List of Titles

American National Standard

ANSI/AAMI EC12:2000

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.

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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*.

List of Titles

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 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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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.

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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.
	George Moody, Massachusetts Institute of Technology
	David Mortara, PhD, Mortara Instrument, Inc.
	Shankara Reddy, PhD, Marquette Medical Systems, 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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Alternates:	John Hughes, GE-Marquette Medical Systems, Inc.
	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).

American National Standard **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.

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.

3.6 nonpolarizing electrode: An electrode that will not form a DC offset voltage when subjected to a DC current at a level normally encountered in clinical use.

3.7 offset instability: The rate of change in DC offset voltage over a period of time due to variations in the half-cell potential of the electrode.

3.8 pouch: The smallest package, for a specific model, that still provides protection for the electrode from environmental conditions.

3.9 pregelled electrode: An electrode in which the manufacturer has placed the electrolyte in contact with the sensing element.

3.10 simulated defibrillation recovery: A test that will evaluate the ability of the electrode to allow the ECG trace to return after defibrillation.

4 Requirements

4.1 Labeling requirements

In addition to the requirements of applicable federal regulations, the labeling for disposable ECG electrodes shall comply with the provisions of this section. The labeling accompanying the device shall include, as a minimum, the following information:

a) a statement indicating the date beyond which conformance of the device with the requirements of this standard cannot be assured (for example, “use before _____”) and the lot number, or a statement indicating the date of manufacture, shelf life, and lot number;

b) appropriate precautions and warnings, including limits of duration of electrode application and an indication of the useful out-of-pouch shelf life of the product; if the electrode should be used immediately upon opening the pouch, then an appropriate caution shall be indicated;

c) appropriate instructions for use, including procedures for skin preparation, and for electrode preparation if the electrode is not pregelled (for example, gel type and gel amount);

d) instructions concerning storage requirements, if applicable.

NOTE—Due to space constraints, particularly on the smaller packages/pouches of ECG electrodes, and because AAMI/ISO TIR15223 is globally accepted, symbols from AAMI/ISO TIR15223 should be used where appropriate in the labeling.

Table 1 provides a summary of the labeling requirements of this standard.

Table 1—Summary of labeling requirements

Section	Requirement description
4.1 a)	A date beyond which the device will not conform to the standard’s performance requirements; lot number; or date of manufacture and shelf life
4.1 b)	Appropriate precautions and warnings, including limits of electrode-application duration; useful out-of-pouch shelf life
4.1 c)	Appropriate instructions for use, including skin-preparation procedures and electrode-preparation procedures
4.1 d)	Instructions concerning storage requirements

Note: Symbols from AAMI/ISO TIR15223 should be used where appropriate in the labeling.

4.2 Performance requirements

4.2.1 Packaging and shelf life

The device shall be manufactured and packaged in such a way that all requirements of this standard will be met up to the “use before” date specified by the manufacturer according to 4.1 a), under the storage conditions recommended by the manufacturer according to 4.1 d).

4.2.2 Electrical performance

4.2.2.1 AC impedance

The average value of 10-hertz (Hz) impedance for at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak (p-p), shall not exceed 2 kilohms (kΩ). None of the individual pair impedances shall exceed 3 kΩ.

4.2.2.2 DC offset voltage

After a 1-minute (min) stabilization period, a pair of electrodes connected gel-to-gel shall not exhibit an offset voltage greater than 100 millivolts (mV).

4.2.2.3 Combined offset instability and internal noise

After a 1-min stabilization period, a pair of electrodes connected gel-to-gel shall not generate a voltage greater than 150 microvolts (μV) p-p in the passband (first-order frequency response) of 0.15 to 100 Hz, for a period of 5 min following the stabilization period.

4.2.2.4 Defibrillation overload recovery

Five sec after each of four capacitor discharges, the absolute value of polarization potential of a pair of electrodes connected gel-to-gel shall not exceed 100 mV. The capacitor discharge overload shall consist of a 10-microfarad (μF) capacitor charged to 200 volts and discharged through the electrode pair with 100 Ω in series. During the 30-sec interval following each polarization potential measurement, the rate of change of the residual polarization potential shall be no greater than ± 1 mV/sec. After the electrode pair has been tested for compliance with this requirement, the 10-Hz impedance of the electrode pair shall not exceed 3 kΩ.

4.2.2.5 Bias current tolerance

The observed DC voltage offset change across a pair of electrodes connected gel-to-gel shall not exceed 100 mV when the electrode pair is subjected to a continuous 200-nanoampere (nA) DC current over the period recommended by the manufacturer for the clinical use of the electrodes. In no case shall this period be less than 8 hours.

Table 2 provides a summary of the performance requirements of this standard.

