

Pulse oximeters — Particular requirements

The European Standard EN 865 : 1997 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/46, Lung ventilators and related equipment, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-care Industries
- Association of Paediatric Anaesthetists
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- Department of Health
- Electro Medical Trade Association Limited
- Institution of Mechanical Engineers
- Institution of Physics and Engineering in Medicine and Biology
- Intensive Care Society
- Royal College of Paediatrics and Child Health
- Safety Equipment Association

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National foreword

This British Standard has been prepared by Technical Committee CH/46 and is the English language version of EN 865 *Pulse oximeters — Particular requirements* published by the European Committee for Standardization (CEN).

Cross-references

Publication referred to	Corresponding British Standard
EN 475	BS EN 475 : 1995 <i>Medical devices. Electrically-generated alarm signals</i>
EN 60601-1 : 1990	BS 5724 <i>Medical electrical equipment</i> Part 1 : 1989 <i>General requirements for safety</i>
EN 60601-1-2	BS EN 60601 <i>Medical electrical equipment</i> Part 1 <i>General requirements for safety</i> Section 1.2 : 1993 <i>Collateral standard. Electromagnetic compatibility — Requirements and tests</i>
IEC 801-2	BS EN 60801 <i>Electromagnetic compatibility for industrial-process measurement and control equipment</i> Part 2 : 1993 <i>Electrostatic discharge requirements</i>

The Technical Committee has reviewed the provisions of IEC 79-4, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

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.

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Descriptors: Electromedical equipment, pulse oximeters, safety requirements, accident prevention, detail specifications, protection against electric shocks, protection against mechanical hazards, radiation protection, explosion protection, fire protection, performance evaluation, tests, markings

English version

Pulse oximeters — Particular requirements

Oxymètres de pouls —
Prescriptions particulières

Pulsoximeter —
Besondere Anforderungen

This European Standard was approved by CEN on 1997-01-17. CEN 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 CEN 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 CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CEN

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

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Foreword

This European Standard has been prepared by Technical Committee TC 215, Respiratory and anaesthetic equipment, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

Annexes AA, BB, CC and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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