List of Titles

American National Standard

ANSI/AAMI NS15:1995/(R)2002

Implantable peripheral nerve stimulators

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Rd., Suite 220
Arlington, VA 22201-4795

Copyright and Permissions

NS15 Implantable Peripheral Nerve Stimulators

American National Standard

ANSI/AAMI NS15:1995/(R)2002
(Revision of ANSI/AAMI NS15:1984)

Implantable peripheral nerve stimulators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 1 February 1995 and reaffirmed 17 December 2002 by
American National Standards Institute, Inc.

Abstract:

This standard establishes minimum labeling, safety, and performance requirements for implantable peripheral nerve stimulators. Also covered are referee test methods and the rationale for the provisions of the standard.

Marvin L. Sussman, PhD

Members:
Richard Black, MD, University of Texas
Chris Castel, Physio Technology Inc.
Robert Flink, Medtronic, Inc.
Marc Flitter, MD, Erie, PA
Gideon Kantor, PhD, U.S. Food and Drug Administration/Center for Devices and Radiological Health
Richard North, MD, The Johns Hopkins Hospital, Baltimore, MD
Warren Starkebaum, PhD, Medtronic Inc.
Marvin L. Sussman, PhD, Cordis Corporation

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

This standard was developed by the AAMI Implantable Neurostimulator Subcommittee of the Neurosurgery Committee.

The scope of this revision has been clarified. The standard establishes minimum safety and performance requirements for internally and/or externally powered implantable neurostimulators. It covers all elements of the peripheral nerve stimulator system, which consists of an implanted pulse generator, connecting electrodes, and an external transmitter or programmer for transmitting energy and/or information across the patient's skin to the implanted pulse generator.

Labeling requirements have been revised and stimulation parameters have been updated in this latest edition. A standard means of testing and reporting the performance of the stimulus generator is important so that physicians are able to make informed comparisons of and selections from commercially available equipment.

The concepts incorporated in this standard should be considered flexible and dynamic. To remain relevant, this standard, like any other, must be reviewed and updated periodically to assimilate new data and to reflect advances in the technology.

This standard reflects the conscientious efforts of concerned physicians, engineers, and other health care professionals, in cooperation with manufacturers, to develop a standard for those characteristics of vascular prostheses that could be addressed at this time, in view of new technology and information.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the standard; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate a course of action is permissible within the limits of the standard; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

Suggestions for improving this standard are invited. These should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword is not a part of the American National Standard, *Implantable peripheral nerve stimulators* (ANSI/AAMI NS15—1995).

Implantable peripheral nerve stimulators

1 Scope

1.1 General

This standard establishes safety and performance requirements for internally and/or externally powered implantable peripheral nerve stimulators.

1.2 Inclusions

This standard covers all elements of the peripheral nerve stimulation system, which consists of an implanted pulse generator, connecting electrodes placed on or around the nerve, and an external transmitter or programmer for transmitting energy and/or information across the patient's skin to the implanted pulse generator.

1.3 Exclusions

Excluded from the scope of this standard are transcutaneous electrical nerve stimulators, implantable spinal cord stimulators, brain stimulators, and all forms of functional muscle stimulators.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standard listed below.

2.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus.* ANSI/AAMI ES1. Arlington (Va.): AAMI, 1993. American National Standard.

3 Requirements

3.1 Labeling requirements

In addition to the requirements of applicable federal regulations, labeling on or accompanying implantable peripheral nerve stimulators shall include the following.

3.1.1 Device markings

The device shall be labeled as an implantable peripheral nerve stimulator. The transmitter and pulse generator shall display:

— the manufacturer's name;

— the model number; and

— the serial number and/or manufacturing lot number.