Table 2—Summary of performance requirements

Section	Requirement description	Test conditions	Units	Value (Min/Max)
4.2.1	All requirements of this standard shall be met	Up to the “use before” date according to 4.1 a), under the storage conditions according to 4.1 d)		
4.2.2.1	Average value of 10-Hz impedance for 12 electrode pairs Individual pair impedance	Pairs connected gel-to-gel, impressed current not exceeding 100 μA	kΩ kΩ	2 (max) 3 (max)
4.2.2.2	Offset voltage	Pair connected gel-to-gel, after 1-min stabilization	mV	100 (max)
4.2.2.3	Combined offset instability and internal noise	Pair connected gel-to-gel, after one-minute stabilization period, in the passband of 0.15 to 100 Hz, for 5 min	μV	150 (max)
4.2.2.4	Defibrillation overload recovery (polarization potential) Rate of change of polarization potential After test, 10-Hz electrode impedance	Pair connected gel-to-gel, 5 seconds after each of four discharges of 200 volts During 30-sec interval following polarization potential measurement	mV mV/sec kΩ	100 (max) 1 (max) 3 (max)
4.2.2.5	DC voltage offset	Pair connected gel-to-gel, continuous 200 nA DC current applied over clinical use period (in no case less than 8 hours)	mV	100 (max)

4.3 Safety requirements

4.3.1 Biological response

The device shall be biocompatible. For this application (i.e., an electrode in contact with the skin) biocompatibility requires evaluation of cytotoxicity, skin irritation, and either skin sensitization or intracutaneous reactivity.

4.3.2 Pre-attached leadwire safety

Electrodes with pre-attached (permanently attached) leadwires shall be constructed in such a manner that the leadwire connector used to mate with the instrument trunk cable cannot contact ground or a possibly hazardous potential. In particular, this connector shall be constructed to prevent conductive contact with a mains outlet or a detachable power cord.

NOTE—ANSI/AAMI EC53:1995, *ECG cables and leadwires*, should be reviewed and considered in the process of designing and manufacturing ECG electrodes with pre-attached leadwires.

4.4 Adhesive performance (duration of use)

The electrode's adhesive performance, as it impacts the duration of use, should meet the claims or applications that the manufacturer has indicated. For example, for a short-term, resting electrocardiogram, an adhesive should be able to maintain its contact to the body for a period of time normally associated with this procedure; a projection would be from 5 min to 30 min. Long-term monitoring, on the other hand, may require the electrode to be on the patient for a period of days, depending upon hospital protocol. Therefore, an adhesive that is to be utilized in an ECG electrode should have performance characteristics that meet the intended use of the device.

5 Tests

This section contains test methods that provide means of verifying the performance and safety of disposable ECG electrodes. These test methods and procedures are intended as referee tests in determining compliance with the requirements of 4; while they may be used for design qualification, they are not necessarily suitable for purposes of quality assurance. The paragraphs of this section are numbered, with the exception of the first digit, to correspond to the requirements of 4; for example, compliance with 4.2.2.1 can be determined by the test method of 5.2.2.1.

NOTES—

1) Unless otherwise specified in 4, it is not necessarily intended that the same electrode pairs be used for the full series of tests. Also, unless the number of electrode pairs to be tested is specified in section 4, "n" electrode pairs in the tests means the number needed to establish, statistically, that the performance of the electrode pairs tested is representative of the product type.

2) For non-pregelled electrodes, tests shall be conducted with electrolyte applied in accordance with manufacturer's instructions.

5.1 Labeling

Compliance with the requirements of 4.1 a), 4.1 c), and 4.1 d) can be determined by inspection. For 4.1 b), if an out-of-pouch shelf life is indicated, the tests of 5.2.2 shall be applied to verify that acceptable performance is maintained for the period indicated by the manufacturer.

5.2 Performance

5.2.1 Packaging and shelf life

The tests of 5.2.2 can be used to determine whether the packaging is adequate to preserve the performance characteristics of the electrode over the shelf life specified by the manufacturer.

5.2.2 Tests for electrical performance

NOTE—All tests shall be performed at 23° C ± 5° C, and 40% ± 10% relative humidity.

5.2.2.1 AC impedance

The impedance of a pair of electrodes connected gel-to-gel can be determined by applying a sinusoidal current of known amplitude and observing the amplitude of the resulting voltage across the electrodes. The magnitude of the impedance is the ratio of the amplitude of the voltage to that of the current. An adequate current generator can be assembled utilizing a sinusoidal signal (voltage) generator with a 1-megohm (MΩ) (or greater) resistor in series with the electrode pair. The level of the impressed current should not exceed 100 μA p-p.

5.2.2.2 DC offset voltage

The DC offset voltage shall be measured by connecting two electrodes gel-to-gel to form a circuit with a DC voltmeter having a minimum input impedance of 10 MΩ and a resolution of 1 mV or better. The measuring instrument shall apply less than 10 nA of bias current to the electrodes under test. The measurement shall be made after a 1-min stabilization period but before 1.5 min have elapsed.

5.2.2.3 Combined offset instability and internal noise

After a 1-min stabilization period, the output voltage of the test circuit (figure 1) shall not exceed 150 μV p-p over 5 min. Output voltage shall be measured with an instrument having a frequency response range of 0.01 to 1,000 Hz and a minimum input impedance of 10 MΩ. Alternatively, an oscilloscope with 1-MΩ input impedance may replace the 1-MΩ resistor shown in figure 1. Component tolerance shall be ± 10%. Capacitors shall be nonpolar.

