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AAMI Standard

AAMI NS4:1986/(R)2002

Transcutaneous electrical nerve stimulators

AAMI
Association for the Advancement of Medical Instrumentation

List of Titles

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NS4 Transcutaneous Electrical Nerve Stimulators

AAMI Standard for Transcutaneous Electrical Nerve Stimulators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 1986; reaffirmed 1 October 2002

Abstract:

This standard establishes labeling, safety, and performance requirements and referee tests for transcutaneous electrical nerve stimulators intended for use in the treatment of pain syndrome; also covered are labeling requirements for patient leads and electrodes. The standard includes an appendix providing labeling/user guidelines for TENS devices and an appendix providing the rationale for the provisions of the standard.

Committee Representation

Association for the Advancement of Medical Instrumentation Neurosurgery Committee

This standard was developed by the TENS Subcommittee under the auspices of the AAMI Neurosurgery Committee. Committee approval of the standard does not necessarily imply that all committee and subcommittee members voted for its approval. The AAMI Neurosurgery Committee has the following members:

Cochairmen: Richard Penn, M.D.
Thomas H. Thomson

Members: Roger Avery, Avery Laboratories
Richard Black, M.D., Johns Hopkins Hospital
Gilbert Buchalter, R.P., M.Sc., Pharmaceutical Innovations
Alan Coombes, Codman and Shurtleff
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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* 

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

The objective of this standard is to provide labeling requirements, certain performance requirements, test methods, terminology, and guidelines that will help establish a reasonable level of safety and effectiveness for transcutaneous electrical nerve stimulators used in the treatment of pain syndromes.

The concepts incorporated in this document should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological advancements. To remain relevant, it must be modified as advances are made in technology and new data are brought forward.

This standard reflects the conscientious efforts of those substantially concerned with its scope and provisions to develop a standard for those performance levels that could be reasonably achieved at this time.

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

AAMI Standard for Transcutaneous Electrical Nerve Stimulators

1. Scope

1.1 General

This standard establishes certain requirements for portable, battery-powered, transcutaneous electrical nerve stimulators (TENS devices) that are used in the treatment of pain syndromes, that are intended for use on intact skin and mucous membranes, and that do not require surgical intervention or violation of the skin surface.

1.2 Inclusions

1.2.1 Labeling requirements for the stimulus generator and for patient leads and electrodes are within the scope of the standard.

1.2.2 Minimum safety and performance requirements for the stimulus generator, including limits on output characteristics, are also within the scope of this standard.

1.3 Exclusions

1.3.1 This standard does not cover requirements for the electroconductive medium (gel) used to establish electrical contact between the patient electrodes and the skin, nor does it cover performance requirements for TENS leads/electrodes.

1.3.2 This standard does not cover requirements for line-powered TENS devices, diagnostic stimulators, stimulators for muscle exercise, electrostatic stimulators, electromagnetically coupled stimulators, or electrosleep devices.

Note: For an explanation of the need for this standard, and the rationale for its provisions, see Appendix B.

2. Applicable Documents.

The following document is applicable to the extent specified herein:

2.1 AAMI

American National Standard, *Safe Current Limits for Electromedical Apparatus* (ANSI/AAMI ESI—1985) [revision of ANSI/AAMI SCL 12/78]. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1978.

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3. Requirements

3.1 Labeling Requirements

In addition to the requirements of applicable federal regulations, labeling on or accompanying transcutaneous electrical nerve stimulators shall comply with the following requirements.

3.1.1 Device Markings

Federal regulations and labeling requirements of the Food and Drug Administration (FDA) specify that the device or its retail package display the established name of the device, the name and address of the manufacturer, a prescription legend, and other applicable information. In addition, a model number, lot number, and/or serial number shall be displayed on the stimulus generator; and labeling on or accompanying the device shall provide recommended storage conditions, or the following or substantially similar statement: "For storage conditions see package insert." Each TENS stimulus generator shall also be marked with the following functional information:

(1) The function of each control or adjustment intended for clinician or patient use shall be clearly identified with letters or symbols. The letters or symbols shall be defined in the appropriate clinician or patient informational materials.

(2) The direction of movement of a control that causes increases in output energy shall be clearly indicated.

(3) The "on" or "off" status of the stimulus generator shall be easily determinable by visual inspection.

(4) The polarity connections of the output (where applicable) shall be identified.

(5) If the output of the stimulus generator exceeds Q microcoulombs (μC) per pulse into a 500-ohm load, as defined in 3.2.2.2(1), the following warning statement, in these or substantially similar words, shall be placed on the device: "Not Recommended for Transthoracic Use."

3.1.2 Clinician Information

A package insert or information manual containing clinician information pertaining to the stimulus generator or TENS leads/electrodes or both, as appropriate, shall be supplied.