3.1.2 Information manual/package insert

A physician information manual or package insert and a patient information manual (which may be combined with the physician manual) shall be supplied with each device and shall contain at least the following:

a) a prescription legend as required by federal regulations;

b) instructions for using the implantable peripheral nerve stimulator so that physicians are able to implant, test, and demonstrate the use of the device correctly;

c) instructions for implanting the pulse generator, including: (1) information about the proper method of placing the electrodes on or around the nerve; (2) instructions for making the proper connections

between the electrode leads and the pulse generator; (3) a warning, if applicable, that the electrode may cause compression of the nerve if it is too small;

d) instructions for proper sterilization of the implantable components (If the device is supplied sterile by the manufacturer, the method of sterilization, date of sterilization, the lot number, the date by which the device must be used, and proper steps to ensure that sterility is not compromised should be specified);

e) labeling that includes warnings, cautions, and precautions related to the use of the device, including possible interactions with other devices;

f) a table of stimulation parameter ranges, including at least amplitude, frequency and pulse width, and a representation of the stimulation waveform;

g) instructions for the disposal of the transmitter and implantable pulse generator;

h) for a device with implanted life-limiting components, a statement as to shelf life and the projected useful life of the system over a typical range of load and stimulation parameters;

i) instructions on preimplant testing for proper functioning.

3.1.3 Registration

The manufacturer shall provide means by which each implanted device can be registered with the manufacturer. A card to be returned to the manufacturer shall be provided with each device. This card shall provide space for:

— the name;

— model number;

— serial number and/or manufacturing lot number of the device;

— patient, hospital, physician name and addresses;

— date of implantation.

3.2 Performance requirements

3.2.1 Electrical safety

In accordance with 2.1, the risk current from any insulated wires shall not exceed 10 microamperes (μA) (source risk current limit, dc to 1 kiloHertz [kHz]). However, leakage currents above 100 nanoamperes (nA) may cause electrode corrosion and should be evaluated.

3.2.2 Stimulation parameters

A safe and effective current to stimulate the peripheral nerve depends on a number of factors, including frequency of stimulation, duty cycle of stimulation, length of time of continuous stimulation, current density in the nerve, and charge per stimulation phase. The output of the device shall operate within the following parameter ranges:

a) *Pulse frequency* — 1 to 1,500 pulses per second (pps);

b) *Pulse width* — 1 to 2,000 microseconds (μsec);

c) *Output voltage/current* — 0 to 15 volts (V) through a 500-ohm load (0 to 30 mA).

3.2.3 Waveform

The waveform shall consist of balanced positive and negative phases, so that the net dc current through the electrodes does not exceed 10 μA (see 4.2.3).

3.2.4 Controls

Each device shall have an output-limiting control that can be set by the physician as clinical findings indicate to limit the output of the device.

3.2.5 Design of peripheral nerve electrodes

Precise design rules for peripheral nerve electrodes have not yet been established. Electrodes should be designed to prevent damage to the nerve. Damage may occur if the electrode constricts the nerve and restricts blood flow in the nerve. Satisfactory design depends upon choice of materials as well as electrode dimensions. Spiral and helical self-sizing electrodes may be designed to be close-fitting on the nerve. For a cuff electrode system of fixed diameter, the cuff diameter shall be at least one and one-half times the diameter of the nerve to be stimulated.

3.2.6 Materials

Components in direct tissue contact (such as the encapsulant and/or coating of the implanted pulse generator, the electrical insulation of the lead wires, the electrode pad, and the electrode) shall be composed of materials shown to be biocompatible (see A.3.2.6).

4 Tests

This section provides referee test methods that can be used to verify compliance of the device with the labeling and performance requirements of section 3. The paragraph numbers correspond, with the exception of the first digit, to those of section 3.

4.1 Compliance with the labeling requirements

4.1.1 Device markings

Compliance with the requirements of 3.1.1 can be determined by visual inspection.

4.1.2 Information manual/package insert

Compliance with the requirements of 3.1.2 can be established by visual inspection, except for the electrical performance specifications required in (f). The test circuits of figure 1 shall be used to measure the output characteristics to be reported and verified.

4.1.3 Registration

Compliance with the requirements of 3.1.3 can be determined by visual inspection.

4.2 Compliance with the performance requirements

4.2.1 Electrical safety

Test methods for establishing compliance with the American National Standard, *Safe current limits for electromedical apparatus*, are provided in that standard.

4.2.2 Stimulation parameters

The test circuit for all parameter measurements shall consist of a simple, 500-ohm, resistive load, as shown in figure 1(a) or 1(b) (see next page). For radiofrequency coupled systems, the pulse generator output shall be tested at the maximum coupling efficiency achievable in the body (half-centimeter spacing between the transmitter antenna and the pulse generator).

a) *Pulse frequency* or *repetition rate* (PRR) is measured as the reciprocal of the interval between two consecutive pulse onsets (PI), regardless of polarity. See figure 2(a), page 4.

b) *Pulse width* (PW) is measured at the midpoint of the pulse at the maximum pulse amplitude. See figure 2(b), page 4.

c) *Pulse amplitude* (PA) is measured, at a pulse width of 200 sec or nearest setting, as the linear estimate of the average value of the pulse height from the start of the pulse onset. See figure 2(c), page 4.