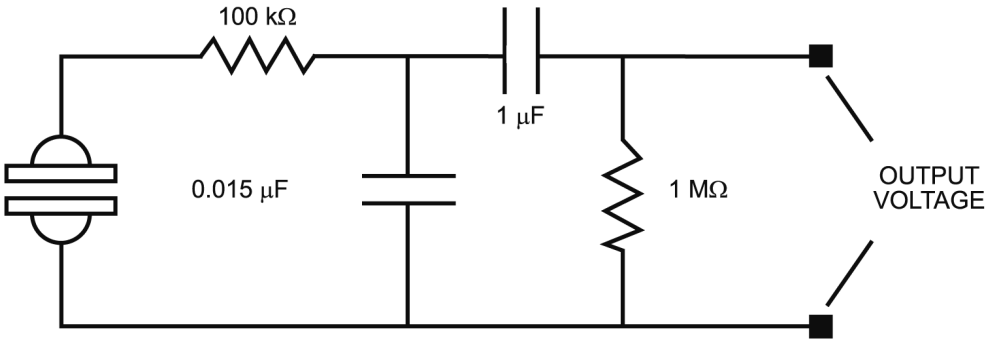

Figure 1—Test circuit for offset instability/internal noise determination

5.2.2.4 Defibrillation overload recovery

This test measures the electrode's ability to reduce its acquired voltage, permitting the ECG trace to return after defibrillation, and shall be conducted as follows:

a) A pair of electrodes shall be connected gel-to-gel and joined to the test circuit (figure 2) with switch SW1 closed and SW2 and SW3 open.

b) At least 10 sec must be allowed for the capacitor to fully charge to 200 V; switch SW1 is then opened.

c) The capacitor is immediately discharged through the electrode pair by holding switch SW2 closed long enough to discharge the capacitor to less than 2 V. (This time shall be no longer than 2 sec).

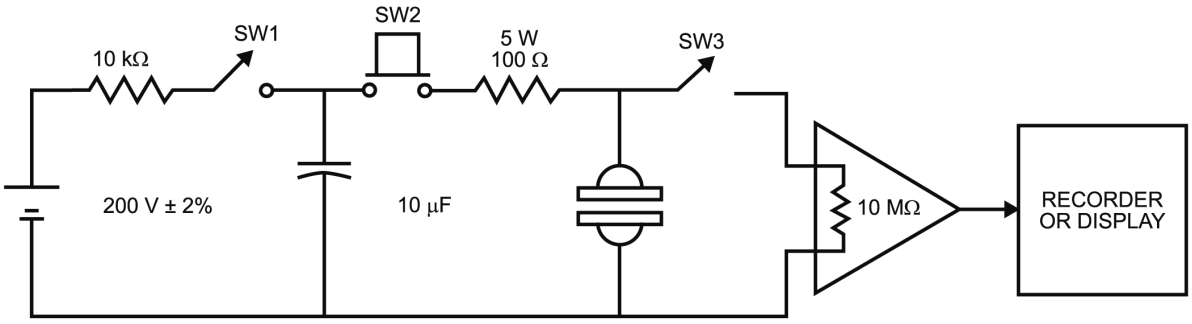

Figure 2—Defibrillation overload test circuit
(all capacitor and resistor values have a tolerance of ± 10%)

d) Switch SW2 is opened and SW3 is closed immediately, thereby connecting the electrode pair to the offset measurement system.

e) The electrode offset is recorded to the nearest 1 mV 5 sec after the closure of switch SW3 and every 10 sec thereafter for the next 30 sec. The overload and measurement are repeated three times.

f) The test sequence above is repeated for *n* electrode pairs. For all electrode pairs tested, the 5-sec offset voltage after each of the four discharges of the capacitor shall not exceed 100 mV, and any difference in adjacent 10-sec values (after the initial 5-sec period) shall not exceed ± 11 mV (± 1 mV/sec).

NOTE—The test circuit of figure 2 shall have the following characteristics: All capacitors and resistors shall be within 90 to 110% of the specified values. The input amplifier of the offset recorder must have an input impedance, from 0 to 10 Hz, of 10 MΩ ± 10%, and a bias current of less than 200 nA. The error of the voltage-recording equipment shall be no greater than ± 5% of full scale of 100 mV. A 10-mV change must be measurable with an error no greater than ± 1 mV. For this purpose, the full-scale range and resolution of the recording instrument may be adjusted as needed.

5.2.2.5 Bias current tolerance

A 200-nA DC current shall be applied to a pair of electrodes connected gel-to-gel, utilizing a current source consisting of at least a 2-V voltage source connected in series with an appropriate current-setting resistor. The potential across the pair of electrodes should be monitored with a DC voltmeter having a minimum input impedance of 10 MΩ, a resolution of 5 mV or better, and an input bias current of less than 10 nA. The differential voltage across the electrodes should be measured at least once per hour over the period of observation. The initial offset voltage should be measured within 1 to 5 min after joining the electrodes and before the bias current is applied. The offset voltage change caused by the applied bias current is then measured relative to the initial offset voltage.

