American National Standard

ANSI/AAMI EC53:2013

ECG trunk cables and patient leadwires

AAMI
Advancing Safety in Medical Technology

Objectives and uses of AAMI standards and recommended practices

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

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

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

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

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

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

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

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

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

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

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American National Standard

ANSI/AAMI EC53:2013
(Revision of ANSI/AAMI EC53:1995 and ANSI/AAMI EC53A:1998)

ECG TRUNK CABLES and PATIENT LEADWIRES

Developed by
Association for the Advancement of Medical Instrumentation

Approved 19 November 2013 by
American National Standards Institute, Inc.

Abstract: The objective of this standard is to allow ECG TRUNK CABLES and PATIENT LEADWIRES to be interchanged between ECG DEVICES with isolated PATIENT connections by establishing a common interface between the TRUNK CABLE and the PATIENT LEADWIRE connectors. Performance and safety criteria for TRUNK CABLES and PATIENT LEADWIRES used with isolated PATIENT connectors are also specified. This standard's original scope related to TRUNK CABLES and PATIENT LEADWIRES used with cardiac monitors. The scope was extended to include PATIENT LEADWIRES used with other ECG DEVICES including diagnostic electrocardiographs, ambulatory ECG (Holter) recorders/event recorders and ECG telemetry.

Keywords: electrocardiographic monitoring; cardiac monitoring; cables; patient leadwires

AAMI Standard

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Contents

Tables

Figures

Glossary of equivalent standards

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

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph (ECG) Committee

This standard was developed by the ECG/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 published, the **AAMI Electrocardiograph Committee** had the following members:

Cochairs:
Richard A. Sunderland
Ahmet Turkmen
Brian J. Young

Members:
Robert William Bain, CBET, Baltimore Medical Engineers & Technician Society
Scott Coggins, Covidien
Prakash C. Deedwania, MD, The VA Medical Center
Laura Dhatt, Physio-Control
Sreeram Dhurjaty, Dhurjaty Electronics Consulting LLC
Richard Diefes, ECRI Institute
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Arthur R. Eddy, Jr.
James J. Greco, Medapprove Inc.
Richard Gregg, Philips Electronics North America
Janice M. Jenkins, PhD, University of Michigan College of Engineering
Dongping Lin, PhD
Walter G. Lloyd, Childrens Hospital Boston
Peter W. Macfarlane, Royal Infirmary
Luis A. Melendez, Partners Healthcare
George Moody, Massachusetts Institute of Technology
Cadathur Rajagopalan, PhD SMIEEE, Mindray DS USA Inc.
Linda Ricci, FDA/CDRH
Johann-Jakob Schmid, Schiller AG
Jonathan Steinberg, MD, St Lukes Roosevelt Hospital Center
Richard A. Sunderland, Welch Allyn, Inc.
Ahmet Turkmen, BS MS PhD, University of Wisconsin-Stout
J.S. Wiley, Draeger Medical Systems Inc.
Jeffrey Wiser, 3M Healthcare
Ted Yantsides, Conmed Corp
Brian J. Young, GE Healthcare

Alternates:
Mark J. Callahan, Covidien
Kejian Chen, 3M Healthcare
Yu Chen, PhD, Draeger Medical Systems Inc.
Steve Duke, Physio-Control
Charles S. Ho, PhD, FDA/CDRH
Shen Luo, PhD, Mindray Medical
Serkan Sezer, Schiller AG
Donald Stewart, Spacelabs Medical Inc.
John J. Wang, Philips Electronics North America
Yinqi Zhang, 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.

Foreword

This standard was developed by the AAMI Electrocardiograph (ECG) Committee. The objective of this standard is to provide minimum labelling, performance, and safety requirements that will help ensure a reasonable level of clinical efficacy and PATIENT safety in the use of ECG TRUNK CABLES and PATIENT LEADWIRES on equipment with isolated PATIENT connections in common ECG applications. The goal of this standard is to promote PATIENT safety by helping to prevent inadvertent mating of PATIENT LEADWIRES with power mains connectors, and by allowing more rapid transfer of PATIENTs who require continuous monitoring under emergency conditions.

This standard's original scope related to TRUNK CABLES and PATIENT LEADWIRES used with cardiac monitors. The scope was extended to include PATIENT LEADWIRES used with other ECG DEVICES including diagnostic electrocardiographs, ambulatory ECG (Holter) recorders/event recorders and ECG telemetry.

This is a revision of ANSI/AAMI EC53:1995, *ECG cables and leadwires* and the amendment, ANSI/AAMI EC53A:1998. In 1998 and in 2001, two mistakes related to defibrillation withstand (section 5.5.3 and figure 7) were fixed by issuing an errata.

Continuous monitoring of a PATIENT's cardiac activity is routine. Monitored PATIENTS are sometimes transferred to other locations, which use different ECG DEVICES. The committee, therefore, felt it was desirable to require all TRUNK CABLES and PATIENT LEADWIRES to share a common interface at the CABLE YOKE – PATIENT LEADWIRE CONNECTOR. The committee also felt that a standardized PATIENT LEADWIRE system would help to reduce confusion, errors, setup time, and training time. Therefore, in addition to specifying safety and performance criteria, this standard also establishes a TRUNK CABLE to PATIENT LEADWIRE interface that supports interchangeability. Although using TRUNK CABLES and PATIENT LEADWIRES from different MANUFACTURERS might affect the quality of an acquired ECG signal, it is unlikely to otherwise compromise performance, which for cardiac monitors includes detection of life-threatening events.

As used within the context of this document, "shall" indicates requirements strictly to be followed to conform to the standard. "Should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the recommended practice. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.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 technological advances are made and as new data come to light.

This standard reflects the conscientious efforts of concerned health care professionals and MANUFACTURERS to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the American National Standard, *ECG trunk cables and patient leadwires* (ANSI/AAMI EC53:2013), but it does provide important information about the development and intended use of the document.

