

BRITISH STANDARD

**BS 6902 :
Part 1 :
Supplement 1 :
1996
EN 50061/A1 :
1995**

Cardiac pacemakers

Part 1. Specification for implantable cardiac pacemakers

Supplement 1. Electromagnetic compatibility

This Supplement implements EN 50061/A1 : 1995

ICS 11.040.40

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/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 September 1996

© BSI 1996

Amendments issued since publication

Amd. No.	Date	Text affected

The following BSI references relate to the work on this standard:
Committee reference CH/92
Draft for comment 90/50313 DC

ISBN 0 580 25524 7

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Supplement	
6.3 Electromagnetic compatibility	3
6.3.1 Protection from spurious injected current	3
6.3.2 Protection from malfunction due to electromagnetic interference	3
6.3.3 Protection against sensing electromagnetic interference	9
6.3.4 Protection against static magnetic fields	10
6.3.5 Final assessment	10
Annex	
E (informative) Rationale for subclause 6.3 Electromagnetic compatibility	14
Figures	
1 Test signal for subclause 6.3.1 at a frequency of 500 kHz and for subclause 6.3.3 at frequencies above 150 kHz	4
2 Low-pass filter to separate spurious low-frequency signals	5
3 Test set-up to check the interference generator for spurious low-frequency noise and to determine the appropriate capacitor C_x	5
4 First tissue interface equivalent circuit for current measurements	6
5 Test set-up for measurement of induced current flow	7
6 Second tissue interface equivalent circuit to check for malfunctions	8
7 Test set-up to check for malfunctions	11
8 Test signal for subclause 6.3.3 at frequencies below 150 kHz	12
9 Test set-up for magnetostatic measurements	13
E.1 Limiting curve for subclause 6.3.3	16
E.2 Limiting curve for subclause 6.3.1 and 6.3.2	16
E.3 Maximum allowed current when injected to the heart	17

National foreword

This Supplement to BS 6902 : Part 1 : 1990 has been prepared by Technical Committee CH/92 and is the English language version of EN 50061/A1 : 1995, which is amendment A1 to EN 50061 : 1988, published by the European Committee for Electrotechnical Standardization (CENELEC). It includes Corrigendum to EN 50061 : 1988/A1 : 1995. This Supplement presents text which had been omitted from the original standard as the detailed examination of the proposed procedures for verifying electromagnetic compatibility had yet to be evaluated. This evaluation has been completed and, accordingly, is now included to replace the existing clause 6.3.

The additional information in the national foreword to BS 6902 : Part 1 : 1990 refers to a draft specification on the identification of connector assemblies. That draft has now been published as ISO 5841-3 : 1992 and EN 50077 : 1993 and has been implemented as BS EN 50077 : 1993 *Specification for low profile connectors (IS-1) for implantable pacemakers*

Cross-references

Publication referred to	Corresponding British Standard
EN 50061 : 1988	BS 6902 <i>Cardiac pacemakers</i> Part 1 : 1990 <i>Specification for implantable cardiac pacemakers</i>

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

UDC 615.817 : 616.12 : 621.313 : 614.8

Descriptors: Medical electrical equipment, surgical implants, pacemakers, definitions, marking, tests, performance tests

English version

Safety of implantable cardiac pacemakers

Sécurité des stimulateurs cardiaques implantables

Sicherheit implantierbarer Herzschrittmacher

This amendment A1 modifies the European Standard EN 50061 : 1988; it was approved by CENELEC on 1992-03-24. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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.

CEN members are the national standards bodies 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 Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

© 1995 Copyright reserved to CENELEC members.

Ref. No. EN 50061 : 1988/A1 : 1995 E

 **Documents**
Document Sharing Hub

Foreword

This amendment was prepared by the Technical Committee CENELEC TC 62, Electrical equipment in medical practice.

The text of the draft was submitted to the formal vote and was approved by CENELEC as amendment A1 to EN 50061 : 1988 on 1992-03-24.

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1996-01-15
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1996-01-15

Supplement

Replace subclause 6.3 by the following.

6.3 Electromagnetic compatibility

The tests defined in subclause 6.3 are not applicable to pulse generators with externally-wired sensors. Tests for these devices are under consideration.