5.3 Safety

5.3.1 Biological response evaluation

This section identifies the recommended tests and their purposes. The procedures for performing these tests are not given in this standard due to the variety of acceptable methods that may be employed. It is recommended that procedures and techniques in ANSI/AAMI/ISO 10993 be considered when addressing these requirements.

5.3.1.1 Cytotoxicity

With the use of cell culture techniques, these tests determine lysis of cells, the inhibition of cell growth, and other effects on cells caused by test material(s) and/or extracts from the materials.

NOTE—Due to the nature of some hydrogels that contain higher than physiologic levels of saline, an adverse test result may not be a correct indication that the hydrogel is truly cytotoxic. It may be necessary to evaluate the gel in light of the other biological/ biocompatibility testing called out in this standard.

5.3.1.2 Sensitization

These tests estimate the potential for contact sensitization of test materials, devices, and/or their extract(s), using an appropriate model. These tests are appropriate because exposure to even minute amounts of potential leachables can result in allergic or sensitization reactions.

5.3.1.3 Irritation

These tests estimate the irritation potential of test materials, devices, and/or their extract(s), using appropriate site or implant tissue such as skin, eye, and mucous membrane in a suitable model. The test(s) performed should be appropriate for the route (skin, eye, mucosa) and duration of exposure to determine irritant effects of device material(s) and potential leachables.

5.3.1.4 Intracutaneous reactivity

These tests assess the localized reaction of tissue to test materials, devices, and/or their extract(s). These tests are applicable where determination of irritation by dermal or mucosal tests are inappropriate (for example, devices having access to the blood path). These tests may also be useful where extractables are hydrophobic.

5.3.2 Pre-attached leadwire safety

Compliance with the requirements of 4.3.2 can be determined by inspection, with particular consideration given to pre-attached leadwire safety characteristics during use and during attempted forced mating with connectors supplying hazardous energy (i.e., power cords).

5.4 Adhesive performance (duration of use)

The adhesive performance should be such that the electrode remains attached to the skin for the application/ duration indicated by the manufacturer while at the same time providing an acceptable electrocardiogram. Testing will require a minimum volunteer pool of 5 women and 5 men.

For evaluating the adhesive performance of an electrode, each volunteer should have 4 electrodes placed on the body; the placement should allow for an electrocardiogram to be done. Each volunteer's skin should be prepared according to the manufacturer's instructions as described in the labeling. The electrodes should be left on for the duration of use claimed by the manufacturer. For example, if the manufacturer claims a duration of use of 5 days, the volunteers will be required to wear the product for a minimum of 5 days. An ECG trace should be obtained on initial placement and at the termination of the study. These traces should be documented accordingly.

In general, due to different skin types, skin conditions, and environmental factors, acceptable performance of an adhesive system overall should be determined by the average of the ten volunteers. For example, if two of the volunteers had electrodes fall off after 5 days, three volunteers had electrodes fall off after 6 days, and the remaining volunteers' electrodes fell off after 7 days, the overall average wear time would be 6.3 days for the volunteer pool. The manufacturer would be able to indicate that the wear time, on average, would be 6 days.

NOTE—This test method is not applicable to electrodes designed for use on neonatal and pediatric patients.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Need for the standard

In 1975, under the auspices of the ECG Committee of the Association for the Advancement of Medical Instrumentation (AAMI), a subcommittee was formed to develop a performance standard for pregelled, ECG, disposable electrodes. This effort was prompted by the need to establish a consensus on those functional requirements necessary to provide reasonable assurance of device safety and effectiveness in clinical use. The principal clinical risk that the standard is intended to address is misdiagnosis of a patient's condition based on faulty transmission of electrocardiographic data. Other potential risks associated with the use of pregelled, ECG, disposable electrodes had been identified but were not covered by the standard (skin irritation, electrode adhesiveness, and cleanliness (see A.1.2 and A.4.3.1).

In October 1974, the Food and Drug Administration established a Cardiovascular Device Classification Panel to serve as an advisory committee to the agency in determining how cardiovascular devices in commercial distribution could best be regulated—by general controls (Class I), standards (Class II), or premarket clearance (Class III). Preliminary recommendations of the panel were reported in September 1975 and again in October 1977. In the 9 March 1979 *Federal Register*, the FDA proposed regulations that would classify electrocardiograph electrodes as Class II (performance standards), based on the final panel recommendations:

> The Panel recommends that establishing a performance standard for this device be a high priority . . . that electrocardiograph electrodes be classified into Class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to transmit accurately the electrical signal produced by the heart, the resulting misdiagnosis could have a significant negative effect upon the patient's health. Because the device is in direct contact with the skin, the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. Performance characteristics involving the device's ability to sense and transmit the electrical signal should also be maintained at a generally satisfactory level. . . . An improper electrode-medium combination creating an excessively high impedance, or a device design, which allows excessive interference from subject movement, can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician might prescribe a course of treatment that places the patient at risk unnecessarily.