ECG TRUNK CABLES and PATIENT LEADWIRES

1 Scope

This standard covers TRUNK CABLES and PATIENT LEADWIRES used to acquire surface electrocardiographic (ECG) monitoring signals for cardiac monitors/telemetry transmitters (ANSI/AAMI/IEC 60601-2-27), diagnostic electrocardiographs (ANSI/AAMI/IEC 60601-2-25) and ambulatory ECG recorders/event recorders (ANSI/AAMI/IEC 60601-2-47). In the broadest sense, this standard applies to any ECG DEVICE that uses PATIENT LEADWIRES and possibly ECG TRUNK CABLES to acquire surface electrocardiographic signals.

This standard covers both disposable and reusable PATIENT LEADWIRES as well as TRUNK CABLES (generally considered to be reusable). The concept of "disposable" applies to products intended to be used for a single PATIENT stay, typically up to 7 days (SINGLE-PATIENT USE) as well as to products intended to be used one time, typically a few hours (SINGLE USE). For terminological consistency, the concept of "reusable" is referred to as MULTI-PATIENT USE.

Some PATIENT LEADWIRES and TRUNK CABLES used for recording applications might not be intended to be DEFIBRILLATOR-PROOF, but otherwise must meet all the requirements in this standard. Such PATIENT LEADWIRES and TRUNK CABLES are included within the scope of this standard but must be clearly labelled as not being DEFIBRILLATOR-PROOF.

The tests in this standard allow MANUFACTURERS to verify compliance of their products to this standard's specifications. These tests are not intended to be performed by OPERATORS or RESPONSIBLE ORGANIZATIONS.

ECG TRUNK CABLES and PATIENT LEADWIRES used in applications that require special characteristics, such as a magnetic resonance imaging (MRI) suite, are excluded from this standard. TRUNK CABLES and PATIENT LEADWIRES covered by this standard might support physiologic functions in addition to ECG monitoring, such as respiration monitoring by impedance pneumography. However, the TRUNK CABLE and PATIENT LEADWIRES must meet all of the requirements of this standard, unless a requirement is specifically excluded.

2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. AAMI maintains a register of currently valid AAMI technical documents.

2.1 ANSI/AAMI ES60601-1, *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance.* AAMI. 2005.

2.2 ANSI/AAMI/IEC 60601-2-27, *Medical electrical equipment — Part 2-27: Particular requirements for basic safety and essential performance of electrocardiographic monitoring equipment.* AAMI. 2011.

2.3 IEC 60601-2-49, *Medical electrical equipment — Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment.* International Electrotechnical Commission. 2011.

3 Definitions

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

3.1 CABLE ASSEMBLY: The assembly of individual wires and/or wires bundled into one jacket that connects the PATIENT to an ECG DEVICE. Typically, this consists of a TRUNK CABLE and a set of PATIENT LEADWIRES. PATIENT LEADWIRES may be separable from the TRUNK CABLE or may be integrated as a single assembly into the TRUNK CABLE (a one piece TRUNK CABLE and PATIENT LEADWIRE assembly).

3.2 CABLE YOKE: The end of the TRUNK CABLE into which PATIENT LEADWIRES plug.

NOTE—PATIENT-worn ECG DEVICES such as ambulatory ECG recorders and ECG telemetry transmitters usually incorporate a built-in CABLE YOKE. In this case, the PATIENT LEADWIRES plug directly into the ECG DEVICE rather than by mating a TRUNK CABLE to the ECG DEVICE'S INSTRUMENT CONNECTOR RECEPTACLE.

3.3 ECG DEVICE: ME EQUIPMENT that is used to acquire and to display/record surface electrocardiographic signals.

Examples:
Cardiac monitor
Ambulatory ECG (Holter) recorder
Cardiac event recorder
ECG telemetry transmitter
Diagnostic electrocardiograph

3.4 FLEX RELIEF: The portion of the TRUNK CABLE or PATIENT LEADWIRE assembly at the junction of the connector to the assembly that prevents flexure of the assembly from damaging the assembly or the connector.

NOTE—FLEX RELIEF may be part of the strain relief. Strain relief is the part of a connector/cable that supports the connection and prevents forces that are applied to the cable from being transferred to the contacts and wires within the connector housing.

3.5 INSTRUMENT CONNECTOR: The connector on a TRUNK CABLE that mates to an INSTRUMENT CONNECTOR RECEPTACLE on an ECG DEVICE.

3.6 INSTRUMENT CONNECTOR RECEPTACLE: The connector on an ECG DEVICE that mates to an INSTRUMENT CONNECTOR.

3.7 MULTI-PATIENT USE: Products specifically not labeled for SINGLE USE or SINGLE-PATIENT USE.

3.8 PATIENT-END TERMINATION: The connector on a PATIENT LEADWIRE that connects to an electrode on the PATIENT.

3.9 PATIENT LEADWIRE CONNECTOR: The connector on a PATIENT LEADWIRE that allows the leadwire to mate to a CABLE YOKE (or directly to the ECG DEVICE having an integrated CABLE YOKE).

3.10 PATIENT LEADWIRE: A cable that ends with a PATIENT-END TERMINATION and a PATIENT LEADWIRE CONNECTOR.

3.11 SINGLE USE: Products specifically labeled as being for a single use on a single PATIENT.

3.12 SINGLE-PATIENT USE: Products specifically labeled as being for longer term use on a single PATIENT only.

3.13 TRUNK CABLE: The portion of the CABLE ASSEMBLY within which all wires are bundled together into one jacket or are in some way bound permanently together. Typically, this has a CABLE YOKE at one end with connectors for PATIENT LEADWIRES, and an INSTRUMENT CONNECTOR at the other end for connecting to the ECG DEVICE.

4 Test methods

NOTE—The test methods specified in Clause 5 are considered to be referee test methods. Other test methods may be used to prove designs, provided the MANUFACTURER establishes equivalence with the referee tests a priori to ensure comparability of test results. These test methods do not identify measures that should be taken in order to safely perform each test.

Instrumentation

The following test instruments are required.