3.1.2.1 Stimulus Generator.

The following information concerning the stimulus generator shall be supplied to the clinician with each device:

(1) Name and place of business of the manufacturer;

(2) Instructions for properly unpacking the unit, if necessary, so that physical damage is prevented;

(3) Established name and trade name of the device;

(4) A statement that transcutaneous electrical nerve stimulators are indicated for use in the symptomatic relief and management of chronic pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain;

(5) A description of the medical conditions for which the device is contraindicated, if any1;

(6) Appropriate precautions and warnings advising the clinician of known hazards or side effects associated with the use of the device1;

(7) Adequate instructions for proper application, maintenance, and use of the device;

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(8) Electrical performance specifications for the device, including power sources and output parameters as determined according to the test methods of Section 4. Output characteristics determined by other methods may also be reported, along with the particulars of such methods. At least the following specifications shall be provided:

(a) A graphical representation of the typical output signals, showing voltage and current waveforms, at the midpoint of the specified range for adjustable parameters, obtained while the stimulus generator is loaded as specified in the test procedure of 4.1.2 (i.e., at 200 ohms, 500 ohms, and 1000 ohms); additionally, a statement shall be made describing the output characteristic as nominally constant current or nominally constant voltage, as applicable, over the resistance range of 4.1.2.

(b) A graphical representation of the typical output signals, showing voltage and current waveforms, at the midpoint of the specified range for adjustable parameters, obtained while the stimulus generator is operating in an open-circuit load condition (specifically, a load of at least 1 megohm);

Note: If the output signal is reduced to 0 by an open-circuit load, the graphical representation requirement of 3.1.2.1(8)(b) shall not apply.

(c) A graphical representation of the output waveform amplitudes, along with a description of the amplitude range, range of repetition rate, and range of pulse width. The output waveform amplitudes shown shall be those obtained for a 500-ohm (± 5 percent), purely resistive load.

(d) A description of outputs and their controllable parameters;

(e) Polarity of output, where applicable;

(f) A description of the power source, i.e., battery type, whether or not the battery is replaceable, and whether it is rechargeable or non-rechargeable; and

(g) A description of the battery condition monitor, if applicable.

(9) Mechanical specifications for the stimulus generator, including dimensions of the housing in centimeters and weight of the device (including batteries) in grams;

(10) A legend conforming with federal labeling requirements *(Code of Federal Regulations,* Title 21, Chapter 1, Section 801.109); and

(11) Instructions for the clinician's use in determining whether the stimulus generator is functioning properly.

3.1.2.2 TENS Leads/Electrodes.

Clinician information shall be supplied with each unit container for TENS leads/electrodes. This information shall include the following as a minimum:

(1) Name and place of business of the manufacturer;

(2) Instructions for properly unpacking the leads/electrodes, if necessary, to prevent physical damage, and recommended handling and maintenance instructions;

(3) Established name and trade name of the device;

(4) A statement that only an electrically conductive medium intended for use with TENS leads/electrodes is recommended by the TENS device manufacturer, if applicable;

(5) Any special precautions concerning the possible adverse effects of using leads/electrodes with

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stimulus generators having certain electrical characteristics; and

(6) The length of the lead (in centimeters) and the electrode area intended to contact the surface of the skin (in square centimeters).

3.1.3 Patient Information

Information for the patient shall be supplied with each stimulus generator, battery charger, and lead/electrode system, individually or combined as required, and this information shall include the following as a minimum:

(1) Name and place of business of the manufacturer;

(2) Established name and trade name of the device;

(3) Appropriate warnings and precautions for the use of the device;

(4) Adequate instructions for proper application, use, and maintenance of the device;

(5) A legend conforming with federal labeling requirements *(Code of Federal Regulations,* Title 21, Chapter 1, Section 801.109);

(6) For stimulus generators, a statement requesting the patient to consult his/her clinician if there is any change in an existing condition or if any new condition develops;

(7) For stimulus generators, a clear statement to the patient that this device is for symptomatic therapy only, that the transcutaneous electrical nerve stimulator is a prescription device, and that the device should not be given to other individuals; and

(8) For stimulus generators, space for the clinician to write any special instructions.

3.2 Safety and Performance Requirements for the Stimulus Generator

3.2.1 Electrical Safety

If the patient's leads can be connected to the stimulus generator and line power, the TENS system (including charger) shall meet the requirements of the American National Standard, *Safe Current Limits for Electromedical Apparatus* (Applicable Document 2.1).

3.2.2 Output Characteristics

3.2.2.1 Efficacy Considerations.

The stimulus generator shall produce *either:*

(1) A maximum output charge per pulse of at least 7 µC into a load of 500 ohms; *or*

(2) A complex waveform whose average stimulating component amplitude is at least 500 µA into a load of 500 ohms.

