List of Titles

American National Standard

ANSI/AAMI EC53:1995/(R)2001

ECG cables and leadwires

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Rd., Suite 220
Arlington, VA 22201-4795

Copyright and Permissions

EC53 ECG cables and leadwires

American National Standard ANSI/AAMI EC53:1995/(R)2001

ECG cables and leadwires

Developed by
Association for the Advancement of Medical Instrumentation

Approved 7 December 1995 and reaffirmed 11 May 2001 by
American National Standards Institute, Inc.

Abstract:

The objective of this standard is to allow cable leadwires to be interchanged between ECG monitors with isolated patient connections by establishing a common cable/leadwire connector interface. Performance and safety criteria for patient cables and leadwires used with isolated patient connectors are also specified.

Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph Committee

This standard was developed by the ECG/Cables and Leads Working Group of the AAMI Electrocardiograph Committee. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

The AAMI **Electrocardiograph Committee** has the following members:

Cochairpersons	James J. Bailey, MD
	David Mortara, PhD
Members:	James J. Bailey, MD, National Institutes of Health
	Edward Berbari, PhD, Indiana University
	Alan S. Berson, PhD, National Heart, Lung, and Blood Institute
	Francis Charbonnier, PhD, Hewlett Packard Company
	Stephen Daleo, Nellcor, Inc.
	David Daly, U.S. Food and Drug Administration
	George Moody, Massachusetts Institute of Technology
	David Mortara, PhD, Mortara Instrument, Inc.
	Bill Saltzstein, Instromedix
Alternates:	Robert Cangelosi, PE, U.S. Food and Drug Administration
	Peter Galen, Hewlett Packard Company
	Roy D. Wallen, Hewlett Packard Company

The committee's **ECG Cables and Leads Working Group** has the following members:

Chairperson:	Robert J. Cangelosi
Members:	Michael Allaire, NDM Corporation
	Robert Bain, CBET, The Johns Hopkins Hospital, Baltimore, MD
	Seymour Ben-Zvi, CCE, ScD, SUNY Health Science Center at

Brooklyn, NY
Alan S. Berson, PhD, National Heart, Lung, and Blood Institute
Mike Bravo, Hewlett Packard Company
Robert J. Cangelosi, PE, U.S. Food and Drug Administration
John Collins, Northwestern Memorial Hospital, Chicago, IL
Stephen Daleo, Nellcor, Inc.
Melvin N. Fink, CBET, ServiceMaster
Robert Frank, Tronomed, Inc.
Pradeep M. Gupte, MSBME, Westchester County Medical Center, Valhalla, NY
Karen J. Higgins, BMET, Memorial Mission Hospital, Ashville, NC
Walter Lloyd, Childrens Hospital at Boston
Dave Lovejoy, Marquette Electronics, Inc.
Craig Oster, 3M Company
Roy E. Owens, Volex Interconnect Systems
Kay Rutishauser, RN, Association of Acute Care Nurses
Louis P. Scheps, CAS Medical Systems, Inc.
Dwight E. Shields, BA, University of Washington Hospital
Wayne Shockloss, ARBO Medical, Inc.
Alan J. Stankus, John F. Kennedy Memorial Hospital, Lansdale, PA
Jerry Sweeten, Plastics One, Inc.
Kenneth S. Wade, ME, BME, Spacelabs Medical, Inc.

Alternates:
Richard A. Benedict, Hewlett Packard Company
Joseph DeRosa, PhD, NDM Corporation
Don Lockery, Marquette Electronics, Inc.
Michael McQuiston, 3M Company
Katherine Stankus, Spacelabs Medical, Inc.

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.

Acknowledgment

The working group gratefully acknowledges the contributions of James Rooks of Medical Data Electronics. Mr. Rooks provided valuable leadership as the producer cochairman of the AAMI ECG Cables and Leads Working Group from 1990 until 1994.

Foreword

ECG cables and leadwires was developed by the ECG Cables and Leads Working Group of the AAMI Electrocardiograph Committee. This standard, which is voluntary, is intended to apply primarily to ECG cables and leadwires for use on equipment with isolated patient connections and in the most common ECG monitoring applications. The goal of the standard is to promote patient safety by helping to prevent inadvertent mating of patient leads with power main connectors, and by allowing more rapid transfer of patients who require continuous monitoring under emergency conditions.

Serious incidents have occurred of patients being burned or killed when detachable patient leads with male pin connectors were inadvertently mated with power main connectors. The number of these accidents is extremely low, and of these, only a few involved ECG equipment. However, in light of their serious nature, the AAMI Electrocardiograph Committee charged its working group in 1988 with the task of developing a new safety

standard for ECG cables and leadwires that would contribute to the prevention of such incidents.

During the early drafting of the document, the working group also discussed the desirability of an interchangeable leadwire/trunk interface. The continuous monitoring of a patient's physiological biopotential activity is common practice, and it is often necessary to transfer such patients rapidly to another location and monitor. Although design specifications are usually avoided in standards, the working group agreed that more rapid transfer of patients and monitors was both desirable and possible if all monitoring cables and leadwires have a common interface at the cable yoke and leadwire connector, and that a standard leadwire system would also help to reduce confusion, errors, setup time, and training time. Therefore, in addition to specifying safety and performance criteria, this standard also establishes a preferred cable and leadwire interface for monitoring ECG potentials that allows interchangeability. While the quality of the ECG signal can vary when cables and leadwires of different manufacturers are interchanged, the ability of the monitor to detect life-threatening events will not be compromised.

This standard reflects the conscientious efforts of concerned physicians, biomedical and clinical engineers, manufacturers, and government representatives to develop a standard for those performance levels that could reasonably be achieved at this time.

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 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.

Suggestions for improving this standard are invited. Comments and/or suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword is not a part of the American National Standard, *ECG cables and leadwires* (ANSI/AAMI EC53—1995).

ECG cables and leadwires

1 Scope

This standard covers cables and patient leadwires used for surface electrocardiographic (ECG) monitoring in cardiac monitors as defined in ANSI/AAMI EC13—1992, *Cardiac monitors, heart rate meters, and alarms*.

