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## **Transcutaneous electrical nerve stimulators**



**Association for the Advancement  
of Medical Instrumentation**

1110 N. Glebe Rd., Suite 220

Arlington, VA 22201-4795

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**McKenna & Cuneo, L.L.P.**  
**1900 K Street, N.W.**  
**Washington, DC 20006**  
**Attn: Jacqueline A. Henson, Esq.**  
**Phone: (202) 496-7500**

**AAMI Standard for Transcutaneous Electrical Nerve Stimulators**

Developed by  
**Association for the Advancement of Medical Instrumentation**

Approved 1986; reaffirmed 10 August 2009

**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  
Eric R. Cosman, Ph.D., Radionics  
Robert M. Crowell, M.D., University of Illinois, Chicago  
Ronald Doctors, General Medical Industries  
Marc A. Flitter, M.D., Miami Beach, FL  
Wesley T. Frazier, M.D., American Society of Anesthesiology  
Harry Friedman, M.D., Memphis Neurosurgical Clinic  
Edward Ganz, M.D., Lawrence Berkeley Laboratory, University of  
California, Berkeley  
Eric King-Smith, Ph.D., 3M Medical Products Laboratory  
Nir Kossovsky, M.D., The New York Hospital — Cornell Medical  
Center, New York, NY  
Pierre L. LeRoy, M.D., Wilmington, DE  
Alex Lifson, M.D., Sister Kenny Institute, Minneapolis  
Saul Liss, Pain Suppression Laboratories, Inc.  
Donlin Long, M.D., Johns Hopkins Hospital  
Carl P. Mason, M.S.B.E., VA Rehabilitation Center, New York, NY

Robert Munzner, Ph.D., Center for Devices and Radiological Health,  
FDA  
Roger Paulson, Medtronic  
Richard Penn, M.D., Rush Presbyterian/St. Luke's Medical Center,  
Chicago, IL  
Michael Salcman, M.D., University of Maryland, Baltimore  
Sidney Steinberg, Ph.D., consultant, Spring Valley, NY  
Marvin Sussman, Ph.D., Cordis Corporation  
Thomas H. Thomson, consultant, Boulder, CO  
Clark Watts, M.D., University of Missouri Health Science Center,  
Columbia  
Stephen L. Weitz, M.D., Albert Einstein School of Medicine, Bronx,  
NY

*Alternates:* Deryck Duncalf, M.D., American Society of Anesthesiology  
Keith Mullett, Medtronic  
R. L. Pratt, 3M Medical Products Laboratory  
Peter Tarjan, Ph.D., Cordis Corporation

#### TENS Subcommittee

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The TENS Subcommittee has the following members:

*Cochairmen:* Richard Black, M.D.  
Thomas H. Thomson

*Members:* William W. Abraham, Consolidated Medical Equipment  
Richard Black, M.D., Johns Hopkins Hospital  
Gilbert Buchalter, R.P., M.Sc., Pharmaceutical Innovations  
Alan Coombes, Codman and Shurtleff  
Eric R. Cosman, Ph.D., Radionics  
Ronald Doctors, General Medical Industries  
George J. Frye, Frye Electronics  
Eric King-Smith, Ph.D., 3M Medical Products Laboratory  
Pierre L. LeRoy, M.D., Wilmington, DE  
Kenneth Levin, Ntron Electronics  
Saul Liss, Pain Suppression Laboratories  
Carl P. Mason, M.S.B.E., VA Rehabilitation Center, New York, NY  
George E. Mathieson, EMPI  
Robert Munzner, Ph.D., Center for Devices and Radiological Health,  
FDA  
Donald Osborne, M.D., San Antonio, TX  
Roger Paulson, Medtronic  
Sidney Steinberg, Ph.D., consultant, Spring Valley, NY  
Marvin Sussman, Ph.D., Cordis Corporation  
Thomas H. Thomson, consultant, Boulder, CO

*Alternate:* Whit Athey, Center for Devices and Radiological Health, FDA

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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.*

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#### Foreword\*



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](#).*