3.2.2.2 Safety Considerations.

The output of the stimulus generator shall exceed *neither* the maximum charge *nor* the maximum current levels specified below:

(1) Maximum charge per pulse: The warning of 3.1.1(5) shall be placed on the device if the maximum charge per pulse exceeds Q, where Q = 20 µC + (0.8)(35t) µC into a 500-ohm load (with t = pulse width in milliseconds and with pulse width measured at 50 percent of the pulse amplitude). In no event, even if there is a single component failure and even if the warning of 3.1.1(5) is placed on the device, shall the maximum charge per pulse, into a 500-ohm load, exceed 75 µC.

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(2) Maximum average current: The maximum average current shall not exceed 10 milliamperes (mA) (average absolute value) into a load of 500 ohms.

3.2.3 Functional Controls

3.2.3.1

The functional controls on stimulus generators designed to be worn on the patient shall be such that while the unit is in normal use, the output cannot be easily changed through inadvertent contact with the controls.

3.2.3.2

Unless interdependency of controls is clearly specified in the labeling, the output parameter associated with a given control shall not change by more than 5 percent of its adjusted value when the remaining controls are adjusted over their ranges in any combination.

3.2.4 Open/Short Circuit Performance

The stimulus generator shall function normally after any combination of open-and short-circuited conditions between output jacks, with the device operating for a minimum of 15 minutes in each condition at the maximum available settings of pulse width, pulse rate, and pulse amplitude.

3.2.5 Incorrect Battery Installation

If the design of the device is such that incorrect installation of batteries is possible, the device shall meet the following requirement: With the batteries installed incorrectly (i.e., with the supply voltage reversed from the normal operating polarity), and with pulse width, pulse rate, and pulse amplitude at their maximum available settings, a minimum of one half hour in the "on" condition and one half hour in the "off" condition shall not damage the device.

3.2.6 Environmental Performance

The stimulus generator shall withstand the temperature, humidity, water immersion, solvent resistance, vibration, and mechanical shock tests of 4.2.6. The acceptance criteria are defined in the test methods.

4. Test Methods.

This section contains test methods to provide means of verifying compliance with the reporting requirements of 3.1 and the safety and performance requirements of 3.2. Unless otherwise specified, these tests are to be conducted at 23°C ± 5°C and at a relative humidity between 0 and 80 percent. Also, the tests are to be conducted at the designed battery voltage of the device.

4.1 Compliance with the Labeling Requirements

4.1.1 Device Markings

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

4.1.2 Clinician Information

Compliance with the requirements of 3.1.2 can be verified by visual inspection, except for the electrical performance specifications required in 3.1.2.1(8). The test circuit of Figure 1 can be used to measure the output characteristics to be reported in the clinician information accompanying the stimulus generator.

4.1.3 Patient Information

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

4.2 Compliance with the Safety and Performance Requirements for the Stimulus Generator

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4.2.1 Electrical Safety

Test methods for verifying compliance with Applicable Document 2.1 are provided in that standard.

4.2.2 Output Characteristics

To determine compliance with the limits on output characteristics specified in 3.2.2, a 500-ohm purely resistive load is used in the test setup of Figure 1 (i.e., R_1 = 500 ohms, and R_2 and C are short-circuited).

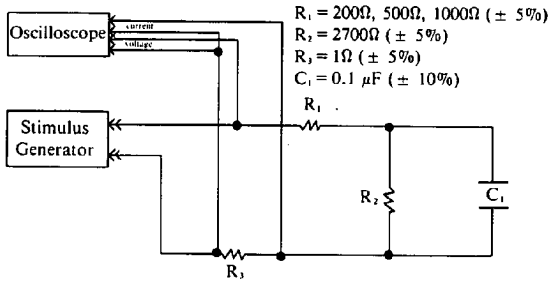

Figure 1. Test setup for waveform measurements.

4.2.3 Functional Controls

4.2.3.1

The design and construction of the device shall be inspected to evaluate whether appropriate consideration has been given to the safety requirement of 3.2.3.1.

4.2.3.2

The test setup of 4.1.2, Figure 1, with R_1 = 500 ohms, shall be used for the measurements needed to determine compliance with 3.2.3.2.

4.2.4 Open/Short Circuit Performance

The stimulus generator shall conform to the electrical performance specifications provided in the labeling, after operating for a minimum of 15 minutes under any combination of open- and short-circuited conditions. See also 3.2.4.

4.2.5 Incorrect Battery Installation

The stimulus generator shall conform to the electrical performance specifications provided in the labeling after a minimum use time of one half hour in the "on" condition and one half hour in the "off" condition, with the batteries installed such that the supply voltage polarity is reversed from the normal operating polarity. See also 3.2.5.