—An alternating current (a.c.) current meter capable of measuring 10 microamperes (μA) with ± 1% accuracy;

—An oscilloscope with a differential amplifier having a 3 decibel (dB) bandwidth between 0.1 and 100 hertz (Hz) (6 dB per octave roll off) capable of resolving a 10 microvolt (μV) signal. The input impedance of the differential channel shall be at least 1 megohm (MΩ). The 3 dB mid-band 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 ± 90°;

—A pull test apparatus capable of applying an axial force along a cable or connector of at least 135 newton (N);

—A volt/ohm meter with the following minimum specifications:
—d.c. voltage range 10 V (±2%);
—a.c. voltage range (rms) 10 V (±2%);
—d.c. resistance 0.1 Ω to 1 MΩ (±2%).

Test circuits

Unless otherwise specified, use resistors with a maximum ± 5% tolerance for frequencies up to 1 megahertz (MHz), non-polarized capacitors of suitable rating, with a maximum tolerance of ± 10% and inductors with a maximum tolerance of ± 5%.

Test signals

Unless otherwise specified, input test signals shall be accurate to ± 1% (d.c. voltages) or ± 2 % (a.c. voltages).

5 Requirements

5.1 *Labeling requirements

5.1.1 Package labeling

Each unit package supplied to the clinical OPERATOR shall have the following as part of a package insert or label:

> This cable [or leadwire or set of leadwires] meets the requirements of the standard, *ECG TRUNK CABLES and PATIENT LEADWIRES* (ANSI/AAMI EC53). This cable [or leadwire or set of leadwires] is intended for SINGLE [or SINGLE-PATIENT or MULTI-PATIENT] USE.

For TRUNK CABLES and PATIENT LEADWIRES that are not DEFIBRILLATION-PROOF, each unit package supplied to the clinical OPERATOR shall have the following as part of a package insert or label:

> This cable [or leadwire or set of leadwires] is not defibrillator-proof and should not be used in areas where a PATIENT might be defibrillated.

5.1.2 CABLE YOKE labeling

The CABLE YOKE shall have each PATIENT LEADWIRE position permanently marked (e.g., molded or engraved) with the appropriate electrode designation and color code per ANSI/AAMI/IEC 60601-2-27 or ANSI/AAMI/IEC 60601-2-47 Labeling of connection polarity is not required, but is customary for products such as ambulatory ECG recorders.

5.1.3 PATIENT LEADWIRE termination labeling

If the entire wire is not appropriately color-coded, the terminations on both ends of the PATIENT LEADWIRE shall be color-coded per ANSI/AAMI/IEC 60601-2-27or ANSI/AAMI/IEC 60601-2-47. If the PATIENT LEADWIRE CONNECTOR is not separable from the CABLE YOKE, then only the PATIENT-END TERMINATION shall be color-coded.

The PATIENT-END TERMINATION should include nomenclature that reinforces the color designation (i.e., R, L).

5.1.4 *Labeling to identify the location of current-limiting devices

CABLE ASSEMBLIES or ECG DEVICES that incorporate current-limiting devices (e.g., for defibrillation protection) shall be permanently marked to indicate that current-limiting devices are present. Also see subclause 5.2.2.

When current-limiting devices are intentionally positioned as close to the patient as possible, the unit package supplied to the clinical OPERATOR that is associated with the component that contains the current-limiting devices shall be permanently marked to indicate that current-limiting devices are present.

5.1.5 Optional labeling to identify accessories as not being DEFIBRILLATION-PROOF

TRUNK CABLES and PATIENT LEADWIRES that are not DEFIBRILLATION-PROOF may be permanently marked to indicate that they are not DEFIBRILLATION-PROOF (e.g., IEC 60601-1's symbol for DEFIBRILLATION-PROOF covered by a negation cross).

Compliance with all of clause 5.1 is checked by inspection.

5.2 Construction requirements

5.2.1 *PATIENT LEADWIRE to TRUNK CABLE interconnection

Connector stems (see the 4.5 mm dimension in Figures 1 and 2) may include features intended to ensure proper retention forces for PATIENT LEADWIRE CONNECTORS in the CABLE YOKE provided that interchangeability is not affected.

For CABLE ASSEMBLIES in which non-shielded PATIENT LEADWIRES are separable from the TRUNK CABLE as single leadwires, the connection between PATIENT LEADWIRE CONNECTORS and the CABLE YOKE should meet the tolerances of Figure 1 and the CONDUCTIVE CONNECTION requirements of IEC 60601-1 and IEC 60601-2-49.

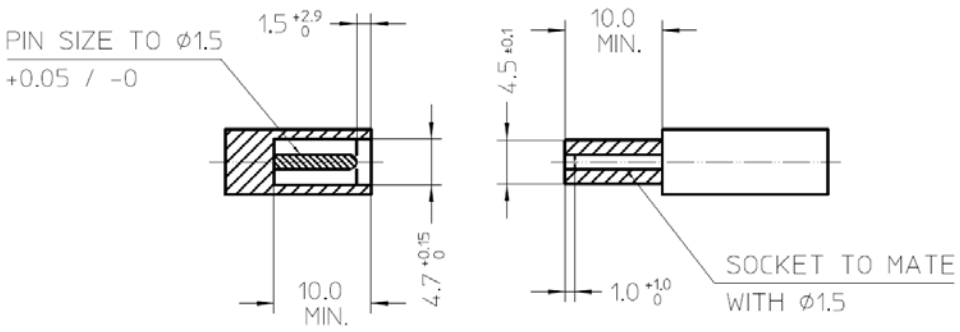

Figure 1 — Non-shielded PATIENT LEADWIRE to CABLE YOKE connection

For CABLE ASSEMBLIES in which PATIENT LEADWIRES are separable from the TRUNK CABLE as shielded leadwires, the connection between PATIENT LEADWIRE CONNECTORS and CABLE YOKE should meet the requirements of Figures 2 and 3.