All protection requirements shall be met for all settings of the pulse generator, except those settings the manufacturer specifies as not meeting the requirements of subclause 6.3.3 in this standard. This does not mean that all combinations of settings shall be tested, but at least the normal setting to which the device is preset by the manufacturer shall be tested completely.

6.3.1 Protection from spurious injected current

6.3.1.1 Requirement

The implanted pulse generator shall be constructed so that ambient electromagnetic fields are unlikely to cause electric currents (r.m.s.) greater than:

- 50 μ A within the frequency (f) range 20 Hz to 1 kHz;
- 50 μ A $\times f/1$ kHz within the frequency (f) range 1 kHz to 400 kHz;
- 20 mA within the frequency (f) range 400 kHz to 5 MHz

to be applied to the heart.

6.3.1.2 Test procedure

Two forms of test voltage are applied in turn.

One test voltage is a sinusoidal signal of peak-to-peak amplitude:

- 1 V within the frequency (f) range 20 Hz to 800 kHz;
- 1 V $\times f/800$ kHz within the frequency (f) range 800 kHz to 5 MHz.

The other test voltage is a sinusoidally-modulated signal with a sinusoidal modulation of 95 % at 130 Hz. The peak-to-peak amplitude is 2 V_{pp} with a 500 kHz carrier (see figure 1).

NOTE. Care should be taken that the interference generator does not of itself produce low-frequency components. (See figures 2 and 3.)

6.3.1.2.1 Single-channel unipolar pulse generators

The test voltages of subclause 6.3.1.2 are applied to the pulse generator through the first tissue interface equivalent circuit (figure 4) connected as shown in figure 5a.

6.3.1.2.2 Multichannel unipolar pulse generators

The test voltages of subclause 6.3.1.2 are applied to the pulse generator with every input/output connected in turn to the interference generator through a first tissue interface equivalent circuit (figure 4) connected as shown in figure 5a. Any terminal not being tested is connected through a resistor of between 10 k Ω and 100 k Ω according to the manufacturer's recommendation for the channel under test.

6.3.1.2.3 Single-channel bipolar pulse generators

Bipolar systems are tested in two configurations.

Common mode performance is tested using the signals described in subclause 6.3.1.2, with the pulse generator connected through the first tissue interface equivalent circuit (figure 4) as shown in figure 5b.

Differential mode performance is tested using signals described in subclause 6.3.1.2 reduced to one-tenth amplitude, with the pulse generator connected through a first tissue interface equivalent circuit as shown in figure 5c.

6.3.1.2.4 Multichannel bipolar pulse generators

Multichannel bipolar systems are tested as described in subclause 6.3.1.2.3 with every pair of inputs/outputs connected in turn to the interference generator through the first tissue interface equivalent circuit (figure 4) connected as shown in figure 5b. Any terminal not being tested is connected through a resistor of between 10 k Ω and 100 k Ω according to the manufacturer's recommendation for the channel under test.

Differential mode performance is tested using signals described in subclause 6.3.1.2 reduced to one-tenth amplitude, with the pulse generator connected through a first tissue interface equivalent circuit (figure 4) as shown in figure 5c.

6.3.1.3 Assessment

This requirement is met for test configurations as shown in figure 5, if the current reading is as specified in subclause 6.3.1.1.

NOTE 1. In the case of the modulated signal, the appropriate r.m.s. current limit is 50 μ A (at 130 Hz).

NOTE 2. No current measurement is made in the period from 10 ms preceding a pulse to 150 ms after the pulse.

6.3.2 Protection from malfunction due to electromagnetic interference

6.3.2.1 Requirement

The implanted pulse generator shall be constructed so that ambient electromagnetic fields are unlikely to cause malfunction of the pulse generator.