During the early deliberations of the AAMI ECG Electrode Subcommittee, it became apparent that additional data on the performance characteristics of commercially available electrodes as well as a suitable bench test for evaluating electrode performance were needed in order to move the 1984 standard forward. Subsequently, the Food and Drug Administration funded a study by the UBTL Division of the University of Utah Research Institute to develop this information.

The test data and methodologies generated by the UBTL study (see references), together with the combined clinical and testing experience of users and manufacturers participating in the development of the AAMI standard, form the general basis for the standard's performance requirements. These remain essentially unchanged from the original (1984) standard.

In 1989, the subcommittee began its revision of the standard. The significant changes are the expansion of the scope to cover disposable ECG electrode systems (not just pregelled electrodes) and the addition of safety requirements, 4.3.1 Biological response, and 4.3.2 Pre-attached leadwire safety.

The specific rationale for each provision is provided in the following sections.

In 1996, the ECG/Electrodes Working Group began another revision of the standard. The working group changed the exclusions (1.2) and a labeling requirement (4.1 b)). The working group also added three notes: one regarding the use of symbols in product labeling (4.1); another directing manufacturers of electrodes with pre-attached leadwires to consider ANSI/AAMI EC53:1995, *ECG cables and leadwires* (4.3.2); and one recommending caution in interpreting the results of cytotoxicity testing of hypertonic hydrogel extracts (4.3.1). Finally, and most significantly, the working group has added a requirement regarding testing the adhesive properties of electrodes; previous committees had postponed addressing this issue due to a perceived lack of data to support any action. Appropriate changes to the rationale, necessitated by these changes to the standard, may be found in the following sections of this rationale.

A.1.1 Inclusions

No rationale has been written for this section.

A.1.2 Exclusions

The working group decided to exclude active electrodes from this standard based on the belief that active electrodes are still being developed and introducing requirements might inhibit their development. Regarding the exclusion of electrodes used with apnea monitors for the non-ECG purpose of impedance plethysmography, the working group decided that the current passed through the electrodes for that purpose was significantly different from the current typically passed through an ECG electrode and could affect the design and performance of those electrodes. This differentiation precluded including those electrodes for coverage by this standard.

Cleanliness: The manufacturer should establish appropriate manufacturing processes and quality control procedures to ensure reasonable cleanliness of the finished electrode. Early in the development of the standard, the committee had attempted to develop cleanliness requirements and test methods. It was ultimately decided that because there was insufficient information available to support a specific requirement for maximum average microbial count per electrode, and because further work was needed to better define appropriate referee test criteria, this electrode characteristic would be set aside and addressed in a separate guideline or in an annex that could be included in a future revision of the standard. In general, the committee felt that the manufacturers were ensuring reasonable cleanliness of finished electrodes; therefore, no requirements were needed in the standard.

A.2 Normative references

The standards cited in section 2 of this document 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. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid AAMI/American National Standards.

A.3 Definitions

For the purposes of this standard, the definitions and abbreviations specified in section 3 apply.

A.4 Rationale for the specific provisions of this standard

A.4.1 Rationale for the labeling requirements

The requirements of this section supplement those that are mandated for all medical devices by federal labeling regulations (*Code of Federal Regulations*, Title 21, Chapter 1, Subchapter H, Section 801). The additional labeling requirements provided by this standard address the specialized information needed in the safe use of ECG electrodes.

4.1 a) requires that the labeling include information necessary to adequately identify and trace the product, to segregate problem products, and to ensure that the user is aware of how long the device can be stored and still maintain satisfactory performance.

4.1 b) was developed to minimize the possibility of patient injury through prolonged use of the electrode.

There have been many product and packaging improvements over the last 10 years that improve the out-of-pouch “shelf life” of electrodes. For example, there are resealable bags (or pouches) that are used for keeping food fresh after the package is opened. If the end user follows the manufacturer’s instructions regarding resealing, then the product “shelf life” can be extended. In regard to the electrodes themselves, new designs and product improvements make it possible to maintain the performance characteristics for a period of time once the unit package is opened (in some cases, up to weeks). This is especially true of some of the so-called bulk packs, where a manufacturer may have 25, 30, or even 50 electrodes in a unit package (or pouch). If the manufacturer has done appropriate testing and has satisfied any requirements that may exist (e.g., GMP or FDA), then it is a benefit to the end users to know that they don’t have to use the product “immediately” upon opening the unit package.

4.1 c) is intended to provide additional assurance that the device will perform under use conditions in accordance with this standard, because several studies (Baker, Schoenberg, and Booth, 1979; Schoenberg *et al*., 1979) have shown that the procedures used to abrade and/or clean the skin have a profound influence on disposable electrode performance. When the scope was changed in 1991 to include both manufacturer-assembled and end-user-assembled electrode systems, the subcommittee determined that the performance of the system depends on how the components are combined. In order to ensure adequate performance of the end-user-assembled system, the manufacturer must provide the user with the instructions required for properly combining the components.

4.1 d) helps ensure that the device user will be made aware of any special storage requirements for a particular device that are necessary for the maintenance of reliable performance.