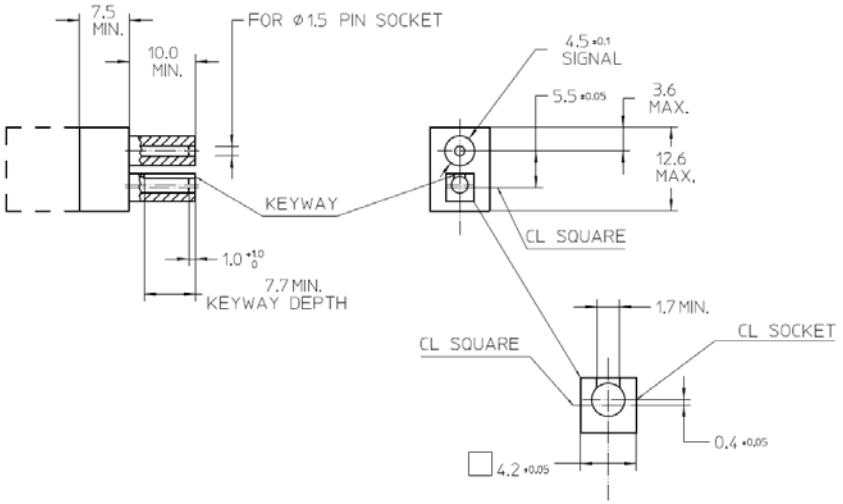

Figure 2 — Shielded PATIENT LEADWIRE to CABLE YOKE connection (equipment side)

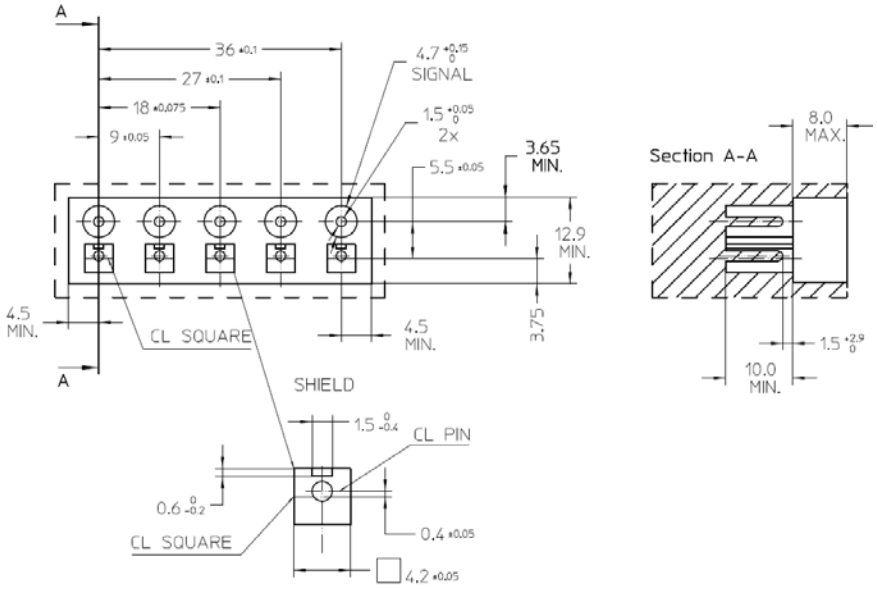

Figure 3 — Shielded PATIENT LEADWIRE to CABLE YOKE connection (PATIENT side)

NOTE—Figures 2 and 3 illustrate a five-wire CABLE YOKE. Fewer or more PATIENT LEADWIRES may be used as necessary and PATIENT LEADWIRES may be stacked in multiple rows.

For the shielded interconnection shown in Figure 3:

a) The following lead order should be used in a shielded CABLE YOKE when all PATIENT LEADWIRES are in a single row, starting with the appropriate PATIENT LEADWIRE at the end marked "*" (as shown in Figure 3, from left to right): for IEC Code 1 – N (or RF), L, F, R, C1, C2, …; for IEC Code 2 – RL, LA, LL, RA, V1, V2, …). If a TRUNK CABLE includes PATIENT LEADWIRES other than these, the additional PATIENT LEADWIRES should not interfere with the specified order, but may otherwise be positioned as desired, provided that the width spacing is ≥ 0.9 mm and individual shielded patient leadwires can plug in.

b) Other lead orders are permissible if appropriate based upon the INTENDED USE.

Compliance is checked by inspection.

5.2.2 *Current-limiting devices

PATIENT LEADWIRES for all ECG DEVICES, except those intended for use in MRI environments, shall not contain current-limiting devices unless at least one of the following conditions is met:

1) The PATIENT LEADWIRES are integrated into the TRUNK CABLE and cannot be replaced by the clinical OPERATOR.

2) The interconnection between the PATIENT LEADWIRE CONNECTOR and the CABLE YOKE/ECG DEVICE is a proprietary or patented design not used by other MANUFACTURERS.

3) The current-limiting device is located entirely within the PATIENT-END TERMINATION of the PATIENT LEADWIRE.

For 2) and 3) above, the CLINICAL OPERATOR shall be strongly cautioned by prominent labeling and in the instructions for use to only use the appropriate MANUFACTURER'S PATIENT LEADWIRES with this TRUNK CABLE/ECG DEVICE (using other PATIENT LEADWIRES could compromise PATIENT safety).

Compliance is checked by inspection.

5.3 Performance requirements — TRUNK CABLES and PATIENT LEADWIRES

All requirements of this standard shall be met while tests are performed in any sequence on the same TRUNK CABLES and PATIENT LEADWIRES.

5.3.1 *Non-DEFIBRILLATION-PROOF TRUNK CABLES and PATIENT LEADWIRES

TRUNK CABLES and PATIENT LEADWIRES that are explicitly labelled as not being DEFIBRILLATION-PROOF shall not be treated as DEFIBRILLATION-PROOF APPLIED PARTS nor shall they be subjected to IEC 60601-1's requirements for DEFIBRILLATION-PROOF APPLIED PARTS. Subclause 5.1.5 describes suitable labelling requirements.

5.3.2 *Cable and leadwire noise

A 150 centimeter (cm) section of cable material shall not produce noise > 50 µV peak-to-valley.

Compliance is checked using the test setup of Figure 4 with an oscilloscope differential amplifier that has a 3 dB bandwidth between 0.1 and 100 Hz (6 dB per octave roll off).

Mount a 152 cm length of cable between clamps positioned 122 cm apart. At one end of the cable, connect three signal wires together through 4.3 (kilohm) kΩ series resistors.