1.1 Inclusions

This standard covers both disposable and reusable leadwires, with certain sections of the standard applicable to both, and certain sections applicable only to one (applicability is marked on appropriate sections after the section title in the following manner: "BOTH," "DISPOSABLE," or "REUSABLE").

The tests in this standard are designed to enable manufacturers to verify compliance of their products to the safety and performance specifications contained herein. These tests are not intended to be performed by device end users.

This standard defines a safe (no exposed metal pins) common interface at the cable yoke and leadwire connector.

1.2 Exclusions

ECG cables and leadwires that are used in applications that may require special characteristics, such as ambulatory ECG devices, telemetry units, the operating room and the cardiac catheterization lab, are excluded

from this standard. The cables and patient leadwires included in this standard may supply other functions in addition to ECG monitoring, such as respiration monitoring by impedance pneumography. However, the cable and patient leadwires must meet all of the requirements of this standard, unless a requirement is specifically excluded.

2 Normative references

The following documents contain provisions which, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All documents 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 documents listed below.

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

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus*. ANSI/AAMI ES1—1993. Arlington (VA.): AAMI, 1993. American National Standard.

2.3 DEUTSCHES INSTITUT FÜR NORMUNG. *Connector, touch proof, for electromedical application*. DIN 42-802. Germany: DIN, 1990.

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 cable assembly: The assembly of either individual wires and/or wires bundled into one jacket that connects the patient to the ECG monitor. Typically, this consists of a trunk cable and a group of patient leadwires. The leadwires may be separable from the trunk cable, or they may be constructed all in one assembly with the trunk cable (a one-piece cable and leadwire assembly).

3.2 cable yoke: The end of the trunk cable into which all of the patient leadwires plug.

3.3 disposable: Products specifically labeled and sold as being for use on a single patient only.

3.4 flex relief: The portion of the cable or leadwire assembly at the junction of connector and cable that prevents flexure of the assembly from damaging the cable or connector (may be integral with the strain relief).

3.5 instrument connector: The connector at the monitor end of the trunk cable that attaches the trunk cable to the receptacle on the monitor.

3.6 instrument connector receptacle: The connector on the monitor into which the trunk cable connector plugs.

3.7 monitor: An ECG device used to acquire and/or display electrocardiographic signals.

3.8 patient end termination: The connector at the end of the patient leadwire that attaches to the patient electrode.

3.9 patient leadwire connector: The connector on the patient leadwire that attaches the patient leadwire to the cable yoke.

3.10 patient leadwires: The individual wire that on one end has a patient end termination that connects to an electrode, and on the other end has a safety receptacle that connects to the cable yoke. Some types of leadwires will connect directly into an instrument without the use of any cable.

3.11 reusable products: Products that are specifically labeled and sold as being able to be used on multiple

patients.

3.12 sink current: The current that flows into a device or any part thereof when an external voltage is applied.

3.13 strain relief: The portion of the cable or leadwire assembly at the junction of the connector and cable that supports the cable/connector junction and prevents forces applied to the cable from being transferred to the connector contacts and wires within the connector housing.

3.14 trunk cable: The portion of the cable assembly in which all the wires are bundled together into one jacket, or are in some way bound permanently together. Typically, this has a yoke at one end with connectors for receiving the patient leadwires, and an instrument connector at the other end for connecting to the monitoring instrument.

4 Requirements [1)]

[1)] See 1.1 for explanation of "(BOTH)," "(DISPOSABLE)," and "(REUSABLE)" after section 4 subheadings.

4.1 Labeling requirements

4.1.1 Package labeling (BOTH)

Each unit package supplied to the medical end user shall have the following package insert or label:

This cable [or lead or leadwires set] meets the requirements of the ANSI/AAMI standard, *ECG cables and leadwires* (ANSI/AAMI EC53—1995). This cable [or lead or leadwires set] is disposable [or reusable].

4.1.2 Trunk cable yoke labeling (BOTH)

The cable yoke shall have each lead position permanently marked (e.g., molded or engraved — these are examples of ways to mark but other ways can be used) with the appropriate lead designation and color coded per ANSI/AAMI EC13—1992 (see 2.1). Labeling of the connection polarity is not required.

4.1.3 Patient leadwire termination labeling (BOTH)

Where the wire itself is not appropriately color coded, the terminations on both ends of the patient leadwire shall be reliably marked with the color code per ANSI/AAMI EC13—1992 (see 2.1). If the patient leadwire connector end of the leadwire is not separable, then only the patient end of the leadwire needs to be color coded.

The patient end termination may also include nomenclature to reinforce the color designation (i.e., RA, LL, etc.). Such nomenclature is optional at the discretion of the manufacturer.

4.2 Construction requirements

4.2.1 Leadwire to trunk cable interconnection (BOTH)

For cable assemblies where the patient leadwires are separable from the trunk cable with a single unshielded conductor leadwire, the interconnection between the patient leadwires and the trunk cable shall meet the requirements of DIN 42-802 (see 2.3), in addition to the tolerances defined in figure 1.

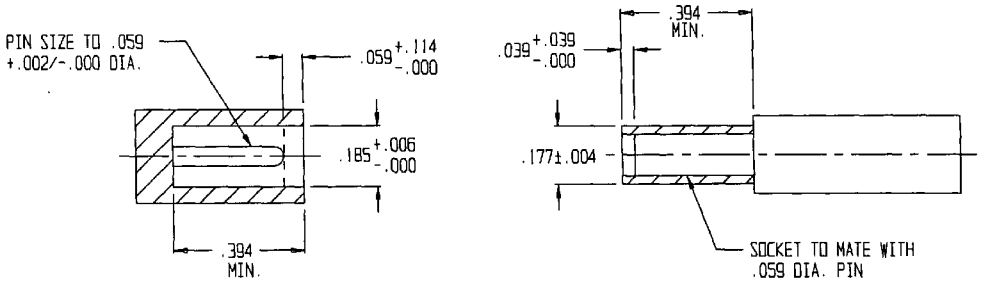

Figure 1—Nonshielded patient leadwire to cable yoke connection. NOTE—The manufacturer of the patient leadwire may incorporate features in the stem area (0.177 in dimension) in order to provide retention forces in the trunk cable yoke, as long as interchangeability is not affected.

For cable assemblies where the patient leadwires are separable from the trunk cable with a shielded conductor leadwire, the interconnection between the patient leadwires and the trunk cable shall meet the requirements of figure 2 (see page 4).