If the purpose of labeling is to clarify and simplify for the clinician the way in which ECG electrodes should be stored, used, etc., then the use of internationally accepted symbols provides a clear advantage to word groups in multiple languages. The use of these symbols, where appropriate, will allow space for such things as bar codes or necessary verbiage that cannot be replaced by symbols.

A.4.2 Rationale for the performance requirements

A.4.2.1 Packaging and shelf life

The requirements of 4.2.1 are necessary to ensure that the electrode remains reliable under ordinary conditions of storage.

A.4.2.2 Electrical performance

A.4.2.2.1 AC impedance

Skin impedance varies from a few hundred to hundreds of thousands of ohms. Although it appears feasible to manufacture low-impedance electrodes, it seemed illogical to limit impedance to much less than skin impedance. Electrode impedance is important, however, because the higher the impedance, the more impedance imbalance is likely to occur between electrodes, thereby lowering the common-mode-rejection ratio (CMRR) of the ECG amplifier and leading to increased AC interference on the ECG trace.

The 2-kΩ level specified in 4.2.2.1 represents a compromise assuring the user of a low probability of interference problems caused by the electrode, while at the same time providing generous flexibility in electrode design. A 5-kΩ limit would be acceptable for electrodes used in most stationary monitoring applications, where preparation is minimal. In those monitoring applications, however, where skin impedances are reduced to 1 kΩ or less by vigorous skin preparation (for example, ambulatory monitoring and stress testing), the clinician would be poorly served by a limit of 5 kΩ. Different limits on AC impedance for different applications were considered impractical, and the committee chose to specify the lower value as an appropriate overall limit.

Another factor considered by the committee is that ECG monitors incorporate protective devices to absorb overloads caused by defibrillation and electrosurgery current. Current-limiting resistors are built into cables and/or monitors to absorb these overload currents and the resultant energy. If the electrode's resistance makes a large enough contribution to the current-limiting protection resistances, a substantial amount of heat might be generated at the skin/electrode interface, raising the probability of electrode failure as well as patient injury.

The AC impedance requirement is specified both as a mean value and as a permissible upper limit for purposes of quality assurance. The exact number of electrode pairs to be tested in a production lot is left to the judgment of the manufacturer, because the appropriate number will depend on the history of variability characteristic of the production facility.

The standard does not specify that AC impedance be determined for 1 Hz. While the impedance measured at 1 Hz is of importance to ECG fidelity, the measurement difficulties encountered when ascertaining the 1-Hz impedance with commonly available equipment are sufficiently great to render such a requirement impracticable. In the process of developing this edition of this standard, the working group discussed the issue of measuring electrode impedance at 1 Hz. The working group decided that the measurement of impedance at 10 Hz, as currently required by the standard, has become an industry standard. Further, the fact that currently marketed electrodes provide adequate performance supports the adequacy of the 10-Hz measurement as a predictor of electrode performance. The working group decided to leave the impedance measurement requirement unchanged.

UBTL tests indicated that the effective impedance of an electrode type, when tested on unprepared human skin, did not correlate well with the bench-test measurements of impedances for electrodes joined gel-to-gel. A 99% correlation was established, however, between the results of tests on prepared (abraded) skin and those obtained using the bench test of 5.2.2.1.

A.4.2.2.2 DC offset voltage

Because the input buffer amplifiers of cardiac monitors will saturate under conditions of excessive DC offset voltage, a reasonable limit must be established on the offset voltage that will be contributed by the electrodes. The magnitude of this limit was the subject of considerable debate during the development of this standard.

The maximum allowable DC offset voltage was originally specified at 300 mV, based on the data that had been gathered during the UBTL study (Schoenberg, *et al*., 1979). The American National Standard *Cardiac monitors, heart rate meters, and alarms* requires that cardiac monitors be capable of tolerating up to ± 300 mV offsets (AAMI,

1992). The committee judged that a 100-mV offset voltage limit for disposable ECG electrodes would provide reasonable assurance that electrodes conforming to this limit would be acceptable for use with most cardiac monitors. The committee considered that, as older equipment is replaced with new cardiac monitors capable of tolerating offsets up to ± 300 mV, the 100-mV limit for ECG electrodes would provide a sufficient operating margin to accommodate increases in electrode offset voltages caused by unequal potentials at the skin/electrode interface, by defibrillation overloads, by pacemaker currents, and/or by ECG amplifier bias current. In addition, the committee believed that further assurance of adequate electrode performance would be provided by the standard's offset instability and internal noise requirements (4.2.2.3).

Nevertheless, some reviewers of the standard argued that the allowed DC offset voltage should be reduced from 100 mV to 10 mV, on the grounds that this more stringent limit was needed not only to minimize motion artifact due to modulation of the DC offset, but also to accommodate some cardiac monitors that saturate at extremely low offsets (40 to 50 mV). Further, it was argued that a 10-mV limit was technologically feasible and that this level of quality, if not specified in the standard, would be difficult for potential purchasers to obtain because of cost containment pressures in health care.