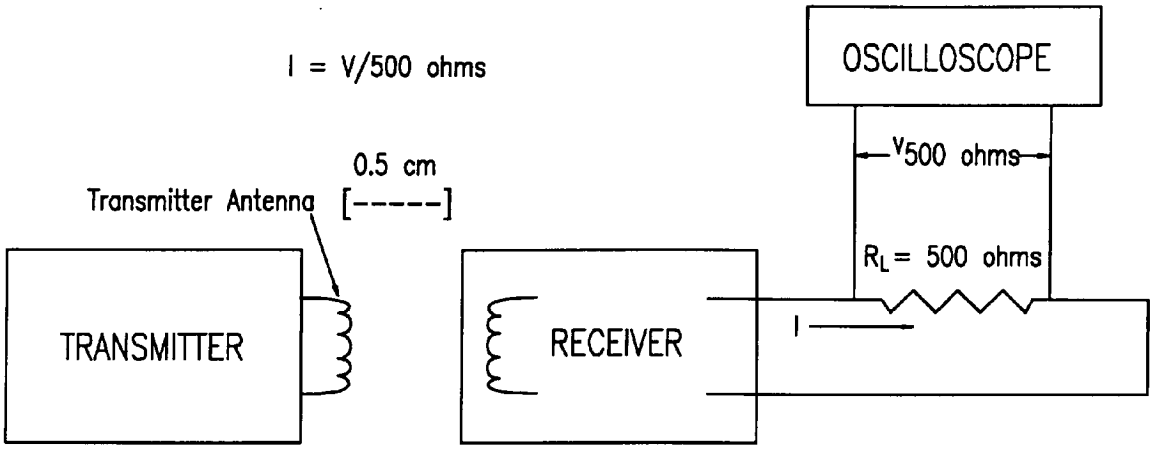

Figure 1(a)—Test circuit for verifying performance specifications of externally powered stimulator

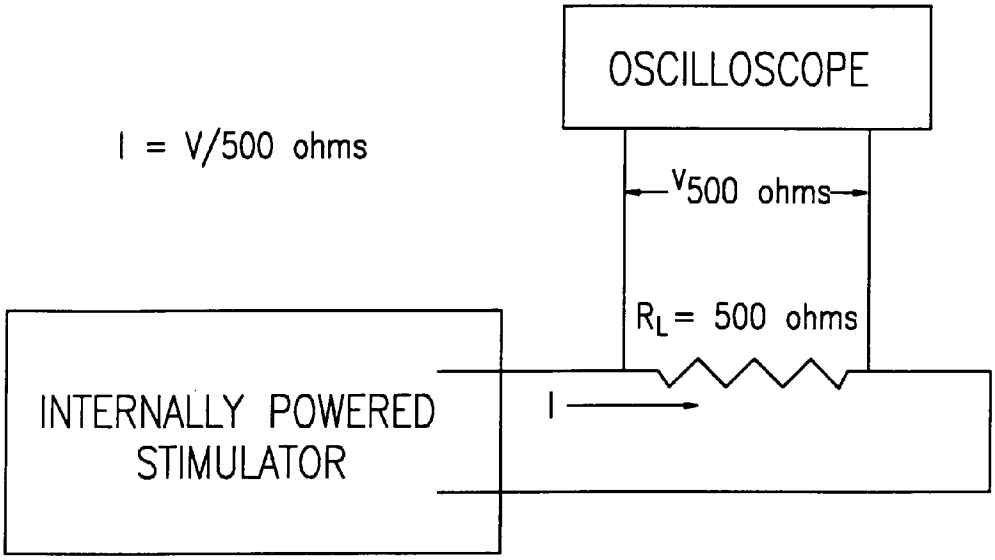

Figure 1(b)—Test circuit for verifying performance specifications of internally powered stimulator

4.2.3 Waveform

The waveform shall be observed by means of the test circuit shown in figure 1(a) or 1(b). The pulse generator output should block the dc component of current into the load. If one checks the dc = 0 V level on the oscilloscope at a high enough sensitivity, one will see the current distribution around 0 V (see figure 3). The net dc current shall be less than 10 µA.