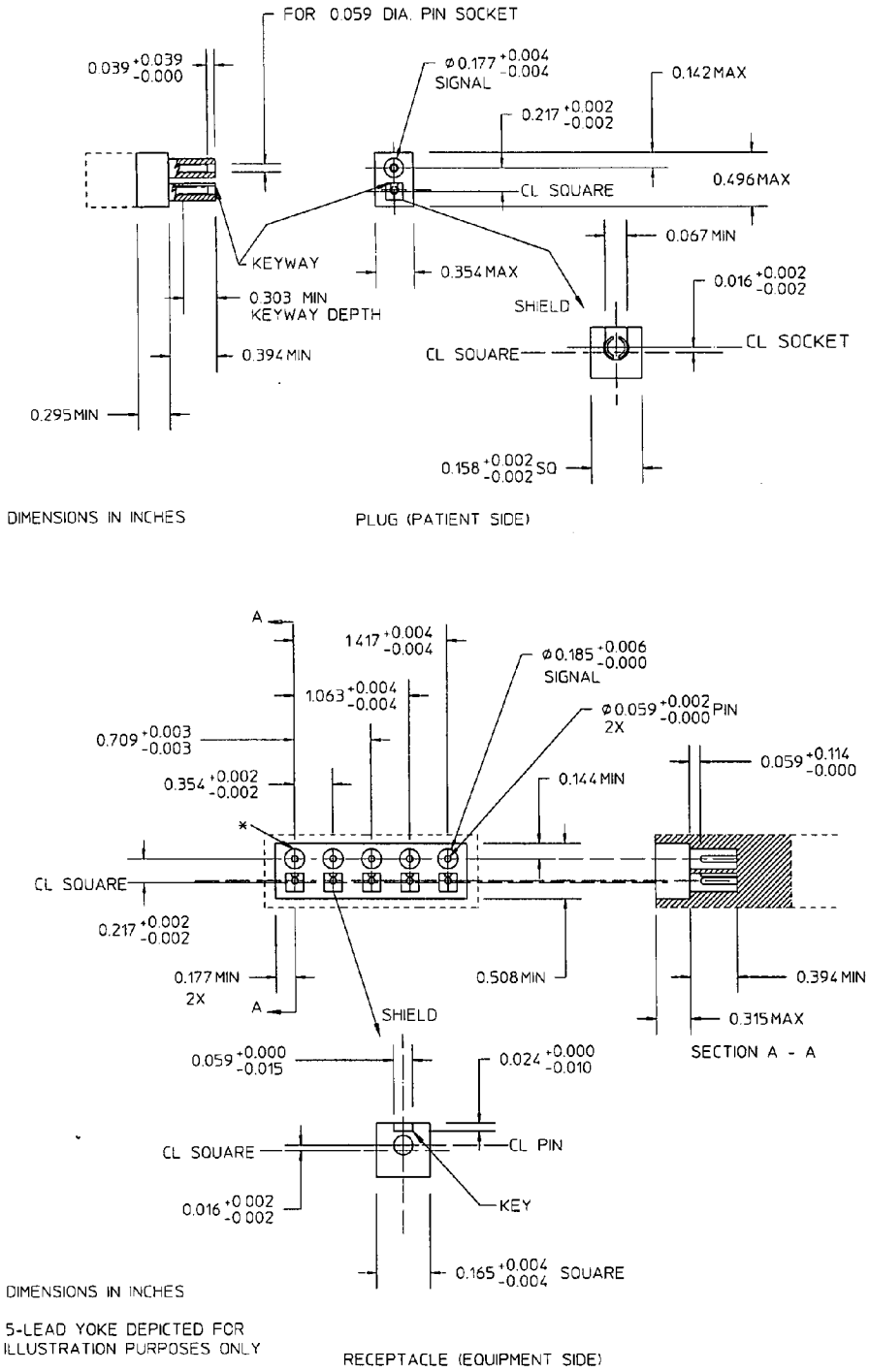

Figure 2 — Shielded patient leadwire to cable yoke connection

NOTE — For the shielded interconnection as shown in figure 2:

a) The following lead order should be used in a shielded trunk cable yoke, starting the appropriate lead at the end marked "*" (as shown in figure 2, from left to right): RL, LA, LL, RA, V. If a trunk cable includes leads other than these, the additional leads should not interfere with the specified order. The additional leads can be located as desired, provided that the width spacing is 0.354 inches (in) or greater, and individual shielded

patient leadwires can plug in.

Examples:
RL, LA, LL, RA, V;
LA, LL, RA;
...x, y, RL, LA, LL, RA, V, z ... (x,y,z denote other leads).

b) The manufacturer of the patient leadwire may incorporate features in the connector stems in order to provide proper retention forces in the trunk cable yoke, as long as interchangeability is not affected.

c) A five-lead yoke is depicted in figure 2 for illustration purposes only. Fewer or more leads can be used as necessary.

4.2.2 Current limiting devices (BOTH)

The patient leadwires shall contain no current limiting devices.

4.3 Cleaning, disinfection, and chemical resistance requirements

All labeling and performance requirements of this standard shall be met after cleaning.

4.3.1 Cleaning and disinfection (REUSABLE)

The trunk cable and patient leadwires shall be capable of being cleaned and disinfected 15 times with the following materials per 5.3.1:

— green soap, green soap tincture (U.S. Pharmacopoeia), or alcohol-free hand soap;

— 2% glutaraldehyde solution (such as Cidex);

— sodium hypochlorite (bleach) solution 10% in water.

4.4 Sterilization exposure requirements

All labeling and performance requirements of this standard shall be met after sterilization.

4.4.1 Exposure to ethylene oxide (EO) sterilization (REUSABLE)

The trunk cable and patient leadwires shall be capable of being subjected to EO sterilization 10 times according to section 5.4.1.

4.5 Performance requirements — trunk cable and patient leadwires

The cables and leadwires described in this standard shall meet all of the requirements of this standard when the tests are performed in any sequence on the same cables and leadwires.