The committee ultimately decided to retain the 100-mV limit for several reasons. Although the special electrode requirements of some users might include the need for much smaller offset voltages than the maximum which the standard permits, reducing the upper limit to 10 mV would deprive other users of the potential economic benefits of less stringent requirements. Also, technological feasibility was not considered sufficient justification for establishing a particular limit on product performance, especially one that could place constraints on design innovation. Moreover, it was not deemed appropriate to attempt to address in the electrode standard what is, in the committee's view, obsolete monitor technology; the committee considered the 100-mV offset voltage limit adequate to accommodate the offset tolerance capabilities of currently available cardiac monitors, most of which can tolerate offsets of at least 200 mV. As noted earlier, promulgation of the AAMI cardiac monitor standard was expected to result in a general improvement of offset tolerance capabilities.

Most importantly, the committee believed that the available evidence was inadequate to link high offset voltages with motion artifact and other interference. In the absence of objective studies, the need for a 10-mV upper limit remained unsubstantiated in the committee's view, and thus the potential adverse effects on design innovation and cost containment could not be justified. It was agreed, however, that the offset voltage criterion should be reconsidered when studies of the relationship between offset voltage and motion-induced interference are completed and their results are made available for consideration.

A.4.2.2.3 Combined offset instability and internal noise

At a 1977 conference on "Optimal Electrocardiography" convened in Bethesda, Md., by the American College of Cardiology, the Task Force on Quality of Electrocardiographic Records reserved its highest rating for baseline drift to those records exhibiting drifts of less than 0.1 mV/sec (Sheffield *et al*., 1978). Recordings exhibiting baseline drifts of 0.1 to 0.4 mV/sec, while judged to be less desirable by the task force, were not considered unacceptable. Although electrocardiographic recording devices generally filter the signals to reduce or eliminate baseline drift, a contribution to the drift rate from the electrode/electrolyte interface of less than 150 μV/sec is desirable to ensure a minimal contribution by the electrode to the baseline wander.

The test circuit of 5.2.2.3 (figure 1) allows determination of both offset instability and internal noise, because any instantaneous spiking in the electrode offset voltage will be displayed as voltage transients outside the specified limit. The offset instability requirement (4.2.2.3) is specified in μV rather than in μV/sec because the test circuit differentiates the offset voltage.

A 1994 letter from the Chinese Academy of Science suggested that the combined offset instability and internal noise allowance was too high. The letter pointed out that the 1988 version of the AAMI standard, *Cardiac monitors, heart rate meters, and alarms* (EC13), only allowed 40 μV p-p total system noise. A subsequent version of that standard further reduced the permissible system noise limit to 30 μV p-p. The working group has had numerous discussions whereupon there has been general agreement that the contemporary electrodes would have no problem meeting more stringent electrical performance requirements. However, the working group was unwilling to accept a change to 40 μV. The working group decided to revert to the previous requirement and to form a task group to study the issue further. The working group decided that any recommendation provided by the task group could be implemented as an amendment to this standard at a later time.

A.4.2.2.4 Defibrillation overload recovery

After a defibrillation attempt, the ECG is important to the clinician in determining whether the heart has been returned to normal sinus rhythm. For this reason, the ECG trace must return within 5 sec to 10 sec to an input offset voltage within the range that can be tolerated by cardiac monitors (see A.4.2.2.2) so that the condition of the patient can be assessed as rapidly as possible. During the next 30 sec, the offset drift with time should not vary by more than ± 1 mV/sec in order to display a clinically useful ECG. Because rapid electrode recovery from defibrillation pulses

enables the clinician to quickly evaluate the outcome of the countershock, minimal change in the baseline after defibrillation is an essential requirement. Electrode recovery with an offset drift rate of less than 1 mV/sec permits the baseline to deviate from the predefibrillation baseline less than 0.5 mV (or 10 mm on a 20-mm/mV scale) and results in a recognizable ECG display. The committee recognized that instruments with larger input impedances are available and that the recovery time can be prolonged in these devices.

As many as 20 to 25 defibrillation attempts for an individual patient have been reported, suggesting the maximum number of consecutive defibrillation overloads that the electrode must absorb. However, this number of attempts is unusual, and it was agreed that such a level need not be specified in the standard. The overload of 2 millicoulombs (mC) used in the test of 5.2.2.4 (figure 2) represents a worst-case condition that would be encountered only if the physician placed the defibrillator paddles in immediate contact with the ECG electrodes (that is, if the paddles touched the electrodes). If the electrodes are even 10 centimeters (4 inches) from the paddles, the overloads are likely to be reduced by half. Furthermore, in most clinical situations, where skin preparation is suboptimal, the circuit impedance will probably be much higher than the average of 1.5 kΩ encountered in UBTL animal testing (Schoenberg *et al*., 1979). On this basis, four consecutive discharges, spaced 15 to 30 sec apart, should provide an adequate criterion for judging the performance of the electrode. The manufacturer may use a higher number of discharges in design qualification testing to ensure sufficient overload capacity in production models of electrodes.