4.2.6 Environmental Performance

4.2.6.1 Temperature (Operating).

The following test shall be performed, both with output parameters set at the midpoint of their specified ranges and with output parameters set at their full maximum values: two full-temperature cycles shall be made between 0°C and +50°C, with a soak time of at least one hour at the temperature extremes. The device shall be operating continuously throughout this test, and the current output, voltage output, and pulse rate and duration monitored using the test setup of 4.1.2, with R_1 set at 500 ohms. Throughout the test, these parameters shall not differ by more than ± 20 percent from their values at room temperature, unless otherwise specified in the labeling.

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4.2.6.2 Humidity (Endurance).

The device shall be exposed to a temperature of at least 40°C and a relative humidity of 90 to 95 percent for 21 days. Batteries may be left in the unit with the unit turned off. Fresh batteries may be installed and any condensate in the circuitry removed after humidity exposure and before testing final electrical performance. The device shall conform to the electrical performance specifications provided in the labeling. Labels shall be legible and firmly attached after exposure.

4.2.6.3 Water Immersion.

The device, while operating with all parameters at maximum value, shall be immersed in distilled water for three minutes. The output shall be monitored and must not increase above the maximum output of 75 μC or 10 mA into a 500-ohm load (as specified in 3.2.2.2).

4.2.6.4 Solvent Resistance.

The exterior of the device shall be wiped or painted with the following common substances: 70 percent isopropyl alcohol, dish soaps and detergents, electrode gels. After a 1-minute period of exposure to these substances, labels shall be legible and firmly attached.

4.2.6.5 Vibration (Operating).

The device, while operating, shall be subjected to three sinusoidal vibration sweeps from 50 to 500 Hz in each of the three orthogonal axes at a level of 2.5 g peak. Each sweep shall be 15 minutes in duration. The electrical output shall be monitored before and after the sweeps. The stimulus generator shall perform within the electrical performance specifications provided in the labeling.

4.2.6.6 Mechanical Shock (Non-Operating).

The device shall be subjected to a half-sine shock of 850-g peak and 0.8-millisecond duration, in each of six orthogonal directions. The output characteristics of the device shall then be measured and shall conform to the electrical performance specifications provided in the labeling.

Note: Units not intended to be worn by the patient are exempted from this requirement.

5. Glossary

Electrode system conductive medium

A conformable substance that provides electrical contact between the electrode surface and the skin.

Lead

An insulated conductor having a means of connecting to a stimulus generator at one end and a means of connecting to an electrode at the other end, and intended for conducting output signals from a stimulus generator to an electrode.

Pulse

That portion of an electrical waveform between two zero voltage crossings.

Serial number

A unique combination of letters or numbers or both, selected by the manufacturer to identify an individual device.

Stimulus generator

A device that generates an output signal with characteristics controlled in a specified manner.

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TENS

Transcutaneous electrical nerve stimulation; transcutaneous electrical nerve stimulator.

Note: Conventional electrical terms used herein are defined in the IEEE Standard Dictionary of Electrical and Electronics Terms, ANSI/IEEE C42.100-1972(1978). New York, NY: Wiley-Interscience, 1978.

Appendix A*
Labeling/User Guidelines for Transcutaneous Electrical Nerve Stimulators (Contraindications, Warnings, Precautions)

A1. Introduction.

These guidelines provide recommendations concerning the warnings and precautions that should be identified by the manufacturer in labeling accompanying TENS devices and that should be considered by the user of TENS devices.

A2. Contraindications.

Except in the case of certain individuals using demand-type cardiac pacemakers, there are no known contraindications.

A3. Warnings.

It is recommended that the following warnings (in the suggested wording or its equivalent) be provided in the clinician information accompanying TENS devices and, as appropriate, in the patient information:

(1) A statement that stimulation over the carotid sinus may be hazardous;

(2) A statement that use of the device on patients with demand-type cardiac pacemakers may be hazardous;

(3) A statement that the safety of TENS devices for use during pregnancy or delivery has not been established;

(4) A statement that transcutaneous electrical nerve stimulation is a symptomatic treatment and as such may suppress the sensation of pain that would otherwise serve as a protective mechanism on the outcome of a clinical process; and

(5) A statement that persistent use of the device in the presence of skin irritation may be injurious and that improper use may result in electrode burns.

A4. Precautions.