4.5.1 Dielectric withstand voltage (BOTH)

With the patient leadwires connected to the trunk cable and the trunk cable plugged into its intended receptacle or equivalent, the assembly shall withstand without breakdown a 1-minute (min) (+/- 20%) application of 1000 volts (V) root-mean-square (rms) (+/- 10%) sine wave at 60 hertz (Hz). The voltage shall be applied to all combinations of any two wires, including the shield.

The assembly shall also withstand, without breakdown, a 1-second (s) (+/- 10%) application of 5000 volts direct current (dc) (+/- 10%) between all wires and shield connected together and any exposed conductive parts.

Breakdown is defined as current flow in excess of 0.25 milliampere (mA) above the theoretical current flow given the voltage and frequency of the stimulus. The current shall be measured at the generator output.

4.5.2 Sink current (BOTH)

Patient cable/leadwire assemblies shall not permit a sink current exceeding 10 microamperes (µA). (See 2.2.)

4.5.3 Defibrillation withstand (BOTH)

The cable/patient leadwire assembly shall withstand three applications, at 60-s intervals (+/-5), of a simulated defibrillator damped sinusoidal waveform conforming to the limits specified in 2.1.

4.5.4 Cable and leadwire noise (BOTH)

A 5-foot (ft) section of cable material shall not produce noise greater than 50 microvolts (µV) peak-to-peak.

4.5.5 Flex life of instrument connector, cable yoke, patient leadwire connector, and patient end termination flex relief (REUSABLE)

The flex life at the instrument connector/trunk cable, trunk cable/cable yoke, patient leadwire/leadwire connector, and patient leadwire/patient end termination junctions shall all withstand flexes of +/- 90 degrees as specified in the following table.

Table 1—Flex life of instrument connctor, cable yoke, patient leadwire connector, and patient end termination flex relief

Test location	Disposable	Reusable
Trunk cable (both ends)	N/A	1000
Leadwire (both ends)	30	500

4.5.6 Tensile strength of cable connections (BOTH)

The cable connections shall withstand an axial pull according to the following table.

Table 2—Tensile strength of cable connections

Test location	Disposable (lbs.)	Reusable (lbs.)
Trunk cable to instrument connector	N/A	15
Trunk cable to yoke connector	N/A	15
Trunk cable material	N/A	20
Patient leadwire to patient leadwire connector	3	7
Patient leadwire to patient end termination	3	7
Patient leadwire material	5	10

4.5.7 Number of connector mate/unmate cycles (BOTH)

The cable and leadwire connectors shall be capable of being mated and unmated per the following table.

Table 3—Number of connector mate/unmate cycles

Test location	Disposable (number of cycles)	Reusable (number of cycles)
Trunk cable connector to instrument receptacle	N/A — trunk cable	300 — trunk cable
Trunk cable yoke to patient leadwire	N/A — trunk cable 30 — leadwire	500 — trunk cable 500 — leadwire
Patient end termination	30	500

After completion of the test the connections shall still meet the requirements of paragraph 4.5.8 and 4.5.9.

4.5.8 Contact resistance

The dc resistance of any of the following connections shall not exceed 1.0 ohm (Ω) when measured:

— each patient leadwire to cable yoke connection;

— each trunk cable to instrument receptacle connection.

4.5.9 Connector retention force (BOTH)

When pulled axially along the direction of connection, the minimum force required to separate the connections shall be as specified below.

Table 4—Connector retention force

Connection	Minimum force
Trunk cable instrument connector to instrument connector receptacle (per lead)	7 lbs
Patient leadwire connector to trunk cable yoke (per leadwire)	1 lb.

4.5.10 Patient leadwire resistance (BOTH)

The dc resistance of the patient leadwires shall be as specified in the following table for the appropriate leadwire material.

Table 5—Patient leadwire resistance

	Resistance (Maximum Ω)		
Leadwire Length (inches)	**Metallic (e.g., copper)**	**Composite (e.g., tinsel)**	**Organic (e.g., carbon)**
0 – 12	1	50	300
13 – 24	1	50	350
25 – 36	1	50	400
37 – 48	1	50	450
49 – 60	1	50	500
61 – 72	1	50	550
73 – 84	1	50	600
85 – 96	1	50	650

5 Test methods

This section provides referee test methods and procedures by which compliance of the device with the requirements of section 4 are verified. The paragraph numbers below correspond with those of section 4 except for the first digit; e.g., conformance with requirement 4.2.3 can be determined by test method 5.2.3.

NOTE—Other tests may be used for purposes of design qualification provided that equivalence with the referee tests can be established in terms of comparability of test results. These referee test methods do not specify safety considerations that should be made by the operator prior to the performance of each test.

Test apparatus

Instrumentation

The following test instruments will be required.

—An alternating current (ac) current meter capable of measuring 10 µA with a +/- 1% accuracy;

—A high voltage power supply and power resistor capable of charging a 32 microfarad (µF) capacitor to 5000 V in less than 20 s;

—An oscilloscope with a differential amplifier having a 3 decibel (dB) bandwidth between 0.1 to 100 Hz (6

dB per octave rolloff) capable of resolving a 10 µV signal. The input impedance of the differential channel shall be at least 1 megohm (MΩ). The 3 dB midband amplitude accuracy shall be +/- 5%;

—A cable flexing apparatus capable of securely clamping the cable to the flexing head and rotating through an arc of +/- 90º;

—A pull test apparatus capable of applying an axial force along a cable of connector of at least 30 lbs;

—A volt/ohm meter with the following minimum specifications:

—dc voltage range 10V (+/- 2%);

—ac voltage range (rms) 10V (+/- 2%);

—dc resistance 0.1 Ω to 1 MΩ (+/- 2%).

Test circuits

Unless otherwise specified, the circuits described in the tests shall be made with resistors having a maximum +/- 5% tolerance for frequencies up to 1 megahertz (MHz). Capacitors shall be nonpolarized, of suitable voltage rating, and have a maximum tolerance of +/- 10%. The maximum tolerance of inductors shall be +/- 5%.

Test signals

Unless otherwise specified, the amplitude accuracy of input test signals shall be +/- 1% for dc voltages and +/- 2% for ac voltages.

5.1 Compliance with labeling requirements

5.1.1 Package labeling

Compliance with 4.1.1 can be verified by inspection.

5.1.2 Trunk cable yoke labeling

Compliance with 4.1.2 can be verified by inspection.

