SLOVENSKI STANDARD
SIST EN 50061:1995/A1:1998

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Safety of implantable cardiac pacemakers - Amendment A1

Safety of implantable cardiac pacemakers

Sicherheit implantierbarer Herzschrittmacher

Sécurité des stimulateurs cardiaques implantables

Ta slovenski standard je istoveten z: **EN 50061:1988/A1:1995**

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English version

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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.

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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

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.

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) 1996-01-15
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1996-01-15

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 pre-set 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 (rms) greater than:

50 μA within the frequency (f) range 20 Hz to 1 kHz;
50 μA $\times$ 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 5 (a).

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 5 (a). Any terminal not being tested in connected through a resistor of between 10 kΩ and 100 kΩ 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 5 (b).

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 5 (c).

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 5 (b). Any terminal not being tested is connected through a resistor of between 10 kΩ and 100 kΩ 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 5 (c).

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 rms current limit is 50 μA (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 7 (a).

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 7 (a).

6.3.2.2.3 Single channel bipolar pulse generators

Bipolar systems are tested in two configurations.

Common mode performance is tested using the signals described in subclause 6.3.2.2 with the pulse generator connected through the second tissue interface equivalent circuit (figure 6) as shown in figure 7 (b).

Differential mode performance is tested using signals described in subclause 6.3.2.2 reduced to one-tenth amplitude, with the pulse generator connected through a second tissue interface equivalent circuit (figure 6) as shown in figure 7 (c).

6.3.2.2.4 Multichannel bipolar pulse generators

Multichannel bipolar systems are tested as described in subclause 6.3.2.2.3 with every pair of inputs/outputs connected in parallel to the interference generator through the second tissue interface equivalent circuit (figure 6) as shown in figures 7 (b) and 7 (c).

6.3.2.3 Assessment

This requirement is met if, while the test voltage is slowly varied over the range defined in subclause 6.3.2.2, the pulse generator continues to operate as set or in its interference mode as characterized by the manufacturer; and when the test voltage is removed, the pulse generator functions as prior to the test without further adjustment of the pulse generator.

If for some value of the test voltage the pulse generator changes from its set mode to its interference mode, or vice versa, then no pause longer than twice the pre-set interval shall occur unless the change of mode is completed within a change of 10 % of the test signal amplitude.

6.3.3 Protection against sensing electromagnetic interference

6.3.3.1 Requirement

The implanted pulse generator shall be constructed so that commonly encountered electromagnetic signals are unlikely to be confused with sensed beats and change the pacing pattern of the pulse generator.

6.3.3.2 Test procedure

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

2 mV within the frequency range 20 Hz to 1 kHz;
2 mV × f/1 kHz within the frequency range 1 kHz to 8 MHz;
16 V within the frequency range 8 MHz to 30 MHz.

For frequencies below 150 kHz, the carrier signal shall be switched at zero amplitude 100 ms on, 600 ms off (see figure 8).

For frequencies above 150 kHz, the carrier shall be amplitude modulated 95 % with a sinusoidal 130 Hz wave which shall be switched at zero: 100 ms on, 600 ms off (see figure 1).

The pulse generator shall be set to its highest sensitivity, unless the labelling of the pulse generator includes a clear warning that for given settings the pulse generator will be influenced by the test signal in which case the pulse generator shall be set to its highest sensitivity for which the manufacturer claims compliance with this standard.

The test is performed in the pacing mode and in a synchronized mode when it is not possible to distinguish between uninfluenced mode and interference mode of operation. The synchronized mode is achieved with an additional signal generator providing the standard test signal (see figure C3 of EN 50061) of twice the amplitude that just synchronizes the pulse generator under test (see figure 7).

NOTE 1. Care should be taken that the interference generator does not itself produce low frequency components. (See figures 2 and 3.)

NOTE 2. When the pulse generator is synchronized by the additional signal generator this should be set without the modulated test signal being applied.

6.3.3.2.1 Single channel unipolar pulse generators

The test voltage of subclause 6.3.3.2 is applied to the pulse generator through the second tissue interface equivalent circuit (figure 6) connected as shown in figure 7 (a).