NOTE—Do not connect any other signal wires (such as the extra pair from a five-wire cable) at this end.

Connect two of the signal wires at the other end of the cable to the inputs of the oscilloscope differential amplifier.

a) For wires that are not individually shielded, connect the third signal wire and the overall cable shield to the oscilloscope ground.
b) For individually shielded wires connect the third signal wire and each wire shield to the oscilloscope ground.

Determine the mass of 0.3 meters (m) of the cable.

Apply a weight of 40 times the identified mass at the center of the cable. Position this weight between the cable clamps and drop the weight freely.

Verify that the maximum peak-to-valley noise measured on the oscilloscope is ≤ 50 µV.

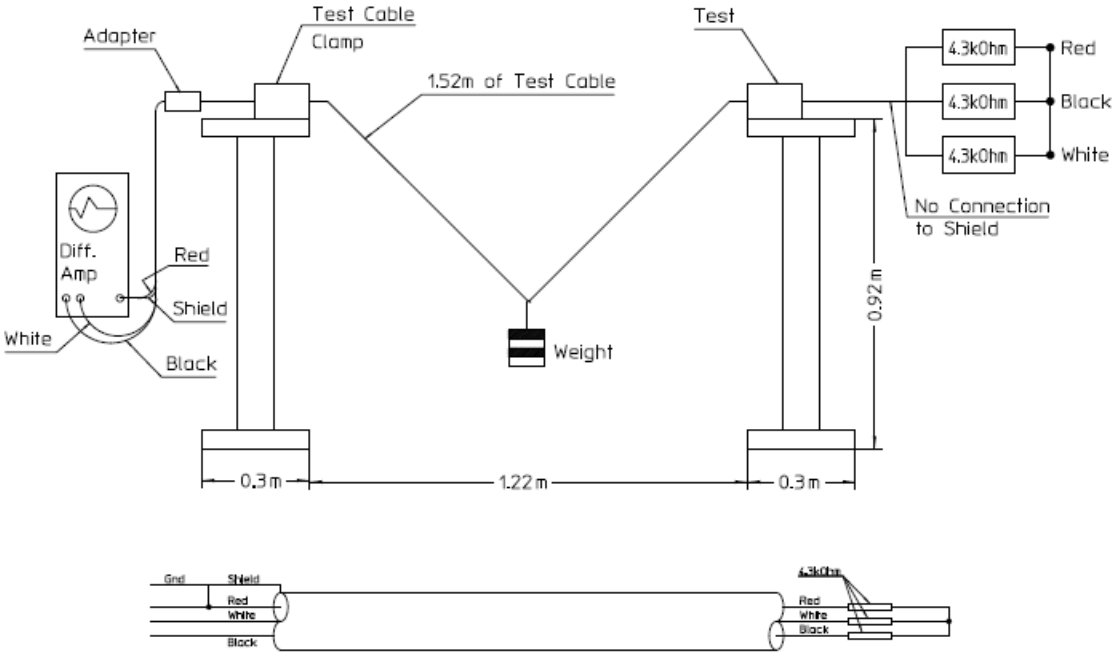

Figure 4 — Test setup for cable noise measurement

5.3.3 *Flex life of TRUNK CABLE and PATIENT LEADWIRE FLEX RELIEF

TRUNK CABLE and PATIENT LEADWIRE interconnections shall withstand flexes of ± 90 degrees as specified in Table 1.

Table 1—Flex life of TRUNK CABLE and PATIENT LEADWIRE FLEX RELIEF

Test location	SINGLE USE	SINGLE-PATIENT USE	MULTI-PATIENT USE
TRUNK CABLE (both ends)	5	10	1000
PATIENT LEADWIRE (both ends)	30	150	500

Compliance is checked using the test setup of Figure 5.

Suspend 0.6 m of cable from the flexing fixture.

Attach a weight to the free end of the cable using a clamp. Ensure that the total mass of the weight and clamp is 0.23 kg (± 5%) if the cable diameter (d) including the jacket is ≤ 3.2 millimeters (mm). If the cable diameter including the jacket is > 3.2 mm, use the following formula to calculate the total mass of the weight and clamp to use:

$$\text{Total mass} = 0.0072 * \pi * d^2 \ (\pm 5\%)$$

Rotate the flexing fixture through the number of flexes specified in Table 1. One flex is defined as rotation from 0 to 90 degrees, back to –90 degrees, and back to 0 degrees.

Failure is defined as any of the following:

a) increase in series resistance of any conductor of more than 50% from original specification;
b) a short between any two conductors;
c) a short between any conductor and shield; or
d) rupture of the specimen jacket (jacket rupture is permitted within 25 mm of the weight attachment position, but a retest of another specimen is required).

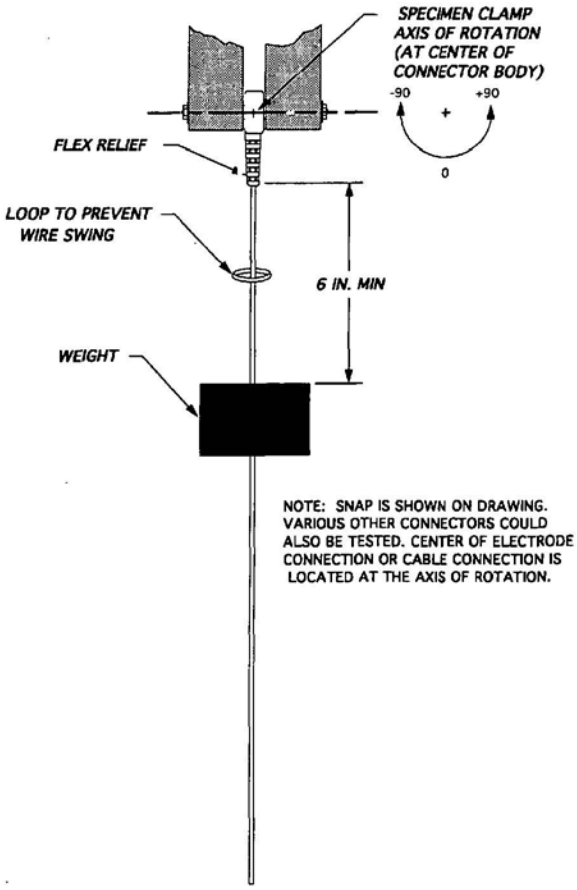

Figure 5 — Flex life test setup

5.3.4 *Tensile strength of cable connections

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

Table 2—Tensile strength of cable connections in N

Test location	SINGLE USE	SINGLE-PATIENT USE	MULTI-PATIENT USE
TRUNK CABLE to INSTRUMENT CONNECTOR	N/A	N/A	65
TRUNK CABLE to CABLE YOKE connector	N/A	N/A	65
TRUNK CABLE material	N/A	N/A	90
PATIENT LEADWIRE terminations	25	25	50
PATIENT LEADWIRE material per lead	25	25	50

Compliance is checked by comparing the results of the following test to the values in 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. Align the pull tester to exert force axially along the cable sample.