6.3.2.2 Test procedure

The test voltage is a continuous sinusoidal signal of peak-to-peak amplitude:

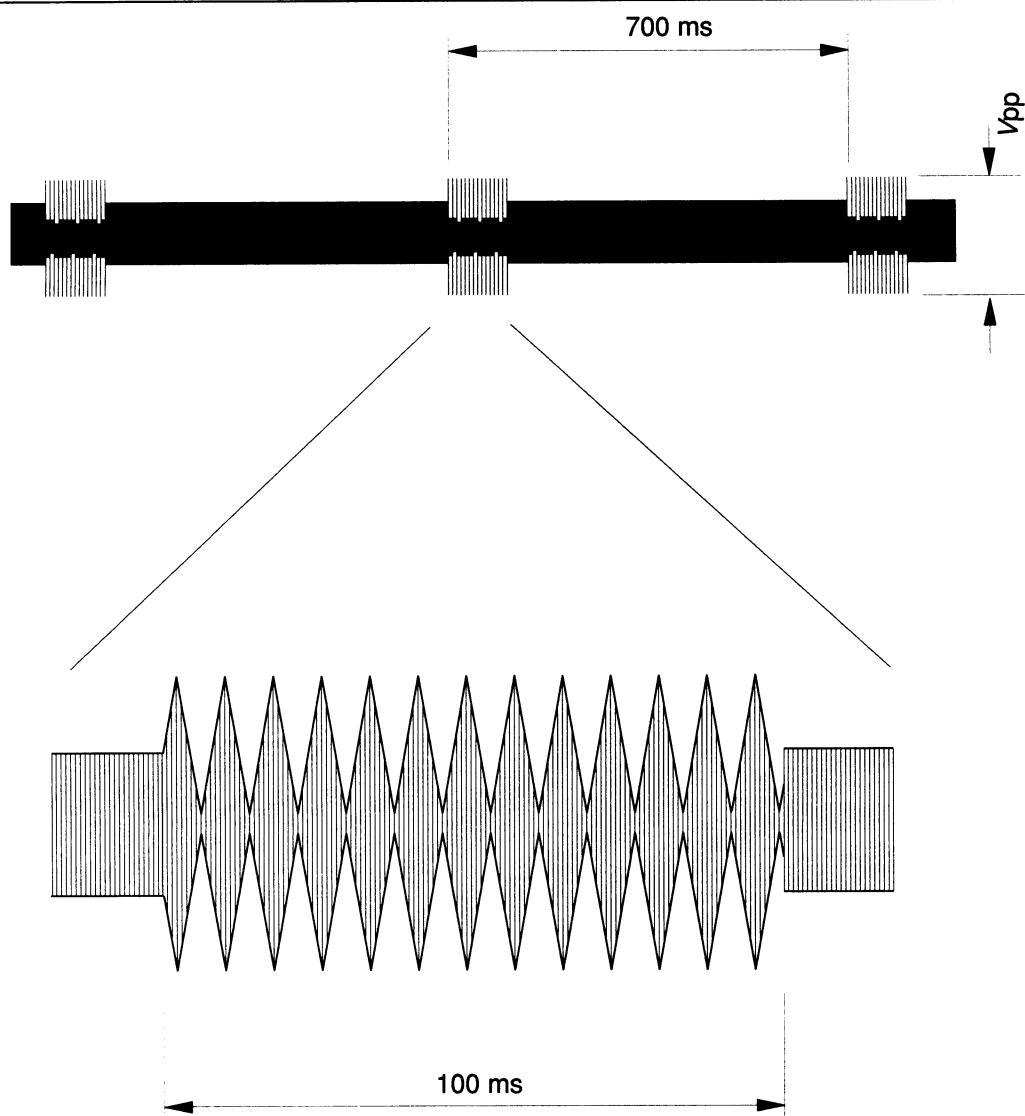
- 1 V within the frequency range 20 Hz to 500 kHz.

6.3.2.2.1 Single-channel unipolar pulse generators

The test voltage of subclause 6.3.2.2 is applied to the pulse generator through the second tissue interface equivalent circuit (figure 6) connected as shown in figure 7a.

6.3.2.2.2 Multichannel unipolar pulse generators

The test voltage of subclause 6.3.2.2 is applied to the pulse generator, with every input/output connected to the interference generator in parallel through the second tissue interface equivalent circuit (figure 6) as shown in figure 7a.



The modulation bursts start and terminate at zero crossings of the modulation signal. Therefore the envelope starts and terminates at a value of 100 %. The burst counts 13 complete modulation cycles. The modulation depth is 95 %.

Figure 1. Test signal for subclause 6.3.1 at a frequency of 500 kHz and for subclause 6.3.3 at frequencies above 150 kHz