

American National Standard

ANSI/AAMI NS15:1995

Implantable peripheral nerve stimulators

AAMI

Association for the
Advancement of Medical
Instrumentation



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NS15 Implantable Peripheral Nerve Stimulators

American National Standard

ANSI/AAMI NS15—1995
(Revision of ANSI/AAMI NS15—1984)

Implantable peripheral nerve stimulators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 1 February 1995 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.

Association for the Advancement of Medical Instrumentation

AAMI Neurosurgery Committee

AAMI Implantable Neurostimulator Subcommittee

This standard was developed by the AAMI Implantable Neurostimulator Subcommittee of the Neurosurgery Committee. Committee approval of the standard does not necessarily imply that all committee members voted for its approval. The **Implantable Neurostimulator Subcommittee** has the following members:

Cochairs: Richard North, MD
 Warren Starkebaum, PhD

Members: Harry Friedman, MD, Memphis Neurosurgery Clinic, PC
 Eugene Goldsand, St. Louis, Missouri
 Pierre LeRoy, MD, CCE, Newark, DE
 Marc Mayberg, MD, University of Washington
 Robert Munzner, PhD, U.S. Food and Drug Administration/Center for Devices and
 Radiological Health
 Richard North, MD, The Johns Hopkins Hospital, Baltimore, MD
 Joseph H. Schulman, PhD, Sylmor, GA
 Warren Starkebaum, PhD, Medtronic, Inc.
 Primož Strojnik, DSc, Alfred E. Mann Foundation for Scientific Research
 Reese S. Terry, Jr., Cyberonics, Inc.
 Cedric F. Walker, CCE, PhD, Tulane University

Alternates: Whit Athey, U.S. Food and Drug Administration/Center for Devices
 and Radiological Health
 Allen W. Hill, Cyberonics, Inc.

At this time, the **Neurosurgery Committee** has the following members:

Cochairs: Marc Flitter, MD

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