5.1.3 Patient leadwire termination labeling

Compliance with 4.1.3 can be verified by inspection.

5.2 Compliance with construction requirements

5.2.1 Leadwire to trunk cable interconnection

Compliance with 4.2.1 can be verified by inspection.

5.2.2 Current limiting devices

Compliance with 4.2.2 can be verified by inspection.

5.3 Compliance with cleaning, disinfection, and chemical resistance requirements

5.3.1 Cleaning and disinfection

The cable and leadwires are cleaned/wiped with a cloth saturated with a test chemical in the following manner: Wipe with the test chemical, wipe with clean water, wipe dry. Repeat 15 times for each chemical. (See 4.3.1.) After the cable and leadwires have been subjected to these procedures, all labeling shall be intact and legible, and the assembly shall meet all the requirements of this standard.

5.4 Compliance with sterilization requirements

5.4.1 EO sterilization

The cable and patient leadwires shall meet all labeling and performance requirements of this standard following 10 sterilization cycles according to the method(s) approved by the manufacturer. If no method is specified, the following EO sterilization cycle shall be followed: A minimum of 1 hour of exposure to 100% EO at a temperature between 54°C and 57°C, or a minimum of 4 hours of exposure to 100% EO at temperatures between 34°C and 38°C; chamber humidity shall be between 45% and 75% during exposure. Each exposure to EO shall be preceded by a preconditioning cycle and followed by aeration.

5.5 Compliance with performance requirements—trunk cable and patient leadwires

5.5.1 Dielectric withstand voltage

Compliance with 4.5.1 can be determined by completing the following tests with the patient leadwires connected to the trunk cable and the trunk cable plugged into its intended receptacle or equivalent.

a) Wire-to-wire test—Use test circuit shown in figure 3 (see page 7). Switch positions and wiring must be added to test a five-wire cable and leadwire assembly.

b) Wire-to-shield test—Patient end connectors are shorted together. Use test circuit shown in figure 4.

c) Internal-to-external conductor test — This test is to be performed only if exposed metal components are present (i.e., metal nameplate, garment clip, or ungrounded metal connector shell). Use test circuit shown in figure 5.

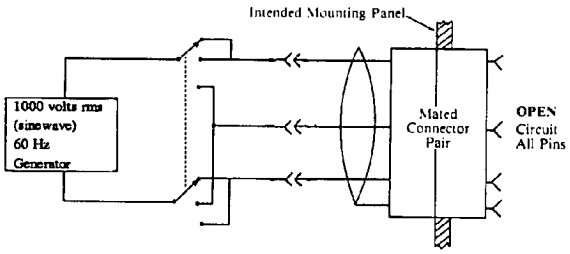

Figure 3—Wire-to-wire (each pair) dielectric withstand test (See 4.5.1 and 5.5.1.)

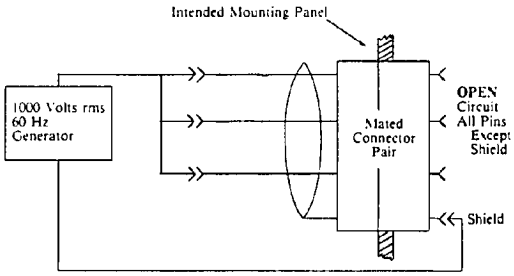

Figure 4—Wire-to-shield dielectric withstand test (See 4.5.1 and 5.5.1.)

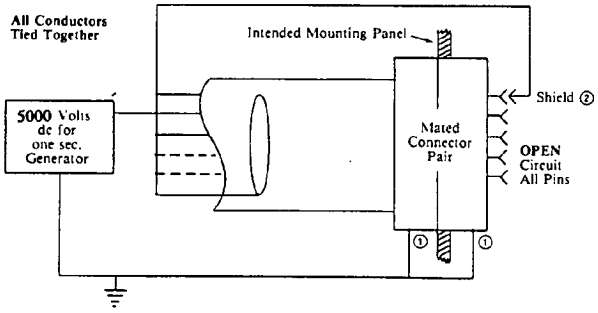

Figure 5—Internal-to-external-conductor dielectric withstand test circuit. (Connection 1 is made if conductive materials will be exposed in usage; connection 2 is made if shield is not available at the patient connection.

5.5.2 Sink current

Compliance with 4.5.2 can be determined by measuring the sink current per figure 6 with all patient end connections shorted together and connected to 120 V rms (+/- 20%). The trunk cable and patient leadwires shall be located 20 centimeters (cm) away from a ground plane connected to earth. The instrument connector end of the trunk cable shall be left open.

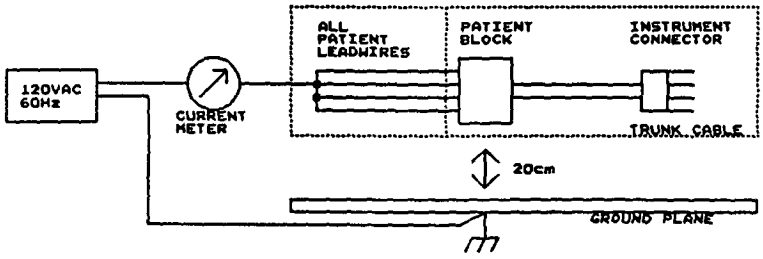

Figure 6—Sink current test circuit

5.5.3 Defibrillation withstand

Measure the resistance of each patient end termination to the corresponding pin in the instrument connector. Record the resistance for later use.

Connect the leadwire under test according to the circuit of figure 7 (see page 8). All pins of the instrument connector shall be shorted together and connected to ground. All patient end connections not being tested shall be left open.

Charge the test circuit to a minimum of 5000 V and discharge into the patient end connection being tested 3 times at 60 s +/- 5 s intervals. The energy delivered to the assembly under test shall be 360 joules (J) ± 20%.

After 3 applications of the pulse, the value of the resistance of the cable assembly shall not have changed by more than 10% or 10 Ω, whichever is greater. Repeat the test for each leadwire.