Record the force (N) required to cause the cable to fail between the cable attachment points (a failure at either cable attachment point does not constitute failure). Cable failure is defined as any of the following:

a) ≥ 50% increase in resistance of any signal wire, including shields;
b) a short between any two conductors; or
c) a short from any signal wire to the shield.

5.3.5 *Number of connector mating/unmating cycles

TRUNK CABLE and PATIENT LEADWIRE connectors shall be capable of being mated and unmated as specified in Table 3. Following this test, the connections shall meet the requirements of5.3.6 and 5.3.7.

Table 3—Number of connector mating/unmating cycles

Test location	Number of cycles		
	SINGLE USE	SINGLE-PATIENT USE	MULTI-PATIENT USE
TRUNK CABLE to INSTRUMENT CONNECTOR RECEPTACLE	N/A	15	300
TRUNK CABLE YOKE to PATIENT LEADWIRE CONNECTOR	N/A — TRUNK CABLE 5 — Leadwire	30	500
PATIENT-END TERMINATION	5	30	500

Compliance is checked by the following test:

Using either a manual or automated device, connect and disconnect each connector termination to/from its intended mating connector, or equivalent, to ensure acceptable product life. Include the INSTRUMENT CONNECTOR, CABLE YOKE, PATIENT LEADWIRE CONNECTOR and the PATIENT-END TERMINATION in the test. Complete the number of mating cycles listed in Table 3 for each connector.

After subjecting the TRUNK CABLE and PATIENT LEADWIRE assemblies to this procedure, verify that these assemblies comply with 5.3.6 and 5.3.7.

5.3.6 *Connector retention force

The minimum axial force required (per leadwire) to separate the PATIENT LEADWIRE CONNECTOR from the TRUNK CABLE YOKE shall be ≥ 4.5 N.

The minimum axial force required to separate the INSTRUMENT CONNECTOR from its intended INSTRUMENT CONNECTOR RECEPTACLE shall be > 30 N.

Compliance is checked by the following test:

Place the intended mating connector, or equivalent, in a holding fixture. Insert the INSTRUMENT CONNECTOR or PATIENT LEADWIRE CONNECTOR into the mating connector and then attach the pull test device to the cable material approximately 15 cm from the connector assembly.

Axially pull the cable until the connector assembly disconnects from the mating connector. Record the force in N required to cause disconnects. Verify that the force meets or exceeds the minimum values specified above.

5.3.7 *Contact resistance

The d.c. resistance of any of the following connections shall not exceed 1.0 Ω when measured between:

a) each PATIENT LEADWIRE to CABLE YOKE connection;
b) each TRUNK CABLE to INSTRUMENT CONNECTOR RECEPTACLE; and
c) each electrode connection.

Compliance is checked by the following test:

Using a digital volt/ohm meter, measure the resistance of the connection after the specified number of mating and unmating cycles (5.3.5). Before 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.

5.3.8 *Leadwire resistance

The d.c. resistance of the PATIENT LEADWIRES shall be as specified in Table 4 for the appropriate leadwire material.

Table 4—Leadwire resistance (Ω)

Leadwire length (cm)	Resistance (maximum Ω)		
	Metallic (e.g., copper)	Composite (e.g., tinsel)	Organic (e.g., carbon)
0–30	1	50	300
31–61	1	50	350
62–91	1	50	400
92–122	1	50	450
123–152	1	50	500
153–183	1	50	550
184–213	1	50	600
214–244	1	50	650

Compliance is checked by the following test:

Using a volt/ohm meter in resistance mode, record the value obtained with the meter's test leads shorted together. Connect the test leads across the leadwire material under test and subtract the previously recorded value from the meter reading to obtain the final resistance. Compare the final resistance to the values for that material in Table 4.

5.3.9 *Dielectric withstand voltage

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 1,000 V root-mean-square (rms) (± 10%) sine wave at 60 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 (± 10%) application of 5,000 V d.c. (± 10%) between all wires and shield connected together and any exposed conductive parts.

Breakdown is defined as current flow in excess of 9.25 milliamperes (mA) above the theoretical current flow, given the voltage and frequency of the stimulus. The current shall be measured at the generator output.

Compliance 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 the test circuit shown in Figure 6. Switch positions; 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 the test circuit shown in Figure 7.

c) Internal-to-external conductor test: This test is to be performed only if exposed metal components are present (i.e., a metal nameplate, garment clip, or ungrounded metal connector shell). Use the test circuit shown in Figure 8.

