American National Standard

ANSI/AAMI EC12:2000/(R)2010

Disposable ECG electrodes

AAMI Association for the Advancement of Medical Instrumentation

The 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 health care 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 standard's 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.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Vice President, Standards. 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 that has not been developed and communicated in accordance with this procedure and that is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

American National Standard

ANSI/AAMI EC12:2000
(Revision of ANSI/AAMI EC12:1991)

Disposable ECG electrodes

Developed by
Association for the Advancement of Medical Instrumentation

Approved 13 May 2000 and reaffirmed 24 August 2010 by
American National Standards Institute, Inc.

Abstract: This standard contains minimum labeling, safety, and performance requirements; test methods; and terminology for disposable electrocardiographic (ECG) electrodes.

Keywords: disposable electrodes, ECG monitoring, pregelled, nonpolarizing, electrode system

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

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Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph (ECG) Committee

This standard was developed by the ECG/Electrodes Working Group of the Electrocardiograph Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was balloted, the **AAMI Electrocardiograph Committee** had the following members:

Cochairs:	James J. Bailey, MD
	David Mortara, PhD
Members:	James J. Bailey, MD, National Institutes of Health
	Alan S. Berson, PhD, National Heart, Lung, and Blood Institute
	David L. Daly, U.S. Food and Drug Administration
	Arthur R. Eddy, Jr., ConMed Corp.
	Stacy Gehman, Quinton Instrument Co.
	Paul Lander, Flow Metrix, Inc.
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	David Mortara, PhD, Mortara Instrument, Inc.
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Alternate:	Robert J. Cangelosi, U.S. Food and Drug Administration

At the time this document was balloted, the **ECG/Electrodes Working Group** had the following members:

Cochairs:	David L. Daly
	Arthur R. Eddy, Jr.
Members:	Alan S. Berson, PhD, National Heart, Lung, Blood Institute
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	David L. Daly, U.S. Food and Drug Administration
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	Kevin Katzenmaier, 3M Healthcare
	Carla Mond, Agilent Technologies
	Michael Simon, ConMed 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 revised standard (third edition) was developed by the ECG Electrodes Working Group of the AAMI ECG Committee. The objective of this standard is to provide minimum labeling, safety, and performance requirements that will help ensure safety and efficacy in the clinical use of disposable electrocardiographic (ECG) electrodes.

One of the most significant changes in this edition is the inclusion of the adhesive performance section, which was not included in earlier editions because of the lack of data. In the second edition of this standard, one of the most significant changes made in revising this standard (which was first approved in August 1984) was the expansion of the scope to cover all disposable electrodes in keeping with new products on the market. In addition, biocompatibility and pre-attached leadwire safety requirements have been added to the performance requirements.

Many of the electrical performance requirements and methodologies set forth in this standard are based on studies performed at the UBTL Division of the University of Utah Research Institute, under contract with the Food and Drug Administration (FDA), Bureau of Medical Devices. The contributions of UBTL and FDA personnel to this standard's development effort are gratefully acknowledged.

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

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 the present time.

As used within the context of this standard, "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 is undesirable but 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 "unalterable" situations.

Suggestions for improving this standard are invited. Comments or suggested revisions should be sent to AAMI, Vice President of Standards, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword is not a part of the American National Standard, *Disposable ECG electrodes* (ANSI/AAMI EC12:2000).

Disposable ECG electrodes

1 Scope

This standard establishes minimum labeling, safety, and performance requirements for disposable electrodes used for diagnostic electrocardiography (ECG) or ECG monitoring.

1.1 Inclusions

Included within the scope of this standard is any disposable ECG electrode system (see 3.4).

1.2 Exclusions

Devices excluded from the scope of this standard are active electrodes, needle electrodes, reusable (nondisposable) electrodes, electrodes intended to deliver therapeutic energy, and electrodes primarily designed for the measurement of physiologic signals other than the electrocardiogram (e.g., electrodes used with apnea monitors, if the electrode is used for non-ECG purposes, e.g., impedance plethysmography). Also, requirements for electrolyte composition are not covered by this standard.