It is recommended that the following precautions (in the suggested wording or its equivalent) be provided in the clinician information accompanying TENS devices and, as appropriate, in the patient information:

(1) A statement that TENS devices should be used with caution for undiagnosed pain syndromes where etiology has not been established;

(2) A statement that transcutaneous electrical nerve stimulation is not effective for pain of central origin, as compared to pain of peripheral origin;

(3) A statement that transcutaneous electrical nerve stimulation is of no known curative value;

(4) A statement that the treatment outcome will be influenced by the patient's psychological state and use of drugs;

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(5) A statement concerning the risk of skin burns if a metal electrode insert is not fully inserted and/or lies directly against the skin, if applicable;

(6) A statement that TENS devices should be used only under the medical supervision of a physician or under the supervision of a qualified medical practitioner to whom the patient is referred by a physician; and

(7) A statement that TENS devices should be kept out of reach of children.

Appendix B*
Rationale for the Development and Provisions of this Standard

B1. Introduction.

Portable battery-powered transcutaneous electrical nerve stimulators generally consist of a stimulus generator and signal delivery system; the signal delivery system consists of leads, electrodes, and an interface with the skin. The system is used to transmit electrical current to the nervous system through the skin. Transcutaneous electrical nerve stimulators are presently in wide use for the symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

This standard is restricted in scope to transcutaneous electrical nerve stimulators used in the treatment of pain syndromes, in order to: (1) embrace the largest area of use of TENS devices presently on the market; (2) allow timely development of the standard (certain to take longer if other TENS-type devices were included in the scope); (3) avoid placing requirements on other TENS-type devices that may not be appropriate to their design and application; and (4) allow for timely revision as necessary (certain to be delayed if a broader spectrum of devices were considered).

As noted in 1.3.1, this standard does not cover requirements for the electroconductive medium (gel) used to establish electrical contact between the patient electrodes and the skin, nor does it cover performance requirements for TENS leads/electrodes. At the time this standard was developed, there were insufficient data upon which to base such requirements, and the committee judged that, in the interests of completing the standard, TENS leads and electrodes should be addressed herein only via labeling requirements. The committee believes, however, that the development of consensus safety and performance criteria for the gel, leads, and electrodes would be beneficial in providing further assurance of safety and efficacy of the TENS system as a whole. Consequently, the committee has recommended that AAMI consider the initiation of such a standards-development effort. In the meantime, the limitations placed by this standard on the output of the stimulus generator provide reasonable assurance that at least one electrode-related risk, skin burns, can be minimized.

B2. Need for the Standard.

Active work on the development of a standard for transcutaneous electrical nerve stimulators began in 1974, with the objective of establishing labeling, safety, and performance criteria that would help assure that these devices could be used safely and effectively by patients. There was particular concern about the need to develop standard means of testing and reporting the performance characteristics of the stimulus generator, so that physicians obtaining TENS devices on behalf of patients would have available adequate information to compare and select from commercially available equipment.

In February 1976, the Food and Drug Administration (FDA) Advisory Panel on Review of Neurological Devices prepared a report providing its initial recommendations with respect to the classification of TENS devices for pain relief. This report, while acknowledging that "long term trials in this country have

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documented a degree of efficacy which is reasonable and acceptable, particularly in view of the very low potential risk to the patient and the absence of alternate low risk therapy," cited the need for improved device labeling, manufacturing controls, and design criteria in order to facilitate appropriate device application and performance.

In the *Federal Register* notice of 28 November 1978, the Food and Drug Administration published the recommendation of the Advisory Panel that TENS devices for pain relief be classified as Class II (Performance Standards) and that the establishment of a performance standard for these devices be a high priority. FDA, concurring with this recommendation, proposed in the notice that transcutaneous electrical nerve stimulators be regulated as Class II devices. Specific risks to health cited in the preamble of the proposed rule were skin burns "if the output current levels are excessive or if the electrodes are too small," and skin reactions to the electrode or electrode gel.

Public review of the proposed rule yielded no comments, and in the *Federal Register* notice of 4 September 1979, the FDA published a final rule classifying transcutaneous electrical nerve stimulators as Class II devices, effective 4 October 1979.

B3. Rationale for the Specific Provisions of the Standard

B3.1 Rationale for the Labeling Requirements.

The requirements of section 3.1 of the standard are intended to ensure that sufficient product information is available to the medical community and to patient users for the safe and effective use of transcutaneous electrical nerve stimulators.

B3.1.1 Device Markings.

The information that manufacturers must supply on or with TENS devices is primarily dictated by federal regulations and labeling requirements applicable to prescription devices in general *(Code of Federal Regulations,* Title 21, Chapter 1, Subchapter H, Part 801). The primary consideration at this level is to adequately identify the device to the clinician, rather than to provide performance specifications and operational data. The additional device marking requirements of 3.1.1 were judged necessary to allow the patient to safely use the device. It was considered essential that the patient be able to determine, by visual inspection, the on/off status of the device and the relative magnitude settings of the electrical output controls. Unexpected stimulation may cause patients to react with sudden motion, which may be harmful.

