

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.31 Specification for external cardiac pacemakers with internal power source

The European Standard EN 60601-2-31:1995 with the incorporation of amendment A1:1998 has the status of a British Standard

ICS 11.040.40

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee HCC/92, Active implants, upon which the following bodies were represented:

- Association of British Health-care Industries
- Biological Engineering Society
- British Cardiac Society
- British Pacing and Electrophysiology Group
- British Surgical Trades Association
- Department of Health
- Electricity Association
- Institute of Physical Sciences in Medicine (IPSM)
- Institution of Electrical Engineers
- Medical Research Council
- Ministry of Defence
- National Heart and Lung Institute
- National Radiological Protection Board
- Royal College of Physicians of London
- Society of Cardiothoracic Surgeons of Great Britain and Ireland

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 1995

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The following BSI references relate to the work on this standard:
Committee reference HCC/92
Draft for comment 91/53412 DC

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Amendments issued since publication

Amd. No.	Date	Comments
10132	November 1998	Indicated by a sideline in the margin

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National foreword

This section of BS EN 60601 has been prepared by Technical Committee HCC/92 and is the English language version of EN 60601-2-31 *Medical electrical equipment Part 2: Particular requirements for the safety of external pacemakers with internal power source*, including Amendment A1:1998 published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-31:1994 including Amendment 1:1998 published by the International Electrotechnical Commission (IEC).

This Particular Standard amends and supplements BS 5724-1:1989 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.

General guidance in the application of this Particular Standard and a rationale for the more important requirements are 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. Neither this annex nor Annex BB form a part of this standard.

Cross-references

International standard	Corresponding British Standard
EN 60601-1:1990 (IEC 601-1:1988)	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i>
EN 60601-1-2:1993 (IEC 601-1-2:1993)	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>
EN 60801-2:1993 (IEC 801-2:1991)	BS EN 60801 <i>Electromagnetic compatibility for industrial-process measurement and control equipment</i> Part 2:1993 <i>Electrostatic discharge requirements</i>

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 BS 5724-1: in SMALL CAPITALS.

For the purposes of this British Standard, any references to IEC page numbers in the text should be ignored.

Textual errors. When adopting text of the international standard, the textual errors listed below were discovered. They have been marked in the text and have been reported to IEC in a proposal to amend the text of the international standard.

In Table AA.1, the first two lines of text should be deleted and replaced by the following.

Failure to pace	Low battery	Battery indicator	49.101
	Poor connection	Test of connection	6.8.2 aa) 12)

In clause **6.1 aa)** of Annex AA, last line, delete “white and blue” and substitute with “white and a contrasting colour”. Also, re-number this clause as “**6.1 aa), bb)**” and re-number “**6.1 bb)**” as “**6.1 cc)**”.

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 24, 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.

Descriptors: Medical electrical equipment, external cardiac pacemaker, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source

(includes amendment A1:1998)
(IEC 60601-2-31:1994 + A1:1998)

Appareils électromédicaux
Partie 2-31: Règles particulières de sécurité des
stimulateurs cardiaques externes à source
d'énergie interne
(inclut l'amendement A1:1998)
(CEI 60601-2-31:1994 + A1:1998)

Medizinische elektrische Geräte
Teil 2-31: Besondere Festlegungen für die
Sicherheit von externen Herzschrittmachern
mit interner Stromversorgung
(enthält Änderung A1:1998)
(IEC 60601-2-31:1994 + A1:1998)

This European Standard was approved by CENELEC on 1994-12-06; amendment A1 was approved by CENELEC on 1998-04-01. 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

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of document 62D(CO)78, future edition 1 of IEC 601-2-31, 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 60601-2-31 on 1994-12-06.

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) 1995-12-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1995-12-01

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 AA, Annex BB and Annex ZB are informative. Annex ZA and Annex ZB have been added by CENELEC.

Foreword to amendment A1

The text of document 62D/252/FDIS, future amendment 1 to IEC 60601-2-31:1994, 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 60601-2-31:1995 on 1998-04-1.

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) 1999-01-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2001-01-01

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