The committee considered permitting an exemption from the defibrillation overload requirements if the labeling for otherwise suitable electrodes included a warning that the device should not be used in circumstances where defibrillation attempts were likely. It decided, however, that, in view of the practical difficulties involved in ensuring that certain electrodes would not be used in emergency defibrillation situations, such an exemption should not be allowed.

During public review of the 1984 standard (prior to its final approval), it was pointed out that the defibrillation overload and bias current could add to the initial allowable 100-mV DC offset of the electrode pair, thereby creating an offset exceeding 100 mV. To avoid undue complexity of test interpretation, the committee decided that the same electrode pair need not be used for these three electrical tests. Nevertheless, the 100-mV defibrillation overload recovery limit should include any initial offset voltage of the electrode pair.

A.4.2.2.5 Bias current tolerance

The reactants for the chemical reactions occurring at the electrode/electrolyte interface, which are necessary for an ECG electrode to pass current, can become depleted, causing significant variations in the electrode half-cell potential when subjected to DC bias currents. Therefore, the compatibility of electrodes with the 200-nA bias current allowed for cardiac monitors must be demonstrated. Older monitors can have higher bias currents, so that a higher bias current tolerance for electrodes might be desirable. It was decided, however, that a limit as high as 1000 nA (1 μA) would necessitate a significant change in present electrode technology, and that the corresponding cost increase to the consumer could not be justified by the slight improvement in electrode performance.

A.4.3 Rationale for the safety requirements

A.4.3.1 Biological response

In the 1984 version of this standard, a section entitled “Skin Irritation” was included in the rationale explaining why the committee chose *not* to include a corresponding requirement.

The committee recognized that certain materials, if used in the fabrication of ECG electrodes, could cause skin sensitivity or skin irritation problems, especially if skin abrasion prior to electrode application is recommended by the manufacturer to enhance ECG signal transmission. Because of the lack of definitive data, the committee chose not to attempt to develop material requirements to address this risk. The committee judged that the collection of data necessary to establish such requirements would have inordinately delayed the completion of the standard.

The biological response testing requirement is new and was added because of the availability of testing programs that are now considered standard in the industry (see ANSI/AAMI/ISO 10993:1997).

The tests cited in 5.3.1.1, 5.3.1.2, 5.3.1.3, and 5.3.1.4 are recommended for medical devices/materials that contact the skin. For further details, refer to the document noted above.

A number of independent laboratories were contacted to determine if there was an established universal grading system such as that used in these tests. The responses indicated that there is no universal system in place at this time; if testing is performed, the biocompatibility expert will evaluate the test results and determine whether or not the material is biocompatible for the intended application. (It should be noted that the determination of biocompatibility does not necessarily require testing for *each new design*. A biocompatibility expert, using his/her professional judgment, may determine that, based on the availability of biocompatibility data for the components, in conjunction with an evaluation of the intended application of the new design, additional testing is not required.)

A.4.3.2 Pre-attached leadwire safety

Historically, many electrodes with pre-attached leadwires utilized male pins to connect to the patient cable. There have been incidents where these pins were inserted into detachable power cords, thus applying full-line voltage to the patient. To ensure patient safety, the leadwire/patient-cable connector must not be permitted to contact a possibly hazardous potential, or a conductive surface which may be at ground potential, thereby compromising patient isolation. This standard and the previous edition require electrical safety without imposing a specific design that might limit innovation. However, since the previous edition was published, another AAMI standard (ANSI/AAMI EC53:1995, *ECG cables and leadwires*) was published that addresses this issue by requiring a specific design. This working group decided to ensure that electrode manufacturers complying with this standard were aware of the AAMI standard that specifically addresses this safety issue. However, with the same intent of not imposing a specific design requirement that might inhibit innovation, this standard informs the manufacturer by means of a note.

A.4.4 Electrode adhesiveness

The ability of an electrode to adhere satisfactorily to the skin over the expected period of use is an important performance characteristic. During the development of the initial 1984 standard, a study by UBTL of the adhesiveness characteristics of disposable ECG electrodes did not yield a suitable bench test for evaluating adhesion performance; that is, a bench test that would correlate well with adhesiveness as observed clinically (Baker, Schoenberg, and Booth, 1979). The committee chose not to address this particular performance characteristic for purposes of the initial standard or in this revision, due to the continued lack of any definitive clinical study.

In the last 10 years, progress has been made in identifying adhesive tests that can indicate how well certain adhesive systems will perform for ECG electrode applications. Several medical device companies, including some of the ECG electrode manufacturers, have developed inhouse test methods based on the test methods developed by the Technical Committee of the Pressure Sensitive Tape Council.[1)] Other manufacturers have relied on independent test laboratories to provide test results on adhesive systems used in skin contact applications.

More recently, some manufacturers have been requested to provide adhesive performance data to the FDA for 510(k) submissions. This is related to duration-of-use information that the FDA wants manufacturers to provide to the clinician/end user.

In view of the foregoing, the working group deemed it appropriate to establish an adhesive test method that will address the needs of the end user and, at the same time, satisfy the FDA requirement.

[1)] Pressure Sensitive Tape Council, 401 North Michigan Avenue, Chicago, IL 60611-4267.

Annex B
(informative)

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