

Immediately after the reference to appendix AA insert the following text.

'**ZA** Other international publications quoted in this standard with the references of the relevant European publications.'

AMD 7319
December 1992

National foreword

At the end of paragraph 1 insert the following text.

'This Section of BS 5724 also implements Harmonization Document HD 395.2.19.S1, which was published by the European Committee for Electrotechnical Standardization (CENELEC) on 24 March 1992. There are no CENELEC modifications in HD 395.2.19.S1.

Annex ZA to HD 395.2.19.S1, which is normative, is appended to this Particular Standard.'

AMD 7319
December 1992

New annex page

Immediately after appendix AA insert the attached new annex ZA.

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

Contents

	Page
Committees responsible	Inside front cover
National foreword	iii
Introduction	1
Section one. General	
1 Scope and object	1
2 Terminology and definitions	2
3 General requirements	3
4 General requirements for tests	3
5 Classification	3
6 Identification, marking and documents	4
7 Power input	5
Section two. Safety requirements	
10 Special environmental conditions	5
11 Special measures with respect to safety	5
Section three. Protection against electric shock hazards	
20 Dielectric strength	6
Section four. Protection against mechanical hazards	
21 Mechanical strength	6
22 Moving parts	7
23 Surfaces, corners and edges	7
24 Stability and transportability	7
Section five. Protection against hazards from unwanted or excessive radiation	
Section six. Protection against hazards of explosions in medically used rooms	
Section seven. Protection against excessive temperatures, fire and other hazards, such as human errors	
42 Excessive temperatures	9
43 Fire prevention	10
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	11
45 Pressure vessels and parts subject to pressure	12
46 Human errors	12
49 Interruption of the power supply	12
Section eight. Accuracy of operating data and protection against incorrect output	
50 Accuracy of operating data	12
Section nine. Fault conditions causing overheating and/or mechanical damage; environmental tests	
Section ten. Constructional requirements	
54 General	15
55 Enclosures and covers	15
56 Components and general assembly	15

	Page
Section eleven. Additional requirements	
101 Alarms	17
102 Sound pressure level	18
103 Humidifying unit	19
104 Maximum air velocity in the enclosure	19
105 Concentration of carbon dioxide (CO ₂)	19
Appendix	
AA Rationale	22

National foreword

This revision of this Section of BS 5724 has been prepared under the direction of the Health Care Standards Policy Committee. It supersedes BS 5724 : Section 2.20 : 1982 which is withdrawn, the numbering system has been amended to maintain alignment with the IEC numbering system. It is identical with IEC Publication 601-2-19 'Medical electrical equipment' Part 2 'Particular requirements for safety of baby incubators', published in 1990 by the International Electrotechnical Commission (IEC). This Particular Standard amends and supplements BS 5724 : Part 1 : 1979 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.

As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc. and additional items are lettered aa), bb), etc. The changes from the text of the General Standard are specified by the use of the following words.

'Replacement' means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.

'Amendment' means that the clause, subclause or specified paragraph of the General Standard is amended as indicated by the text of this standard.

'Addition' means that the text of this standard is additional to the requirements of the General Standard.

A rationale for the most important requirements is given in appendix 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 appendix does not form part of the standard.

BS 5724 : Part 1 : 1979 has now been revised and this Particular Standard will be revised in due course to refer to the new edition, BS 5724 : Part 1 : 1989. BS 5724 : Part 1 : 1979 is expected to remain in effect until at least 1991.

Cross-references

International standard	Corresponding British Standard
IEC 601-1 : 1977	BS 5724 Medical electrical equipment Part 1 : 1979 Specification for general safety requirements (Technically equivalent)
IEC 601-1 : 1988	Part 1 : 1989 General requirements for safety (Identical)
IEC 601-2-20 : 1990	Part 2 Particular requirements for safety Section 2.120 : 1991 Specification for transport incubators (Identical)
IEC 651 : 1979	BS 5969 : 1981 Specification for sound level meters (Identical)

International standard	Corresponding British Standard
ISO 3743 : 1988	BS 4196 Sound power levels of noise sources Part 3 : 1981 Engineering methods for determination of sound power levels for sources in special reverberation test rooms (Identical)
ISO 7767 : 1988	BS 5724 Medical electrical equipment Part 2 Particular requirements for safety Section 2.27 : 1989 Specification for oxygen analyzers for monitoring patient breathing mixtures (Identical)

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

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.