4.2.4 Controls

Compliance with the requirement of 3.2.4 can be determined by inspection.

4.2.5 Dimensions of cuff electrodes

Compliance with the requirement of 3.2.5 can be determined by inspection.

4.2.6 Materials

Test methods are under study. (See A.3.2.6.)

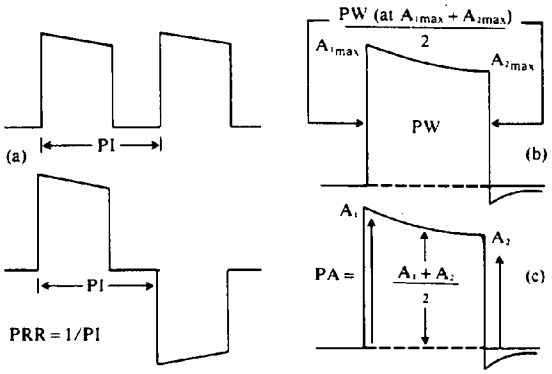

Figure 2—Measurement of pulse repetition rate (a), pulse width (b), and pulse amplitude (c)

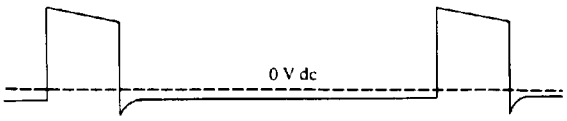

Figure 3—Current distribution around 0 volts dc

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

This standard was developed by the Implantable Neurostimulator Subcommittee of the AAMI Neurosurgery Committee. It sets forth the labeling and reporting requirements and the performance materials requirements that the committee considered would provide reasonable assurance of the safe and effective use of peripheral nerve stimulators for the relief of chronic pain. Like all standards, this standard reflects current technology, and as advances in the field occur, it must be modified to accommodate new data.

A.1.1 Peripheral nerve stimulator systems

Peripheral nerve stimulators for pain relief are devices that electrically stimulate the nervous system. Peripheral nerve stimulators are used in patients to relieve severe, intractable pain of peripheral origin, or in a peripheral nerve distribution (FDA, 1978).

Radiofrequency-coupled neural stimulators, as used for peripheral nerve stimulation, are partially implantable pulse generator systems consisting of an external battery-powered transmitter/antenna system and a subcutaneously implanted receiver/lead system. Pulse-modulated radiofrequency energy produced by the external transmitter is radiated by the antenna. When the antenna is affixed to the skin overlying the implanted receiver, the stimulating pulses are transmitted across the skin to the implanted receiver. The receiver detects the pulsed energy and produces electrical pulses of variable frequency (repetition rate), height (amplitude), and width (duration). These electrical pulses are transmitted—via implanted, insulated lead wires with bare electrode surfaces—to specific neural tissues (that is, peripheral nerves).

The stimulation pulse repetition rate, pulse amplitude, and pulse width are adjustable by means of controls on the external transmitter. For optimal efficiency, the transmitting coil of the antenna must be placed directly over and in proximity to the implanted receiver (Kahn & Maveus, 1972; Ray & Mayer, 1975). The

characteristics of the stimulus pulse (e.g., amplitude) may vary with changes in antenna/receiver coupling.

"Totally implanted" pulse generators, used for peripheral nerve stimulation, are powered by an implanted primary (or rechargeable) battery. These devices allow stimulation to be delivered autonomously, that is, independently of any externally worn device. Control of the implant by the patient may be accomplished by using a magnet or by using a radiotelemetry device.

Some implanted pulse generators, of both radiofrequency-coupled and "totally implanted" design, allow noninvasive selection of anodes and cathodes from an array of electrodes, hardwired to the pulse generator. These devices may be described as "multichannel" in common usage; technically, contemporary new devices are single-channel generators, with programmable gates to multiple outputs (North et al., 1991).

A.1.2 History

The idea that electrical stimulation of body organs can serve as a therapeutic modality for the modification of abnormal physiology in humans has been applied in several fields, most notably cardiology. The use of electrical stimulation of peripheral nerve fibers in the management of chronic, intractable pain began in the 1960s.