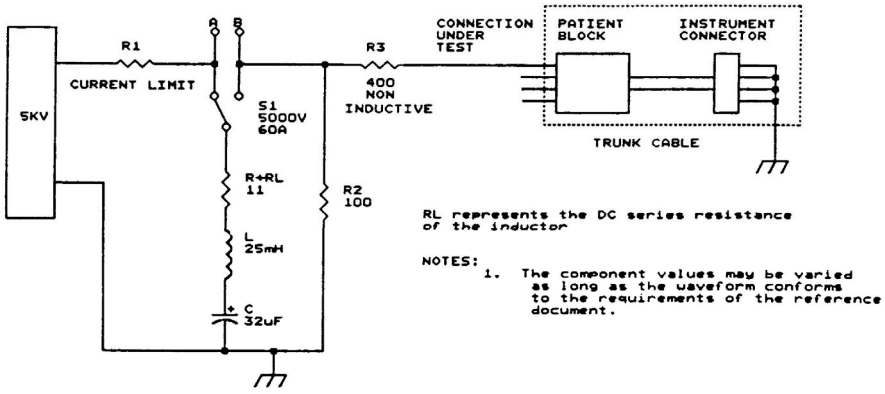

Figure 7—Defibrillator withstand

5.5.4 Cable and leadwire noise

Test a representative sample of the cable material for noise in accordance with the following protocol. The test setup is shown in figure 8 (see page 8).

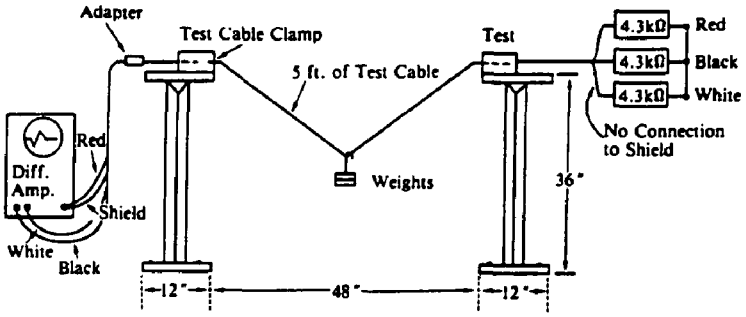

Figure 8—Test setup for cable noise measurement. The total length of cable to be tested shall be 7 feet. (Colors are designated for clarity only.)

A 5-ft length of cable is mounted between clamps positioned 4 ft apart. At one end of the cable, connect three signal wires together through 4.3 kilohm (kΩ) series resistors.

NOTE—Any additional signal wires (such as in a five-wire cable) are not connected at this end.

At the other end of the cable, two of the signal wires are connected to the inputs of an oscilloscope differential amplifier, having a 3 dB bandwidth between 0.1 to 100 Hz (6 dB per octave rolloff). The third signal wire and the overall cable shield are connected to the oscilloscope ground.

If each wire is individually shielded, two of the signal wires are to be connected to the inputs of an oscilloscope differential amplifier, having a 3 dB bandwidth between 0.1 to 100 Hz (6 dB per octave rolloff). The third signal wire and each of the wire shields are to be connected to the oscilloscope ground.

A weight equal to 40 times the weight of 1 ft of the cable is attached at the cable center, raised to the position directly between the cable clamps, then dropped freely.

The maximum peak-to-peak noise, as measured on the oscilloscope, shall be less than 50 µV.

5.5.5 Flex life of instrument connector, cable yoke, patient leadwire connector, and patient end termination flex relief

The test setup is shown in figure 9 (see page 9). A 2-ft section of cable is suspended from the flexing fixture.

A weight is attached to the free end of the cable with a clamp. The total weight of the weight and clamp shall be 0.5 lbs (+/- 5%) if the cable diameter (d) including the jacket is 0.125 in or less. If the cable diameter including the jacket is greater than 0.125 in, the total weight used is calculated using the formula:

Total weight = 10 * 3.14159 * d^2 (+/- 5%)

The flexing fixture is rotated through the specified number of flexes (see table 1). One flex is defined as rotation from 0 to 90, back to –90 degrees, and back to 0.

Failure is defined as any of the following:

— increase in series resistance of any conductor of more than 50% from original specification;

— a short between any two conductors;

— a short between any conductor and shield; or

— rupture of the specimen jacket (jacket rupture is permitted within 1 in of the weight attachment position, but a retest of another specimen is required).

5.5.6 Tensile strength of cable connections

Compliance with 4.5.6 can be determined by comparing the results of the following test with table 2.

Place one end of the cable sample in the wire holding fixture so that no wire is pinched.

Set the distance between the wire holding fixture and the pull tester to the minimum possible for the wire being tested. The pull tester shall be aligned so that the force is exerted axially along the cable sample.

Record the force in pounds required to cause cable failure. Cable failure at the cable attach point at either end does not constitute failure; the sample must fail between the attachment points.

Cable failure is defined as any of the following:

— a 50% or greater increase in resistance of any signal wire;

— a short between any two conductors; or

— a short from any signal wire to the shield.

5.5.7 Number of connector mate/unmate cycles

Using either a manual or automated device, each connector termination needs to be connected and disconnected with its intended mating connector, or equivalent, to ensure acceptable product life. This test shall include the instrument connector, cable yoke, patient leadwire connector and the patient end termination. Each connector shall complete the mating cycles defined in the tables listed in 4.5.7.

After the cable and leadwire assemblies have been subjected to this procedure, they shall meet all the requirements of 4.5.8 and 4.5.9.

