

Medical electrical equipment —

Part 3: Particular requirements for performance —

Section 3.1: Specification for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment

The European Standard EN 60601-3-1:1996 has the status of a
British Standard

ICS 11.040.50

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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 Healthcare Engineering and Estate Management
- Institution of Physics and Engineering in Medicine and Biology
- Royal College of Physicians of London

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National foreword

This British Standard has been prepared by Technical Committee CH/96. It is the English language version of EN 60601-3-1:1996 *Medical electrical equipment — Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-3-1:1996 published by the International Electrotechnical Commission (IEC).

Attention is drawn to BS 5724-2.123 which specifies particular requirements for the safety of transcutaneous partial pressure monitoring equipment.

Cross-references

Publication referred to	Corresponding British Standard
IEC 601-1:1988	BS EN 60601-1 <i>Medical electrical equipment</i> Part 1: <i>General requirements for safety</i>
IEC 601-2-23:1993	BS 5724 <i>Medical electrical equipment</i> Part 2: <i>Particular requirements for safety</i> Section 2.123:1996 <i>Specification for transcutaneous partial pressure monitoring equipment</i>

In this Particular Standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type.
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type.
- *test specifications: in italic type.*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE AND IN IEC 601-1: SMALL CAPITALS

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 12, 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, monitoring equipment, transcutaneous partial pressure, performance, test conditions

English version

Medical electrical equipment
Part 3-1: Essential performance requirements for
transcutaneous oxygen and carbon dioxide partial pressure
monitoring equipment

(IEC 601-3-1:1996)

Appareils électromédicaux
Partie 3-1: Prescriptions essentielles
de performances pour les appareils de
surveillance de la pression partielle
transcutanée de l'oxygène et du
dioxyde de carbone
(CEI 601-3-1:1996)

Medizinische elektrische Geräte
Teil 3-1: Wesentliche Anforderungen an
die Leistungsfähigkeit für Geräte für die
transkutane Partialdrucküberwachung
von Sauerstoff und Kohlendioxid
(IEC 601-3-1:1996)

This European Standard 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.

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

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Foreword

The text of document 62D/189/FDIS, future edition 1 of IEC 601-3-1, 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 EN 60601-3-1 on 1996-10-01.

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) 1997-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-07-01

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 A is informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-3-1:1996 was approved by CENELEC as a European Standard without any modification.

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