Interest in this field was sparked by the publication of the "Gate Control Theory" (Melzack & Wall, 1965). According to this theory, sensory mechanisms for the perception of pain are controlled by a negative feedback or gating mechanism located in the spinal cord. Activated by impulse activity in large-diameter, myelinated, peripheral, cutaneous nerve fibers or their collaterals in the dorsal columns of the spinal cord, this "gate" closes to inhibit the transmission of nerve impulses from the smaller fibers associated with nociception. Although such impulse activity could be achieved by mechanical stimulation of peripheral mechanoreceptors, electrical stimulation is easier to apply. The "Gate Control Theory," though later questioned, has served as the rationale for the clinical use of electrical stimulation of the nervous system as a therapeutic modality in the management of pain.

The initial clinical application of current to nerves for the relief of pain involved the stimulation of myelinated afferent nerve fibers in peripheral nerve pathways. Shelden (1966) proposed that the pain relief observed upon stimulation of the trigeminal nerve was due to depolarization and the reduction of afferent impulses. Wall & Sweet (1967) reported that stimulation of peripheral nerves caused temporary pain relief that outlasted the period of application of current, occasionally by several hours. Sweet & Wepsic (1967) reported that peripheral nerve stimulation produced continued satisfactory pain relief in a small group of patients.

In an effort to apply stimulation to larger anatomic regions, Shealy et al. (1967) suggested that by stimulating the dorsal columns of the spinal cord one would be able to control pain over wider areas, involving not only one extremity but also bilateral extremities and areas of the trunk. The effect of spinal cord stimulation could be perceived over a wide area of the body, in the segments below the region of the spinal cord where current was applied. The first reported use of chronic neural stimulator implants in patients took place in 1969 (Shealy et al., 1970).

Neural stimulation offers the clinician an alternative to destructive lesions of the nervous system, which had been the primary neurosurgical method for the management of pain.

Peripheral nerve stimulation may reduce the perception of pain by:

— interfering with action potential conduction, particularly at branch points of primary afferents (frequency related conduction block);

— local "gate" mechanisms in the dorsal horn, where pain signals may be blocked;

— producing effects higher in the central nervous system, possibly by the competitive "jamming" of pain signals;

— initiating an ascending-descending pain control loop that terminates in the spinal "gate";

— influencing release of endogenous factors that act on pain perception or nociception centrally or peripherally, (e.g., sympathetic neurotransmitters).

A.1.3 Electrode systems

Peripheral nerve stimulation begins with the placement of a flexible electrode array or cuff around the appropriate peripheral nerve, at some distance from the nerve lesion. The most common peripheral nerves stimulated are the sciatic, ulnar, and femoral nerves. A radiofrequency-coupled neural stimulator system is connected to the electrode array. Multicontact electrodes may be placed over the sensory components of peripheral nerves. Wrap-around cuff electrodes may produce nerve damage by constriction. Care in electrode cuff placement reduces the likelihood of nerve damage (Nashold & Goldner, 1975; Nashold et al., 1975).

A.1.4 Clinical results of peripheral nerve stimulation

During the 1970s, numerous reports on the use of spinal cord stimulation for pain control appeared in the literature. Electrical stimulation of peripheral nerves was used to relieve chronic intractable pain produced primarily by trauma or injury to peripheral nerves. This technique has been reported to be effective in about 55% of patients (Erickson & Chou, 1974; Long, 1983; Nashold & Goldner, 1975; Picazza, 1977).

In the use of peripheral nerve stimulators for pain management, two major kinds of equipment-related problems occur: those associated with the use and possible abuse of the external equipment (antenna and receiver system); and system failures in the transmitter and receiver circuitry and implanted leads. In addition, complications may occur when the system is misused (e.g., accidental adjustment of the patient controls to suprathreshold stimulus parameters) or as a result of the effects of extraneous radiofrequency wave transmission on the production of stimuli by the implanted receiver (Kahn & Maveus, 1972).

For peripheral nerve stimulation, Law (1983) reported that the most common clinical complication in 37 patients 12 to 46 months after implant was tenderness at the receiver implant site or at the electrode site. He also reported two cases of the formation of a nerve tumor (neuroma) near the electrodes.