6.3.3.2.2 Multichannel unipolar pulse generators

The test voltage of subclause 6.3.3.2 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 7 (a).

The pulse generator shall also be programmed to minimize the occurrence of possible cross-talk between different channels.

6.3.3.2.3 Single channel bipolar pulse generators

Bipolar systems are tested in two configurations.

Common mode performance is tested using the signals described in subclause 6.3.3.2 with the pulse generator connected through the second tissue interface equivalent circuit (figure 6) as shown in figure 7 (b).

Differential mode performance is tested using signals described in subclause 6.3.3.2 reduced to one-tenth amplitude, with the pulse generator connected through the second tissue interface equivalent circuit (figure 6) as shown in figure 7 (c).

6.3.3.2.4 Multichannel bipolar pulse generators

Multichannel bipolar systems are tested for common mode as described in subclause 6.3.3.2.3 with every pair of inputs/outputs connected in parallel to the interference generator through the second tissue interface equivalent circuit (figure 6) as shown in figure 7 (b).

Multichannel bipolar systems are tested for differential mode as described in subclause 6.3.3.2.3 with every pair of inputs/outputs connected in turn to the interference generator through the second tissue interface equivalent circuit (figure 6) as shown in figure 7 (c). Any terminal not being tested is connected through a resistor of between 10 kΩ and 100 kΩ according to the manufacturer's recommendation for the channel under test.

The pulse generator shall also be programmed to minimize the occurrence of possible cross-talk between different channels.

6.3.3.3 Assessment

This requirement is met if while the carrier signal is varied over the ranges defined in subclause 6.3.3.2, with either modulation, the pulse generator at all times functions in its set mode.

6.3.4 Protection against static magnetic fields

6.3.4.1 Requirements

The implanted pulse generator shall not be affected by a static magnetic field of flux density below 1 mT. For magnetic fields less than 10 mT, when the field is removed, the implanted pulse generator shall function as prior to the test without further adjustment of the pulse generator.

6.3.4.2 Test procedure

The implantable pulse generator is connected via a 51 kΩ resistor to a signal generator providing the standard form test signal (see figure C3 of EN 50061) of twice the amplitude that just synchronizes the pulse generator under test, loaded with a 510 Ω

resistor, as shown in figures 9 (a) and 9 (b). The implantable pulse generator is placed within a coil, centred in its field, and aligned so that the long axis of its reed switch is parallel to the axis of the coil.

The field is set to a field strength of 1 mT. The field is then slowly increased to 10 mT. The field is then switched off. The field strength shall be within ± 10 % of the defined value at all points in the region of the pulse generator.

NOTE. Care should be taken to avoid wire loops.

6.3.4.2.1 Single channel unipolar pulse generators

The 510 Ω pulse generator load resistor is connected between the pulse generator terminal and the case as shown in figure 9 (a).

6.3.4.2.2 Multichannel unipolar pulse generators

The 510 Ω pulse generator load resistor is connected between one pulse generator terminal and the case. The other channel is connected to the case via a separate 510 Ω resistor as shown in figure 9 (a).

6.3.4.2.3 Single channel bipolar pulse generators

The 510 Ω pulse generator load resistor is connected between the two pulse generator terminals as shown in figure 9 (b).

6.3.4.2.4 Multichannel bipolar pulse generators

The 510 Ω pulse generator load resistor is connected between one pair of pulse generator terminals. The other channel is connected a separate 510 Ω resistor as shown in figure 9 (b).