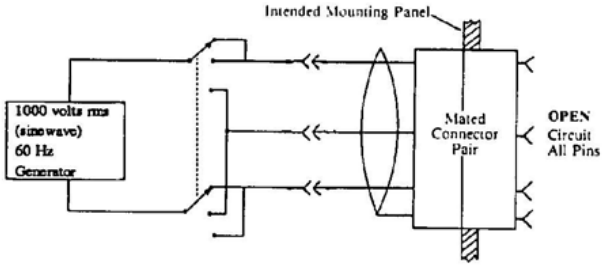

Figure 6 — Wire-to-wire (each pair) dielectric withstand test (See 5.3.9)

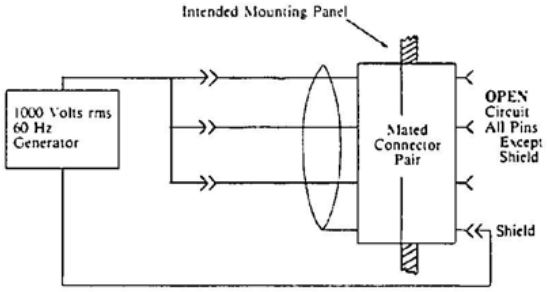

Figure 7 — Wire-to-shield dielectric withstand test (See 5.3.9)

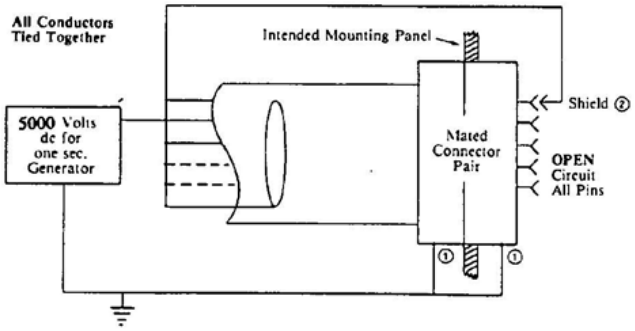

Figure 8 — Internal-to-external-conductor dielectric withstand test circuit. (Connector 1 is made if conductive materials will be exposed in usage; connection 2 is made if shield is not available at the patient connection.)

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

There are reports from the early 1990s of PATIENTs being burned or killed when someone plugged detachable PATIENT LEADWIRES with male-pin connectors into a SUPPLY MAINS connector. These incidents involved non-shielded PATIENT LEADWIRES or PATIENT LEADWIRES with pre-attached electrodes, but this is also a HAZARD for leadwire sets in which several PATIENT LEADWIRES are molded together into one block.

These incidents led to mandates to prevent such tragic accidents by eliminating the use of PATIENT LEADWIRES with exposed male pins. AAMI EC53 was originally written to accelerate the switchover to safer designs. First, EC53 standardized the design of the PATIENT LEADWIRE/TRUNK CABLE interface to support interchangeability in emergency situations, regardless of brand. (Using one MANUFACTURER'S matched set of PATIENT LEADWIRES and TRUNK CABLES usually yields optimal performance, though.) Second, EC53 set minimum requirements and defined standardized test methods to allow OPERATORS (including technical OPERATORS such as biomedical engineers) to correctly select TRUNK CABLES and PATIENT LEADWIRES.

This revision of EC53 clarifies the earlier revision's requirements for disposable and reusable products in light of international use of the terms SINGLE USE and SINGLE-PATIENT USE. Logically, EC53's disposable requirements were largely duplicated for SINGLE USE and SINGLE-PATIENT USE. For consistency, reusable became MULTI-PATIENT USE.

A.2 Rationale for specific provisions of this standard

A PATIENT'S stay varies from an hour to more than 6 days. Clinical input before 1995 led to EC53 being based on the premise that a typical clinical OPERATOR expects MULTI-PATIENT USE TRUNK CABLES to last at least 6 months and MULTI-PATIENT USE PATIENT LEADWIRES to last at least 3 months. The performance characteristics for MULTI-PATIENT USE products support these average lives.

This was obviously an attempt to approximate average use lives for many different clinical situations (use lives for a busy urban emergency room are very different than those for a rural general care ward). The goal is to allow factual comparison of different products in the same way that automobile fuel economy is compared.

A.5.1 Labeling requirements

The labeling requirements for the CABLE YOKE-PATIENT LEADWIRE interconnection and the PATIENT-END TERMINATION-ELECTRODE connection ensure that clinical OPERATORS can readily identify which connection is being affected while connecting electrodes on the PATIENT'S body through PATIENT LEADWIRES to ME EQUIPMENT. Using redundant coding techniques (e.g., pairing color coding with electrode designations [ANSI/AAMI/IEC 60601-2-27] or connection polarity [ANSI/AAMI/IEC 60601-2-47]) greatly enhances usability.

To harmonize EC53 with IEC 60601-1, the earlier revision's requirements for defibrillation withstand were eliminated (Those requirements fundamentally related to how ECG DEVICES implement defibrillation protection.) Current-limiting devices may be located between the PATIENT'S body and the ECG DEVICE. As in earlier revisions, this revision of EC53 prohibits placing current-limiting devices within PATIENT LEADWIRES; but now allows exceptions (see 5.2.2).

A.5.1.4 Labeling to identify the location of current-limiting devices

ECG DEVICES, TRUNK CABLES and PATIENT LEADWIRES must be able to withstand repeated defibrillation pulses without damage. Applying a defibrillation pulse could degrade any current-limiting devices that are present and increases the resistance of carbon leadwires. Repeatedly applying defibrillation pulses could, therefore, destroy the current-limiting devices (or leadwires) which, in turn, could damage or destroy the ECG DEVICE or the CABLE ASSEMBLY.

Permanently marking the CABLE ASSEMBLY (typically, the TRUNK CABLE) or ECG DEVICE to indicate that current-limiting devices are present mitigates a HAZARD related to the use of TRUNK CABLES that are plug-compatible with the INSTRUMENT CONNECTOR RECEPTACLES of different ECG DEVICES. Simply put, PATIENTS are at RISK if TRUNK CABLES with and without current-limiting devices are both available because the incorrect TRUNK CABLE might be used with an ECG DEVICE.

The trend towards hardware miniaturization leads the working group to suspect that future designs might intentionally position current-limiting devices at the PATIENT (possibly within the electrode itself or where the electrode

connects to the PATIENT-END TERMINATION). In such cases, the unit package (rather than the electrode or PATIENT LEADWIRE) needs to be labeled to indicate that it contains current-limiting devices.

