

Medical electrical equipment —

Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment

**BS EN
60601-2-23:
1998
BS 5724-2.123:
1996
IEC
60601-2-23:
1993**

*Incorporating
Amendment No. 1 to
BS 5724:
Section 2.123:1996
(renumbers BS as
BS EN
60601-2-23:1998)*

The European Standard EN 60601-2-23:1997 has the status of a
British Standard

ICS 11.040.50

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

BSI
Documents

AVA

Document Sharing Hub

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/96, Patient monitoring, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-care Industries
- Department of Health
- Electro Medical Trade Association Limited
- Institute of Hospital Engineering
- Institution of Physics and Engineering in Medicine and Biology
- Royal College of Physicians of London

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 August 1996

© BSI 05-1999

The following BSI references relate to the work on this standard:
Committee reference CH/96
Draft for comment 88/52004 DC

ISBN 0 580 25948 X

Amendments issued since publication

Amd. No.	Date	Comments
10042	June 1998	Renumbers the BS as BS EN 60601-2-23:1998

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Introduction	3
Section 1. General	
1 Scope and object	3
2 Terminology and definitions	4
3 General requirements	4
4 General requirements for tests	4
5 Classification	4
6 Identification, marking and documents	4
Section 2. Environmental conditions	
Section 3. Protection against electric shock hazards	
14 Requirements related to classification	5
17 Separation	5
19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	5
20 Dielectric strength	6
Section 4. Protection against mechanical hazards	
21 Mechanical strength	6
Section 5. Protection against hazards from unwanted or excessive radiation	
Section 6. Protection against the hazards of ignition of flammable anaesthetic mixtures	
Section 7. Protection against excessive temperatures and other safety hazards	
42 Excessive temperatures	6
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	7
Section 8. Accuracy of operating data and protection against hazardous output	
Section 9. Abnormal operation and fault conditions, environmental tests	
Section 10. Constructional requirements	
56 Components and general assembly	7
57 MAINS PARTS, components and layout	7
Appendix D (normative) Symbols on marking	12
Annex AA (informative) General guidance and rationale	13
Figure 101 — Test for protection against defibrillator discharge	8
Figure 102 — Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of CLASS I EQUIPMENT, caused by an external voltage on a FUNCTIONAL EARTH TERMINAL	9
Figure 103 — Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of INTERNALLY POWERED EQUIPMENT caused by an external voltage on a FUNCTIONAL EARTH TERMINAL	10
Figure 104 — Foam block test	11
List of references	Inside back cover

National foreword

This British Standard has been prepared by Technical Committee CH/96. It is the English language version of EN 60601-2-23:1997, *Medical electrical equipment. Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment*, published by the European committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 60601-2-23:1993, published by the International Electrotechnical Commission (IEC).

This Particular Standard amends and supplements BS 5724-1 (EN 60601-1:1990) 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 is informative only and does not form part of the requirements of the standard.

References to IEC page numbers should be ignored.

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

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

Test procedures: *in italic type*.

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

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

From 1 January 1997, all IEC publications have the number 60000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

Cross-reference

Publication referred to	Corresponding British Standard
IEC 60601-1:1988	BS 5724 <i>Medical electrical equipment Part 1:1989</i> <i>General requirements for safety</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 and ii, the EN title page, pages 2 to 16, 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.

ICS 11.040.50

Descriptors: Medical electrical equipment, transcutaneous partial pressure monitoring equipment, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment

(IEC 60601-2-23:1993)

Appareils électromédicaux Partie 2: Règles
particulières de sécurité pour les appareils de
surveillance de la pression partielle
transcutané
(CEI 60601-2-23:1993)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von Geräten für die transkutane
Partialdrucküberwachung
(IEC 60601-2-23:1993)

This European Standard was approved by CENELEC on 1997-10-01. 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.

CENELEC members are the national standards bodies of Austria, Belgium, Czech Republic, 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

© 1997 CENELEC — All rights of exploitation in any form and by any means reserved worldwide for CENELEC members.

Foreword

The text of the International Standard IEC 60601-2-23:1993, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-23 on 1997-10-01 without any modification.

The following dates were 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) 1998-09-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-09-01

Endorsement notice

The text of the International Standard IEC 60601-2-23:1993 was approved by CENELEC as a European Standard without any modification.

Section 1. General

Introduction

This Particular International Standard amends and supplements IEC 601-1 (second edition, 1988): *Medical electrical equipment — Part 1: General requirements for safety*, hereinafter referred to as the General Standard (see 1.3).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a “General guidance and rationale” section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

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 annex does not form part of the requirements of this Standard.

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

Addition:

This Particular Standard specifies the particular requirements for the safety of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 2.101, herein- after referred to as EQUIPMENT.

This Standard applies to transcutaneous monitors used with adults, children and neonates and includes the use of these devices in foetal monitoring during birth.

This Standard does not apply to haemoglobin saturation oximeters or to devices applied to surfaces of the body other than the skin (for example conjunctiva, mucosa).

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 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*.

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 Annex AA, Annex 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.