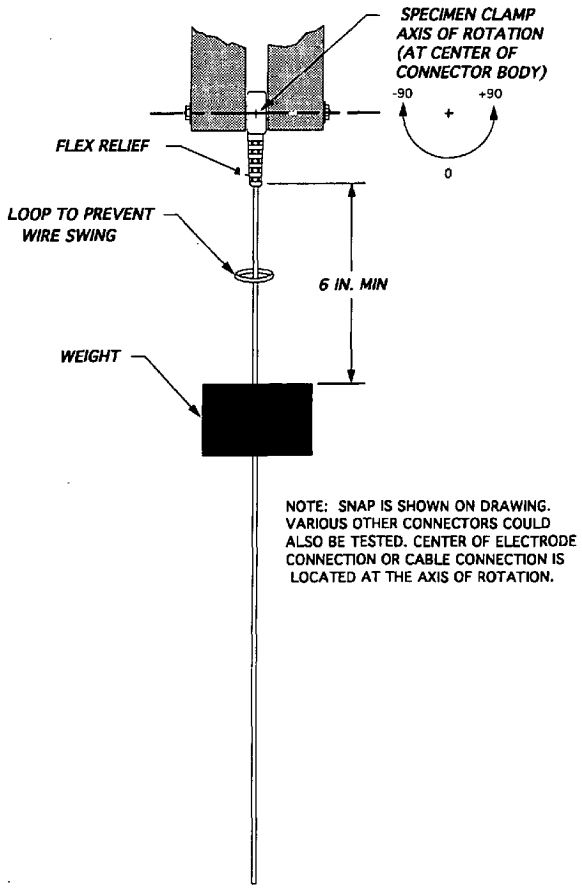

Figure 9 —Flex life test setup

5.5.8 Contact resistance

Using a digital voltmeter, measure the resistance of the desired connection after the specified number of mate and unmate cycles (4.5.7). Prior to measuring the resistance of the actual connection, short the probes of the meter together and record the value. Subtract this value from all contact resistance measurements.

5.5.9 Connector retention force

This test shall include the instrument connector and patient leadwire connector. Place the intended mating connector, or equivalent, in a holding fixture. After the instrument connector or patient leadwire connector has been inserted into the mating connector, attach the pull test device to the cable material approximately six inches from the connector assembly.

Axially pull the cable until the connector assembly disconnects from the mating connector. Record the force in pounds required to cause disconnect. Pull force results must meet or exceed the minimum requirements defined in 4.5.9.

5.5.10 Patient leadwire resistance

Place the volt/ohm meter in resistance mode. Short the test leads of volt/ohm meter together and record the value. Connect the test leads across leadwire under test and then subtract the previously recorded value from the meter reading to obtain the final resistance. Compare to table 5 to determine compliance with 4.5.10.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

The overriding philosophy of the development of this standard was to create a standard that would benefit the clinical end users and their biomedical support staff.

Cases have been documented in the literature of patients being burned or killed when detachable patient leads with male pin connectors were inadvertently mated with power mains connectors. While these incidents typically occurred with individual nonshielded leads or preattached leadwire electrodes, the same type of hazard exists for leadsets where several wires are molded together into one block.

Safety designs that do not have these exposed male pins are now mandated by several regulatory and standards bodies, among them Underwriters Laboratories (UL), the International Electrotechnical Commission (IEC), and the United Kingdom Department of Health Services (DHS).

However, in the United States, the switchover to safety ECG connections has been slow, hampered by a very large installed base and by several competing designs of safety leadwires and cables.

This standard is an attempt to accelerate the switchover to such safety designs, with the goal of eliminating this entire class of tragic accidents.

The standard attempts to do this in two ways: first, by standardizing the design of the leadwire/trunk cable interface to allow interchangeability for emergency situations, regardless of brand. For typical monitoring situations, optimal performance is mostly obtained by using a matched set of leadwire and cable, i.e., from the same manufacturer. Second, this standard attempts to accelerate the switchover to safety ECG connectors by setting minimum performance and quality standards for such products, to give the user an enhanced level of confidence in them. In addition, this document standardizes the tests used to determine performance to give end users and their biomedical engineering support staff the information necessary to make informed choices among the many different types of cables and leadwires currently available.

At the time this standard was published, formal withdrawal of the AAMI standard *ECG connectors* (AAMI ECGC-5/93) was being ballotted.

A.3 Definitions

A.4 Requirements

This standard starts with the premise that a typical end user will expect a monitoring trunk cable to last a minimum of 6 months and reusable leadwire to last a minimum of 3 months. The typical patient stay is 6 days. These figures were derived from talking to actual users about their needs and expectations.

Based on the above figures, this standard projects the performance characteristics required of a cable or reusable leadwire in order for this 3-month average life to be achieved.

Obviously, this is an attempt to approximate average use over a wide variety of different clinical situations. Results in a busy urban emergency room will be very different than those in a quiet rural general care ward. The goal is to allow the factual comparison of different products, in the same way that the U.S. Environmental Protection Agency (EPA) made automobile mileage comparable across manufacturers and model lines.

A.4.1 Labeling requirements

A.4.2 Construction requirements

A.4.2.1 Leadwire to trunk cable interconnection

As outlined in A.1, the goal of this section is to allow interchangeability between leadwires and trunk cables. The DIN 42-802 standard connection has become widely accepted by users of unshielded leadwires. Therefore, it was chosen as a model for the unshielded systems. The configuration of the shielded system incorporates the requirements of DIN 42-802 and therefore allows connection of an unshielded leadwire into a shielded system trunk cable as well as providing a standard connection for shielded leadwire systems.

Currently, some manufacturers provide multiple patient leadwires configured together as a set. The lead order and fixed center distances for the RL, LA, LL, RA, and V leads are provided so patient leadwires and trunk cables of different manufacturers will connect properly. The possibility of having different mating orders between patient leadwire sets and trunk cables is discouraged.

A.4.2.2 Current limiting devices

Since one of the goals of the standard is interchangeability of leadwires at the leadwire/cable yoke interface, specifying that the current limiters are not in the leadwires will ensure that the leadwires will work with any monitor.

A.4.3 Cleaning, disinfection, and chemical resistance

A.4.3.1 Cleaning and disinfection

The number of 15 cleanings and disinfections corresponds to somewhat more than 1 cleaning per week. U.S. Pharmacopoeia (USP) green soap, glutaraldehyde solutions, and sodium hypochlorite (bleach) solutions are representative of cleaning and disinfecting chemicals used in the clinical environment. (These are generic terms for a variety of brand name cleaning agents and disinfectants.) The test method given does not follow the instructions for use of typical commercially available disinfectants/cold sterilants. Typically, these require a soak of several hours to achieve high level disinfecting/sterilization. Since cables and leadwires usually cannot be soaked without fluid entering the connectors or wire, it was decided to specify a wipe. The requirements are intended to reflect current epidemiological practice.

NOTE—The above section is an expansion of 3.3.3.4 of the AAMI ECG connector standard (AAMI ECGC—5/83). It in no way would be considered exhaustive as to cleaning/disinfecting agents or cleaning procedures. It is recommended that the medical facility evaluate and establish an appropriate cleaning/disinfecting protocol that at the same time does not cause deterioration of the cable or leadwire. For further information, reference is made to ANSI/AAMI ST35—1991, *Good hospital practice: Handling and biological decontamination of reusable medical devices*.