B3.1.2 Clinician Information.

The requirements for clinician information to be provided by the manufacturer were selected to ensure that clinicians would have available adequate information by which to choose and apply a TENS device for a particular patient. The clinician must be informed of applications, appropriate warnings and precautions, and technical data concerning the behavior of the device. Only by informing the clinician of the expected device performance can a device be selected with suitable characteristics for specialized patient needs.

The technical data specified in the clinician information requirements are those believed to be significant to the clinician when using the device in its intended manner; other parameters of interest from a purely engineering point of view have been omitted. Some of the requirements are conventional to achieve uniformity of measurement and communication.

Note: The specific requirement of 3.1.2.1(8)(b) was included because the committee members were aware of certain early TENS devices that produced very substantial voltage spikes due to transformer ringing, when operated in the open-circuit load condition. It was the consensus of the committee that any such ringing characteristic should be apparent to the prescribing physician.

B3.1.3 Patient Information.

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Since the patient manipulates and cares for the TENS device, it was considered important to require disclosure information specifically oriented to the patient. This information must convey instructions for use, as well as an understanding of the basic functioning of the device.

B3.2 Safety and Performance Requirements for the Stimulus Generator

B3.2.1 Electrical Safety.

The rationale for the specific risk current limits recommended in the American National Standard, *Safe Current Limits for Electromedical Apparatus,* is provided in the rationale statement which accompanies that standard.

B3.2.2 Output Characteristics

B3.2.2.1 Efficacy Considerations.

The clinical evaluation of the effectiveness of TENS devices is complicated by the subjective nature of pain relief. The development of definitive data concerning efficacious stimulus parameters has been further impeded by the lack of standardized reporting methods. Nevertheless, due to the importance of providing some assurance that TENS devices would perform as indicated, the committee evaluated the relevant medical literature in an attempt to develop minimum output requirements. Linzer and Long (1976) observed that the mean charge per pulse required to achieve pain relief in properly selected patients is less than 3 microcoulombs per pulse. The maximum charge needed to achieve pain relief was observed to be 18 microcoulombs.

Considerable attention was given by the committee to the selection of a proper load impedance for the testing of stimulators to verify adequate output. The electrode/skin impedance into which the stimulator works is essentially complex, providing a rising instantaneous impedance throughout the duration of the stimulating current pulse. In Figure 1, the test load circuit for waveform determination acceptably represents a typical pair of higher-impedance, standard TENS electrodes (5 cm x 5 cm) with R_1 set at 500 ohms, and a typical lower impedance pair with R_1 set at 200 ohms. For rectangular pulse durations of 20, 50, 100, 200, and 300 microseconds, the starting, peak end-pulse, and time-averaged instantaneous impedances are for lower impedance electrodes as in Table B1; values for high impedance electrodes are shown in parentheses. As a practical compromise, a value for test load impedance of 500 ohms resistive was selected.

Based on the above considerations, the committee evolved the requirement that the maximum available output of the stimulus generator be at least 7 microcoulombs per pulse into a resistive load of 500 ohms or, for a complex waveform, an average current of at least 500 microamperes into a resistive load of 500 ohms. The two approaches to defining the output requirements were developed to allow application of the criteria to the various types of TENS devices in conventional use.

Table B1

	Instantaneous Impedance (ohms)		
Pulse Duration (μs)	*Starting*	*Peak*	*Time-Averaged*
20	200 (500)	393 (693)	298 (598)
50	200 (500)	656 (956)	435 (735)
100	200 (500)	1036 (1336)	644 (944)
200	200 (500)	1613 (1913)	933 (1233)
500	200 (500)	2011 (2311)	1270 (1570)

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B3.2.2.2 Safety Considerations.

In order to limit the hazard associated with possible inadvertent excitation of the heart, it is necessary to set a limit on the maximum possible output of the stimulus generator. The data published by Zoll and Linenthal (1964) show that the charge per pulse needed to exceed the threshold for cardiac excitation is approximately linear over the range of pulse widths between 0.5 and 5 milliseconds (msec). This same paper provides a comparison of the external stimulation threshold to the internal stimulation threshold. Based on data points given in the 0.5 to 5-msec range (ibid, Figure 3), the expected value for producing cardiac stimulation was estimated to be between 100 and 325 microcoulombs (μC). This was based on the observation that the ratio between the external threshold current and the internal threshold current, under the conditions of the Zoll and Linenthal study, appeared to 50:3. The nature of the cardiac stimulation observed by Zoll and Linenthal was that 50 milliamperes applied for a duration of 2 milliseconds (i.e., 100 μC) was the minimum total charge that, applied externally in an optimum location, would result in a single early beat. Stimulus intensities ten times greater were required in order to produce fibrillation under conditions where the stimulus is applied at the optimum location for heart stimulation.

