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 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 specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable pain 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.

**INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES**

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the AAMI News. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an official interpretation in the AAMI News.
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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All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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Contents

Committee representation .............................................................................................................................................. v
Foreword ........................................................................................................................................................................ vi

1 Scope ........................................................................................................................................................................... 1

2 Normative references .................................................................................................................................................. 1

3 Definitions .................................................................................................................................................................... 1

4 Test methods .............................................................................................................................................................. 2

5 Requirements............................................................................................................................................................. 3
  5.1 *Labeling requirements ........................................................................................................................................ 3
    5.1.1 Package labeling ........................................................................................................................................... 3
    5.1.2 CABLE YOKE labeling .............................................................................................................................. 3
    5.1.3 PATIENT LEADWIRE termination labeling .............................................................................................. 3
    5.1.4 *Labeling to identify the location of current-limiting devices .................................................................. 3
    5.1.5 Optional labeling to identify accessories as not being DEFIBRILLATION-PROOF ................................. 3
  5.2 Construction requirements .................................................................................................................................. 3
    5.2.1 *PATIENT LEADWIRE to TRUNK CABLE interconnection ............................................................. 3
    5.2.2 *Current-limiting devices .......................................................................................................................... 3
  5.3 Performance requirements — TRUNK CABLES and PATIENT LEADWIRES .............................................. 5
    5.3.1 *Non-DEFIBRILLATION-PROOF TRUNK CABLES and PATIENT LEADWIRES ............................ 5
    5.3.2 *Cable and leadiwire noise ............................................................................................................................ 5
    5.3.3 *Flex life of TRUNK CABLE and PATIENT LEADWIRE FLEX RELIEF ........................................... 6
    5.3.4 *Tensile strength of cable connections ...................................................................................................... 7
    5.3.5 *Number of connector mating/unmating cycles ....................................................................................... 8
    5.3.6 *Connector retention force .......................................................................................................................... 8
    5.3.7 *Contact resistance .................................................................................................................................. 8
    5.3.8 *Leadwire resistance ................................................................................................................................. 8
    5.3.9 *Dielectric withstand voltage ..................................................................................................................... 9

Annex A ........................................................................................................................................................................... 11
  A.1 Introduction .......................................................................................................................................................... 11
  A.2 Rationale for specific provisions of this standard .......................................................................................... 11

Tables

Table 1—Flex life of TRUNK CABLE and PATIENT LEADWIRE FLEX RELIEF ........................................... 6
Table 2—Tensile strength of cable connections in N................................................................................................. 7
Table 3—Number of connector mating/unmating cycles ......................................................................................... 8
Table 4—Leadwire resistance (Ω) ............................................................................................................................ 9

Figures

Figure 1 - Non-shielded PATIENT LEADWIRE to CABLE YOKE connection .................................................. 4
Figure 2 - Shielded PATIENT LEADWIRE to CABLE YOKE connection (equipment side) ............................... 4
Figure 3 - Shielded PATIENT LEADWIRE to CABLE YOKE connection (PATIENT side) ................................. 4
Figure 4 – Test setup for cable noise measurement .......................................................................................... 6
Figure 5 – Flex life test setup .................................................................................................................................. 7
Figure 6 – Wire-to-wire (each pair) dielectric withstand test ............................................................................ 10
Figure 7 – Wire-to-shield dielectric withstand test .......................................................................................... 10
Figure 8 – Internal-to-external-conductor dielectric withstand test circuit ...................................................... 10
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:

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Ahmet Turkmen
Brian J. Young

Members: Robert William Bain, CBET, Baltimore Medical Engineers & Technician Society
Scott Coggins, Covidien
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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.
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.