A.2 Need for the standard

Work on the development of a standard for implantable neurostimulators began in the early 1970s, under the auspices of the AAMI Neurosurgery Committee. A proposed standard, primarily covering labeling requirements, was published in 1975. Subsequently, in 1980, an Implantable Neurostimulator Subcommittee was established to refine the labeling requirements contained in the 1975 proposal and to develop performance criteria for peripheral nerve stimulators and spinal cord stimulators. This subcommittee was reorganized and this standard revised in 1991–1993.

The goal was to establish criteria that would help provide reasonable assurance that these devices are safe and effective for the indications claimed in the labeling. In addition, a standard means of testing and reporting the performance of the stimulus generator was considered important so that physicians would be able to make informed comparisons of and selections from commercially available equipment. The committee's conclusion that a performance standard was needed for implantable stimulators has been reinforced both by the published medical literature (see A.1.4) and by regulatory action taken on these devices under the Medical Device Amendments of 1976.

A.3 Rationale for the specific provisions of this standard

A.3.1 Labeling requirements

A.3.1.1 Device markings/A.3.1.2 information manual/package insert

The requirements of 3.1.1 and 3.1.2 are intended to ensure that sufficient product information will be available to the physician and to patients for the safe and effective use of peripheral nerve stimulators.

A.3.1.3 Registration

The registration of peripheral nerve stimulators is considered to be essential for responsible follow-up of product performance by the manufacturer. The data requested are the minimum needed by the manufacturer for proper assessment of a product's performance and for compliance with device tracking requirements.

A.3.2 Performance requirements

A.3.2.1 Electrical safety

The rationale for the risk current limits specified in the American National Standard, *Safe current limits for electromedical apparatus*, is provided in the rationale statement for that standard.

A.3.2.2 Stimulation parameters

The appropriate limits for maximum current are not clear from the published data. In any case, these limits can vary depending upon the relationship of the electrode surface to the region of the peripheral nerve that is being stimulated. Although there have been no reports of nerve damage in patients due to excessive current, there have been fundamental studies conducted in animals that identify the stimulation parameters windows that allow safe stimulation (Agnew and McCreery, 1990). Since patient discomfort or transient interference with movement or sensation may occur as a result of excessive peripheral nerve stimulation, the standard requires a maximum output control that can be set by the physician.

The rationale for the test circuit of figure 1(a) or 1(b) is, first, simplicity. Second, the pure resistive load presents a worst-case (maximum) measurement of average pulse amplitude. The addition of a parallel resistor capacitor circuit in series with the 500-ohm resistor to simulate the electrode-tissue interface would decrease the average amplitude of each pulse by decreasing the time constant of the pulse drop.

A.3.2.3 Waveform

Because the optimum waveform is not known, only documentation of the waveform is required. Nevertheless, the negative and positive currents must be balanced over time in order to avoid electrode deterioration.

A.3.2.4 Controls

See A.3.2.2.

A.3.2.5 Design of peripheral nerve electrodes

Since peripheral nerve diameters vary, the diameter of the peripheral nerve electrode cannot be specified. In cases where a cuff electrode of fixed diameter is used, a range of cuff sizes must be available at surgery so that the surgeon can choose a cuff that is at least 1.5 times the diameter of the nerve to be stimulated. As noted in A.1.3 and reflected in the warning of 3.1.2(c), the cuff electrode must be large enough to avoid compressing the nerve if nerve swelling occurs after surgery. The requirement that the cuff be at least 1.5 times the diameter of the nerve is based on clinical experience and laboratory studies on nerve repair (Ducker & Hayes, 1968).

In cases where self-sizing helical or spiral electrodes are used, the electrode size may be chosen so that the electrode fits closely around the nerve. A range of self-sizing electrodes may also be required at surgery as nerves that are significantly larger than the self-sizing electrode may be compressed if swelling occurs after surgery.

A.3.2.6 Materials

Criteria for biocompatibility remain a subject of scientific research. Therefore, setting specific requirements for acceptance is not a feasible or responsible approach to this issue. There has been clinical experience with a number of materials for the receiver encapsulant or coating, the wire insulation, and the electrode pad (e.g., silicone rubber, fluorinated polymers, epoxies, polyethylurethanes, and polyester fabrics). Platinum or platinum-iridium metals have been used as materials of composition for the electrodes. New materials that have been shown to be biocompatible for use in cardiac pacemakers and cardiac pacing leads might be appropriate for use in spinal cord stimulators and thus warrant evaluation.