Subsequent communication with Zoll, a presentation by Cywinski and Zoll at the 1982 AAMI Annual Meeting, and a review of the medical literature concerning the transmembrane potentials for cardiac pacing cells provided new information for pulses of less than 100-microsecond (μsec) duration. As empirically derived by Cywinski and Zoll, the expression for current needed to reach the minimum cardiac stimulation threshold with a rectangular dc pulse is: $I = 20/t + 35$, where I = ma and t = msec. Since It = Q = microcoulombs, it follows that Q = 20 microcoulombs + 35 t for pulse widths (durations) t. The data from which these formulae were derived were obtained with small electrodes on optimal locations and with dc pulses. The relatively large electrodes normally used with TENS and the fact that most TENS devices produce ac pulses provides an additional safety factor.

In the course of developing the standard, the committee considered arguments in favor of limiting output charge to 25 microcoulombs (75 microcoulombs if the device were labeled as not intended for transthoracic use), versus specifying the stimulus generator output requirements in terms of the above formula. The committee ultimately opted to utilize the formula for purposes of the performance requirement, since it provided a means of realistically relating pulse parameters to potential cardiac stimulation. It was agreed, though, that the formula should be modified to provide additional assurance of safety, that a labeling provision should be retained to address the concerns of some reviewers about the potential risks associated with transthoracic use of certain TENS devices, and that an absolute limit of 75 microcoulombs should be placed on charge per pulse. It was judged that if the performance requirement was to be based on the extreme case observed in the Zoll and Linenthal study (i.e., a 100-μC stimulus, optimally applied for cardiac stimulation), an additional "safety factor" could be built into the formula by multiplying the second term by 0.8. Also, specifying that the charge be calculated with the pulse width measured at the mid-point of the pulse amplitude ensures that the maximum available charge will be measured for purposes of ascertaining compliance with the requirement. Lastly, the committee reasoned that the modified formula would provide ample assurance of both safety and efficacy, since newer-model TENS devices typically employ outputs that cannot be adjusted beyond 25 μC per pulse ("Q" for typical pulse widths) and since one of the few published studies of TENS efficacy suggested that the maximum charge needed to achieve pain relief is 18 μC (Linzer and Long, 1976; see also B3.2.2.1).

The committee was concerned that the stimulus generator output requirements allow some latitude in device design, especially in view of the paucity of data establishing stimulus efficacy criteria (see B3.2.2.1). Also, the committee was aware that the use of low-frequency pulses, with substantially higher charges, is being attempted clinically for some patients. It was considered improbable that the "worst-case" conditions of the Zoll and Linenthal study would be encountered in the conventional use of TENS devices.

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The committee originally considered specifying an impedance lower than 500 ohms for safety testing; i.e., for determining that a pulse charge of Q (or 75) microcoulombs was not exceeded. However, after reviewing actual test data on several typical stimulators operating into a range of resistive and complex impedances, the latter being the three impedances of Figure 1, and also considering the range of electrode impedances encountered in practice, it was decided that a value of 500 ohms resistive, as for efficacy testing, would be appropriate. Higher stimulator pulse charge outputs are associated with longer pulse durations, where the time-averaged electrode/skin impedances are higher (Table B1).

Lower impedance electrodes are invariably larger, making them far less optimum for cardiac stimulation than the configuration used in the Zoll and Linenthal experiments. Furthermore, when larger electrodes are used, they are almost always long, narrow ones which are placed on either side of an incision for postoperative pain relief. This arrangement confines the major part of the current to superficial tissues. Both these considerations provide an automatic safety factor, should the stimulator output tend to increase with decreasing load impedance.

The committee ultimately devised a requirement for maximum charge per pulse, into a resistive load of 500 ohms, where the absolute limit would be defined as 75 μC, and Q μC would be defined as the limit above which special labeling would be required and as a guide for design qualification of specific device types.

The committee also deemed it important that the standard provide means of assuring the safety of various commercially available TENS devices that produce a dc output. The presence of a dc component in the output can introduce the additional hazard of skin burn. It was the eventual consensus of the committee that a limit on dc current of 10-milliampere stimulus output would provide reasonable protection against skin burn. Further, because the effective skin impedance is many times greater for dc, as compared to ac, currents, the specification of a 500-ohm resistive load creates an additional safety margin.

