American National Standard

ANSI/AAMI NS4:2013

Transcutaneous electrical nerve stimulators

AAMI
Advancing Safety in Medical Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

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ANSI/AAMI NS4:2013
(Revision of AAMI NS4:1986(R)2009)

Transcutaneous electrical nerve stimulators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 20 March 2013 by
American National Standards Institute Inc.

Abstract: This standard establishes labeling, safety, and performance requirements and referee tests for transcutaneous electrical stimulators (including TENS) intended for use in the treatment of pain syndrome. Also covered are labeling requirements for patient leads and electrodes.

Keywords: electromedical equipment, labeling, electrical safety, transcutaneous electrical stimulators, leads, electrodes

AAMI Standard

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Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Dr., Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 1–57020–495–0

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Transcutaneous Electrical Stimulator Working Group

This standard was developed by the AAMI Transcutaneous Electrical Stimulator Working Group under the auspices of the AAMI Neurosurgery Standards Committee. Working Group approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Transcutaneous Electrical Stimulator Working Group** had the following members:

Cochairs: Robert J. DeLuca, FDA/CDRH

Members: Masahiro Ando, Omron Healthcare Co Ltd
Richard North, MD, Sinai Hospital of Baltimore (Independent Expert)
Donald Osborne, MD PE (Independent Expert)
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NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

At this time this document was published, the **AAMI Neurosurgery Committee** had the following members:

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Ashish Shah, PhD, Greatbatch Inc.

Members: Robert J. DeLuca, FDA/CDRH
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NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

This standard was developed by the Transcutaneous Electrical Stimulator working group under the auspices 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. This second edition updates references and corrects typographical errors.

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 that 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.

This standard should be considered flexible and dynamic. As technology advances and as new data are brought forward, the standard will be reviewed and, if necessary, revised.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to: Standards Department, AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the ANSI/AAMI NS4:2013, Transcutaneous electrical nerve stimulators, but it does provide important information about the development and intended use of the document.

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 Annex B.

2 Normative references

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

ANSI/AAMI ES60601-1:2005/(R)2012 (IEC 60601-1:2005, MOD), *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*. Association for the Advancement of Medical Instrumentation. Arlington, VA.

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.