The assessment of the biocompatibility of materials used in medical devices depends to a large degree upon the end use of the device. The committee judged that an evaluation of the biocompatibility of materials for use in implanted stimulators could best be approached by reviewing the tests described in the ASTM *Recommended practice for selecting generic biological test methods for materials and devices* (ASTM, 1982). This standard provides a guide to the selection of biocompatibility tests based upon end use, and it discusses the significance of each test. Selection and use of any or all of these tests should be determined according to the specific intended use of the material in the implanted stimulation device; this determination is best left to the discretion of the device manufacturer. It should be noted that the tests suggested in the ASTM standard address the "effect of the material on body tissue and/or fluid."

Annex B
(informative)

Bibliography

AGNEW, WF., McCREERY, DB. *Neural prostheses, fundamental studies.* Englewood Cliffs, NJ: Prentice Hall, 1990.

AMERICAN SOCIETY FOR TESTING AND MATERIALS. *Recommended practice for selecting generic biological test methods for materials and devices.* F748. Philadelphia: ASTM, 1982.

DUCKER, TB., HAYES, G J. Experimental improvements in the use of silastic cuff for peripheral nerve repair. *J. Neurosurg.*, 1968, vol. 28, p. 582-587.

ERICKSON, D., CHOU, S. Implantable electrical devices for pain relief. *Minn. Med.*, 1974, vol. 57, p. 210-212.

KAHN, AR., MAVEUS, TC. Technical aspects of electrical stimulation devices. *Med. Prog. Technol.*, 1972, vol. 1, p. 58-68.

LAW, J. Spinal stimulation: Statistical superiority of monophasic stimulation of narrowly separated, longitudinal bipoles having rostral cathodes. *Appl. Neurophys*., 1983, vol. 46, p. 129-137.

LONG, DM. Stimulation of the peripheral nervous system for pain control. *Clin. Neurosurg.*, 1983, vol. 31, p. 323-343.

MELZACK, P., WALL, PD. Pain mechanisms: A new theory. *Science*, 1965, vol. 150, no. 3699, p. 971-978.

NASHOLD, BS., GOLDNER, JL. Electrical stimulation of peripheral nerves for relief of intractable chronic pain. *Med. Instrum*., 1975, vol. 9, p. 224-225.

NASHOLD, B., MULLEN, JB., AVERY, R. Peripheral nerve stimulation for pain relief using a multicontact electrode system, *J. Neurosurg.*, 1975, vol. 51, p. 872-873.

NORTH, RB., EWEND, MG., LAWTON, MT., PIANTADOSI, S. Spinal cord stimulation for chronic, intractable pain: Superiority of "multichannel" devices. *Pain*, 1991, vol. 44, p. 119-130.

PICAZZA, JR. Pain suppression chronic effects. *Neurosurg.*, 1977, vol. 1, p. 226-227.

RAY, CD., MAYER, DD. Electrical neurological stimulation systems: A review of contemporary methodology. *Surg. Neurol*., 1975, vol. 4, p. 82-89.

SHEALY, C., MORTIMER, J., RESWICK, J. Electrical inhibition of pain by stimulation of the dorsal columns: A preliminary report, *Anesth. Analg.*, 1967, vol. 46, p. 489-491.

SHEALY, CM., MORTIMER, JT., HAGFORS, NR. Dorsal column electroanalgesia, *J. Neurosurg*., 1970, vol. 32, p. 560-564.

SHELDEN, CH. Depolarization in the treatment of trigeminal neuralgia: Evaluation of compression and electrical methods, clinical concept of neurophysiological mechanism. In *Pain* (Henry Ford Hospital Symposium). Boston: Little, Brown & Co., 1966.

SWEET, W., WEPSIC, J. Treatment of chronic pain by stimulation of primary afferent neuron. *Trans. Amer. Neurol. Assn*., 1967, vol. 93, p. 103.

U.S. FOOD AND DRUG ADMINISTRATION. Medical devices: Classification of implanted spinal cord stimulators for pain relief (Proposed Rule; 21 CFR Part 882). *Federal Register*, vol. 43, no. 229. Washington (DC.): 28 November 1978.

WALL, PD., SWEET, WH. Temporary abolition of pain in man. *Science*, 1967, vol. 155, p. 108-109.