Several times during the development of the standard, the committee considered the possibility of excluding from the scope of the standard stimulus generators that produce dc waveforms. After extensive discussion, however, the committee decided to include such stimulus generators, provided that they meet the requirements of 3.2.2.2. The committee's reasoning was as follows: (1) The committee was aware of the existence of at least one commercially available device and of clinical reports of its efficacy. Also, the device in question appeared to exhibit no greater clinical risks than other stimulus generators included in the scope of the standard. (2) The standard limits dc stimulators to those providing pulses or waveforms that are on for short periods of time and then turned off (the charge limits guarantee an off time). Under the conditions specified, the human body is a largely capacitive, rather than resistive, electrical load. In practical terms, this means that most of the charge produced by the stimulus generator is stored on the skin and returned to the stimulus generator during its off time; i.e., under actual use conditions, the output is effectively ac. (3) It was the consensus of the committee that all other aspects of the standard applied to such stimulus generators and that to eliminate them from the scope of the standard would be unnecessarily restrictive.

B3.2.3 Functional Controls

One potential hazard associated with the use of TENS devices is injury as a result of the reaction of the patient to unexpected stimulation or to a sudden, unexpected increase in stimulation. The requirements of 3.2.3 were developed in order to address this hazard.

B3.2.4 Open/Short Circuit Performance.

Accidental open or short-circuiting of the device may occur in the course of normal use by the patient. The intent of requirement of 3.2.4 is to ensure that the electrical performance of the device will not be impaired as a result of a reasonable period of use under these conditions.

B3.2.5 Incorrect Battery Installation.

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There is a substantial probability that in the course of normal use of the device by the patient, the batteries will be incorrectly installed (that is, the supply voltage will be inadvertently reversed). Therefore, it was considered necessary to require that the device be capable of withstanding this likely misuse without impairment of performance. Some TENS devices are designed in such a way that it is not possible to install the batteries incorrectly, and these devices are, of course, exempted from the requirement.

B3.2.6 Environmental Performance.

Since TENS devices are customarily portable and designed to be worn by the patient during his/her normal activity, it can be expected that the device will be subjected to mechanical shock and other adverse environmental conditions. The requirements of 3.2.6 and the test conditions of 4.2.6 are intended to simulate the "wear and tear" that the device could be expected to encounter in normal use. In particular, the purpose of the water immersion test of 4.2.6.3 is to protect the patient from a dangerous pulse in the event that the pulse generator is dropped into a water closet or sink while in use. The committee's primary concern was that the change in capacitance of a transformer when the air in the windings is replaced with water might substantially increase the output. The test is not intended to ensure, however, that the device itself will not be damaged. Distilled water is specified because its low conductivity (relative to most tap water) represents a "worst-case" condition for the test. With respect to the mechanical shock test of 4.2.6.6, the specified shocks are intended to yield reproducible test results approximating the effects of dropping the device onto a concrete surface from a height of 3 feet.

B4. Rationale for the Test Methods.

The test methods of Section 4 are provided so that the TENS manufacturer or other user of the standard can establish conformance with the requirements of Section 3. Also, these referee tests ensure uniformity in reporting the performance specifications for the output of stimulus generators. It was intended by the committee that the TENS manufacturer be free to select, in addition to the referee tests, different models and to provide more data than the minimum information required by the standard.

The test setup of 4.1.2, Figure 1, was developed to roughly simulate the interface between the TENS system and the skin. This model is consistent with that provided in Robinson (1968). In Figure 1, R_1 was selected to represent the electrical resistance of the stimulus delivery system (leads and electrodes); R_2 and C_1 were selected to approximate the impedance of the body for a typical stimulus generator.

Rationale for Appendix A. Labeling Guidelines.

The labeling guidelines for the reporting of contraindications, warnings, and precautions associated with TENS devices were developed as recommendations based on the current state of medical knowledge. These guidelines are provided as an appendix, rather than in the text of the standard, because they are intended to be flexible enough to rapidly accommodate new clinical data. Both users and manufacturers of TENS devices should therefore consider these guidelines as general recommendations rather than essential requirements.

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Annotations from NS4.pdf

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Annotation 1; Label: AAMI; Date: 9/28/2000 2:43:21 PM
* This Foreword does not contain provisions of the American National Standard for Transcutaneous Electrical Nerve Stimulators (ANSI/AAMI NS4 — 1985), but does provide important information about its development and intended use.

Annotation 2; Label: AAMI; Date: 12/6/2000 4:31:51 PM
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Annotation 1; Label: AAMI; Date: 9/28/2000 2:44:11 PM
1 See Appendix A for guidelines.

Annotation 2; Label: AAMI; Date: 9/28/2000 2:44:42 PM
1 See Appendix A for guidelines.

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Annotation 1; Label: AAMI; Date: 9/28/2000 11:15:11 AM
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Annotation 1; Label: AAMI; Date: 9/28/2000 11:16:50 AM
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