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Disposable ECG electrodes

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Advancing Safety in Health Technology

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American National Standard

ANSI/AAMI EC12:2000/(R)2020
(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 and 30 December 2015 and 9 October 2020 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

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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.
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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 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).

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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.

2 Normative references

The following standards contain provisions that, 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 editions of the standards indicated below. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid AAMI/American National Standards.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Cardiac monitors, heart rate meters, and alarms.* ANSI/AAMI EC13:1992. Arlington (Vir.): AAMI, 1992. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *ECG cables and leadwires.* ANSI/AAMI EC53:1995. Arlington (Vir.): AAMI, 1995. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Biological evaluation of medical devices—Part 1: Evaluation and testing.* ANSI/AAMI/ISO 10993–1:1997. Arlington (Vir.): AAMI, 1997. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied.* AAMI/ISO TIR15223:1999. Arlington (Vir.): AAMI, 1999. AAMI/ISO Technical Information Report.

3 Definitions and abbreviations

For the purposes of this AAMI standard, the following definitions and abbreviations apply.

3.1 DC offset voltage: The voltage across a gel-to-gel electrode pair due to the difference in their electrode half-cell potentials.

3.2 disposable: Designed for single patient use.

3.3 ECG: Electrocardiograph; electrocardiography.

3.4 electrode system: A device composed of a sensing element and an electrolyte provided with the sensing element by the manufacturer or specified by the manufacturer.

NOTE—That is, the sensing element may be pregelled or be a conductive semisolid (see 3.9), or it may require application of an electrolyte by the end user according to manufacturer's instructions (non-pregelled).

3.5 impedance: A combined measure of the opposition to current through the electrode interface (resistance) and of the ability to store charge at the interface (capacitive reactance), in response to a sinusoidal current.