A.5.2 Construction requirements

A.5.2.1 PATIENT LEADWIRE to TRUNK CABLE interconnection

This standard supports interchangeability between PATIENT LEADWIRES and TRUNK CABLEs. EC53:1995 used the widely-accepted DIN 42802 connector (*Connector, touch proof, for electromedical application,* Deutsches Institut für Normung [DIN], Germany, 1989) as the basis for its model for non-shielded systems. By incorporating the requirements of DIN 42802 into the configuration of shielded systems, EC53:1995 also standardized the connection for those systems while allowing non-shielded PATIENT LEADWIRES to connect to a shielded TRUNK CABLE. This latest revision of EC53 recognizes that current designs largely incorporate touch-proof concepts in unique ways. This clause's earlier requirements were, therefore, softened.

Multiple PATIENT LEADWIRES might be configured together as a set. The order of the PATIENT LEADWIRES, the number of leadwires, and their fixed center distances allow PATIENT LEADWIRES and TRUNK CABLEs from different MANUFACTURERS to connect properly. The possibility of having TRUNK CABLES with different mating orders is discouraged, but could be appropriate for specific INTENDED USES.

A.5.2.2 Current-limiting devices

Because a goal of this standard is for any MANUFACTURER'S PATIENT LEADWIRES to connect to any MANUFACTURER'S CABLE YOKE, specifying that current-limiting devices used for DEFIBRILLATION PROTECTION not be within PATIENT LEADWIRES helps to ensure that PATIENT LEADWIRES work with any ECG DEVICE.

Current-limiting devices might be in either the TRUNK CABLE or the ECG DEVICE itself. Having one or two sets of current-limiting devices limits how much defibrillation energy is shunted from the PATIENT. Defibrillating a PATIENT when no current-limiting devices are present is hazardous (the ECG DEVICE absorbs too much energy, possibly compromising resuscitation and potentially damaging or destroying the ECG DEVICE or CABLE ASSEMBLY).

NOTE—Having two sets of current-limiting devices present (e.g., one in the ECG DEVICE and another in the TRUNK CABLE) might make an ECG DEVICE'S impedance pneumography-based respiration feature unusable.

The exceptions for integrated CABLE ASSEMBLIES and proprietary/patented connector designs support clinically proven designs. The exception for intentionally positioning current-limiting devices at the PATIENT supports innovation.

A.5.3 Performance requirements — TRUNK CABLE and PATIENT LEADWIRES

A.5.3.1 Non-DEFIBRILLATION-PROOF TRUNK CABLES and PATIENT LEADWIRES

This subclause allows MANUFACTURERS to explicitly label TRUNK CABLES and PATIENT LEADWIRES appropriately for use in areas where PATIENTS are unlikely to require defibrillation (e.g., a physician's office when a PATIENT is connected to a diagnostic electrocardiograph for a 12-lead ECG report or to an ambulatory ECG recorder for a long-term ECG recording). Requiring DEFIBRILLATION-PROOF APPLIED PARTS for such applications is an unnecessary expense.

A.5.3.2 Cable and leadwire noise

CABLE ASSEMBLIES flex because of PATIENT movement as well as actions taken by attending OPERATORS. Minimizing artifact induced by such movements prevents noise from appearing on ECG waveforms and minimizes inaccurate R-wave detection by ECG devices in general and false alarms by cardiac monitors in particular.

A.5.3.3 Flex life of TRUNK CABLE and PATIENT LEADWIRE FLEX RELIEF

This performance level corresponds to about five hard flexes per day of the INSTRUMENT CONNECTOR to CABLE YOKE or PATIENT LEADWIRE CONNECTOR to PATIENT-END TERMINATION over the expected life of the cable or leadwire.

A.5.3.4 Tensile strength of cable connections

The tensile test limits (5.3.4) and retention thresholds (5.3.6) are based upon the philosophy that when a PATIENT moves a PATIENT LEADWIRE by tugging on it, the consequences should occur in the following order:

a) The PATIENT-END TERMINATION disconnects from the electrode.
b) The electrode comes off the PATIENT's skin.
c) THE PATIENT LEADWIRES disconnect from the TRUNK CABLE (at the PATIENT LEADWIRE CONNECTOR-CABLE YOKE interconnection).
d) The TRUNK CABLE disconnects from the INSTRUMENT CONNECTOR RECEPTACLE;
e) The PATIENT-END TERMINATION is damaged.

f) The PATIENT LEADWIRE CONNECTOR (connection to TRUNK CABLE) is damaged.
g) Either end of the TRUNK CABLE is damaged.
h) The INSTRUMENT CONNECTOR RECEPTACLE is damaged.
i) The ECG DEVICE is ripped from the wall shelf.

A.5.3.5 Number of connector mating/unmating cycles

The performance levels specified in 5.3.5 correspond to two (TRUNK CABLE to INSTRUMENT CONNECTOR RECEPTACLE) or five (PATIENT LEADWIRE CONNECTOR to CABLE YOKE and PATIENT-END TERMINATION to electrode) mating/unmating cycles per day.

A.5.3.6 Connector retention force

This standard specifies the retention force for the connection between a PATIENT LEADWIRE and the TRUNK CABLE YOKE and provides a recommendation for the retention force for the TRUNK CABLE to INSTRUMENT CONNECTOR RECEPTACLE connection. The latter only applies to ME EQUIPMENT or ME SYSTEMS used with a TRUNK CABLE. Also see A.5.3.4.

A.5.3.7 Contact resistance

Contact resistance refers to components that come into contact with each other; the actual contact resistance should be ≤ 0.1 Ω. Resistances at this level cannot be measured reliably using a two-input volt/ohm meter, so a four-input meter is needed. The working group decided that a 1 Ω contact resistance presented no performance limitation, given the high input impedance of modern ECG DEVICES, and would allow MANUFACTURERS to use simple instrumentation for the test.

A.5.3.8 PATIENT LEADWIRE resistance

The working group decided to include maximum resistance numbers for alternate materials because leadwire materials other than copper are used. Input from manufacturers (before 1995) was used to determine the resistance limits for different leadwire lengths on the basis of the state of the art at that time. Although all leadwires could have been required to have a resistance less than some maximum value, the working group felt that quantifying realistic values for different leadwire lengths was important. Mixing leadwires of drastically different resistances could adversely affect the noise and common-mode performance of ECG DEVICES.

NOTE—This rationale was updated since EC53 was originally published in 1995. The corresponding requirement was not changed.