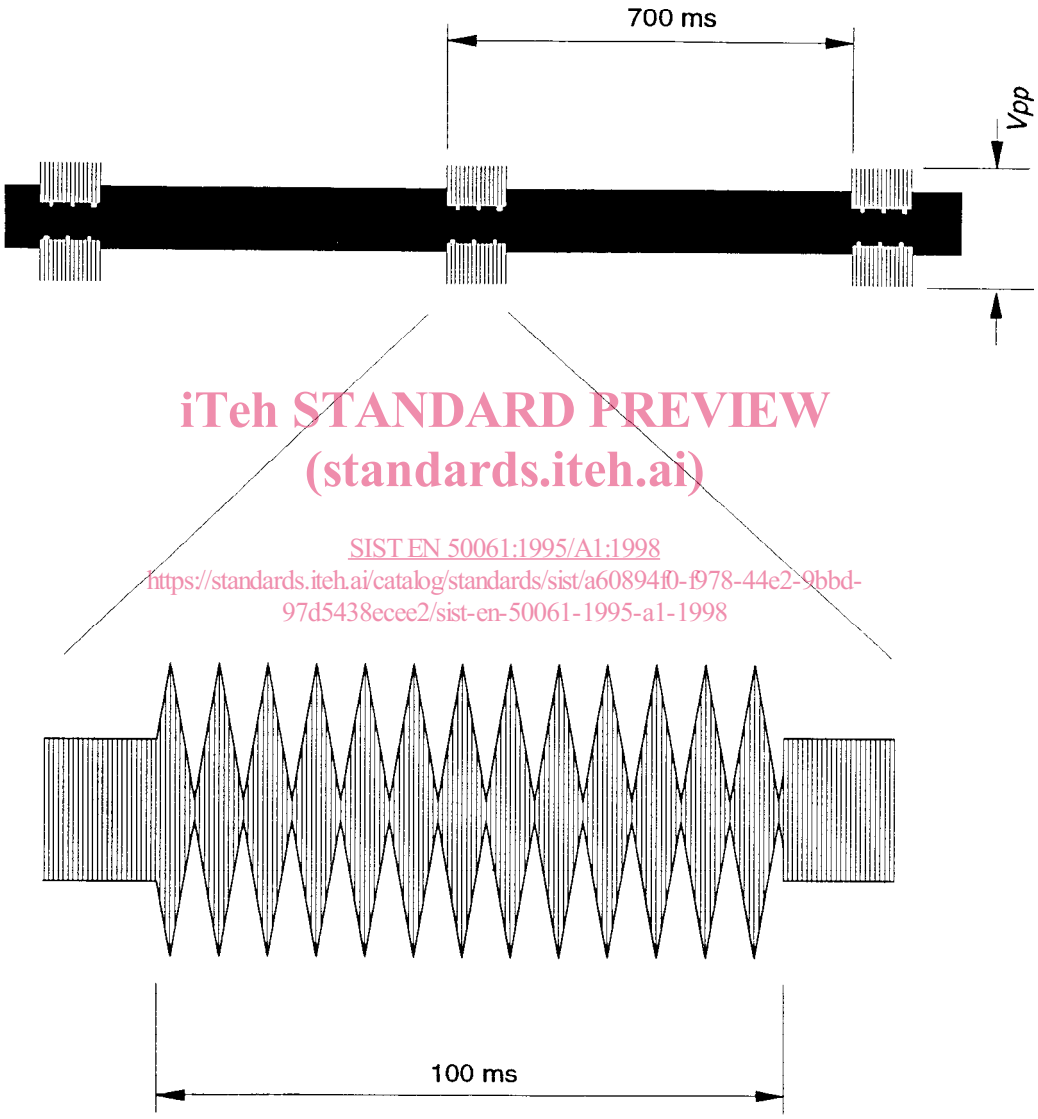
6.3.4.3 Assessment

The requirements are met if, after the field has been increased to 10 mT and switched off, the implantable pulse generator both:

(a) remains inhibited when the field strength is 1 mT; and
(b) without adjustment continues to function as prior to the test.

6.3.5 Final assessment

The requirements of subclause 6.3 have been met if the values of the characteristics listed in subclause 5.6 (h) of EN 50061 when measured, within the accuracies of the measurement procedures, after performing the appropriate procedures described in subclauses 6.3.1, 6.3.2, 6.3.3 and 6.3.4 are as stated by the manufacturer for the pulse generator (see subclause 10.1.2 (c) of EN 50061).



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