A.4.4 Sterilization exposure

The number of 10 sterilizations corresponds to somewhat more than 1 sterilization per week.

NOTE—For more details regarding sterilization, reference is made to ANSI/AAMI ST41—1992*, Good hospital practice: Ethylene oxide sterilization and sterility assurance*. Regarding residual limits, reference is made to ANSI/AAMI/ISO 10993-7—1995, *Biological testing of medical devices ethylene oxide sterilization residuals*.

A.4.4.1 Exposure to ethylene oxide (EO)

The conditions specified are adequate for testing potential degradation of the cable and leadwire set. These conditions are not intended to suggest a suitable sterilization cycle for use in sterile processing in health care facilities.

Due to environmental concerns regarding Freon® and recent EPA regulations that require the phasing out of 12% EO and 88% diluent mixtures (and, therefore, of the sterilizing equipment used by them) by the end of 1994, most hospitals have already taken their 12/88 sterilizers out of service and replaced them with 100% EO sterilizers. Therefore, the test procedure specifies 100% EO sterilization, instead of 12/88.

A.4.5 Performance requirements — trunk cable and patient leadwires

A.4.5.1 Dielectric withstand voltage

This requirement is intended to guarantee that the dielectric strength of the various cable components is sufficient to withstand the maximum voltage developed by a defibrillator.

A.4.5.2 Sink Current

For reasons of patient safety, the connector-cable assembly is restricted to use on apparatus that meets the risk current limits and labeling requirements for isolated patient connections that are specified in the American National Standard, *Safe current limits for electromedical apparatus* (see 2.2). Reasons for the specific risk current limits specified in 2.2 are provided in the rationale statement for that standard.

A.4.5.3 Defibrillation withstand

The cables and leadwires must be able to withstand repeated defibrillation without damage. During defibrillation, the current limiting devices that may be included in the trunk cable can possibly be degraded by the defibrillation pulse. Should these devices be degraded sufficiently, damage to the monitor may result. It should be noted that repeated defibrillation of carbon leadwires can result in significant increases in leadwire resistance. Should the resistance increase sufficiently, monitor performance may be adversely affected.

The 100 Ω resistive load across the pulse generator simulates the impedance of the patient. The 400 Ω resistor in series with the generator output simulates the losses due to body and electrode resistance and the voltage drops due to the electric field distribution found between the defibrillator paddle and the connection to the cable at the patient end.

A.4.5.4 Cable and leadwire noise

Cable assemblies are subject to flexing as a result not only of patient movement but also of movement by attending personnel. Noise artifact introduced by this motion must be minimized in order to prevent degradation of displayed or inscribed (traced) ECG waveforms and to minimize false alarms and inaccurate R-wave detection by cardiac monitors.

A.4.5.5 Flex life of instrument connector, cable yoke, patient leadwire connector, and patient end termination flex relief

— Regarding the instrument connector flex relief and cable yoke, the performance level corresponds to an assumed rate of about 5 hard flexes per day over the life expectancy of the trunk cable.

— Regarding the patient leadwire connector and patient end termination, the performance level corresponds to an assumed rate of about 5 hard flexes per day over the life expectancy of the leadwire.

A.4.5.6 Tensile strength of cable connections and A.4.5.9 Connector retention force

This standard follows the system design philosophy that when the patient tugs on the leadwire by moving, the consequences should occur in the following order:

— end termination disconnects from the electrode;

— electrode rips away from patient's skin;

— leadwires disconnect from trunk cable;

— trunk cable disconnects from monitor;

— end termination is damaged;

— leadwire connection to trunk cable is damaged;

— trunk cable is damaged at either end;

— monitor front panel connector is damaged;

— monitor is ripped from wall shelf.

Thus, the tensile test limits of 4.5.6 and retention thresholds of 4.5.9 were chosen at the given levels in an attempt to implement this philosophy.

A.4.5.7 Number of connector mate/unmate cycles

— Instrument connector and receptacle: This performance level corresponds to an assumed rate of about 2 unplug/plug cycles per day.

— Patient leadwire and trunk cable yoke connection: This performance level corresponds to an assumed rate of about 5 mate/unmate cycles per day.

— Patient end termination: This performance level corresponds to an assumed rate of about 5 mate/unmate cycles per day.

A.4.5.8 Contact resistance

This refers to the contact components only. The actual value of these contacts should be quite low, probably 0.1 Ω or less. However, it is not possible to measure resistances in this range with a normal two-wire Ω meter with any degree of confidence. A four-wire measurement would be required. The committee decided that due to the high input impedance of modern cardiac instruments, a 1 Ω contact resistance presented no performance limitation and enabled the manufacturer to use simple instrumentation to perform the test.

A.4.5.9 Connector retention force

See A.4.5.6.

A.4.5.10 Patient leadwire resistance

Since leadwire materials other than copper have come into wide use, the committee felt that it was important to include maximum resistance numbers for these alternate materials. The resistance limits for the different leadwire lengths were included based on manufacturers' input and represent reasonable values for the current state of the art. While it would have been possible to simply require that all leadwires have a resistance less than some maximum value, the committee felt that it was important to quantify realistic values for the various leadwire lengths. It should be noted that mixing leadwires of drastically different resistances may adversely affect the noise and common mode performance of the monitoring system.

Annex B
(informative)

Cited references

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Good hospital practice: Ethylene oxide sterilization and sterility assurance*. ANSI/AAMI ST41—1992. Arlington (VA.): AAMI, 1992. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Good hospital practice: Handling and biological decontamination of reusable medical devices*. ANSI/AAMI ST35—1991. Arlington (VA.): AAMI, 1991. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals*. ANSI/AAMI/ISO 10993-7—1995. Arlington (VA.): AAMI, 1995. American National Standard.

Annotations from EC53.pdf

Page 3

Annotation 1; Label: AAMI; Date: 1/29/2002 2:07:21 PM
This version of ANSI/AAMI EC53:1995/(R)2001has been corrected to reflect errata issued by AAMI in May of 1998 and December of 2001.