American National Standard

ANSI/AAMI EC38:1998

Ambulatory electrocardiographs

AAMI Association for the Advancement of Medical Instrumentation

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

American National Standard

ANSI/AAMI EC38:1998
(Revision of ANSI/AAMI EC38:1994)

Ambulatory electrocardiographs

Developed by
Association for the Advancement of Medical Instrumentation

Approved 29 October 1998 by
American National Standards Institute, Inc.

Abstract: This standard provides labeling, performance, and safety requirements for long-term electrocardiographic monitoring devices, commonly called ambulatory electrocardiographs.

Keywords: AECG, ST segment, ambulatory electrocardiographic monitor, atrial fibrillation, ischemic ST, hysteresis

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-5762

© 1999 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, contact Kurt C. Larrick, Director, Technical Publishing, at AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201. Phone: (703) 525-4890, Ext. 239; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1-57020-115-3

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

Contents

Page

Committee representation v

Foreword vii

1 Scope 1

1.1 General 1
1.2 Inclusions 1
1.3 Exclusions 2
1.4 Partial application 2

2 Normative references 2

3 Definitions 3

4 Requirements 4

4.1 Labeling/disclosure requirements 4
4.1.1 Device markings 4
4.1.2 Operator's manual 6
4.1.3 Physician's guide 6
4.1.4 Service manual 7
4.1.5 Summary 7
4.2 Performance requirements 8
4.2.1 Operating conditions 8
4.2.2 Lead definition 9
4.2.3 ECG input channels 10
4.2.4 Risk currents 10
4.2.5 Overload protection 10
4.2.6 Gain control, accuracy, and stability 11
4.2.7 Accuracy of input signal reproduction 11
4.2.8 Time base selection, accuracy, and stability 13
4.2.9 Temporal alignment 14
4.2.10 Electromagnetic compatibility 14
4.2.11 Auxiliary output 16
4.2.12 Monitoring time and battery capacity 16
4.2.13 Special requirements for intermittent event recorders (patient- or event-activated) 16
4.2.14 Automated analysis (optional) 16
4.2.15 Minimum requirements for clinical report 19

5 Tests 21

5.1 Labeling/disclosure requirements 22
5.2 Performance requirements 22
5.2.1 Operating conditions 22
5.2.2 Lead definition 22
5.2.3 ECG input channels 23
5.2.4 Risk currents 26
5.2.5 Overload protection 26
5.2.6 Gain control, accuracy, and stability 27
5.2.7 Accuracy of input signal reproduction 28
5.2.8 Time base selection, accuracy, and stability 31
5.2.9 Temporal alignment 31
5.2.10 Electromagnetic compatibility 32
5.2.11 Auxiliary output 33
5.2.12 Monitoring time and battery capacity 33
5.2.13 Special requirements for intermittent event recorders 33
5.2.14 Automated analysis 34
5.2.15 Minimum requirements for clinical report 39

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

Annexes

A Rationale for the development and provisions of this standard 40
B References 57

Tables

1 Color coding of leads 5
2 Summary of labeling/disclosure requirements 7
A.1 Values for each of the three gains 43

Figures

1 Vibration test for patient-worn AECG using random vibration spectrum (see 4.2.1.2) 9
2 Example of time and amplitude measurement 21
3 General test circuit—The 100 Ω and 100 kΩ resistors are 0.1% so as to provide an accurate voltage division 23
4 Sine wave with pattern of isolated single cycles repeating once per second 24
5 AECG unit under test as in 5.2.3.4—Unit is enclosed in conductive foil wrap 25
6 Test circuit for defibrillator energy-shunting test (5.2.5.2)— Switch S1 must withstand peak current of 60 A in the closed position and not break down for voltages up to 5000 V in the open position 27
7 Test signal simulating the QRS complex of the ECG— QRS amplitude is noted by “a”; “ar” is 0.8750a, and “as” is 0.1250a 29
8 Test circuit for pacemaker pulse tolerance and display 30

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph (ECG) Committee

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

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

Cochairs:	James J. Bailey, MD
	David Mortara, PhD
Members:	James J. Bailey, MD, National Institutes of Health
	Alan S. Berson, PhD, National Heart Lung Blood Institute
	Robert E. Bruce, Medicomp
	David L. Daly, U.S. Food and Drug Administration
	Arthur R. Eddy, Jr., Conmed Corp.
	Stacy Gehman, Quinton Instrument Company
	George Moody, Massachusetts Institute of Technology
	David Mortara, PhD, Mortara Instrument
	Shankara Reddy, PhD, Marquette Medical Systems
	William Saltzstein, Medtronic Physio Control Corporation
	Jonathan Steinberg, MD, St. Luke's Roosevelt Hospital
	Roy D. Wallen, Optical Sensors
Alternate:	Robert Cangelosi, PE, U.S. Food and Drug Administration

The committee's **ECG/Ambulatory Electrocardiograph Working Group** has the following members:

Cochairs:	James J. Bailey, MD
	Robert E. Bruce
Members:	James J. Bailey, MD, National Institutes of Health
	Alan S. Berson, PhD, National Heart Lung Blood Institute
	Richard P. Bowman, BSEE, New Product Development
	Robert E. Bruce, Medicomp
	Luis Conti, SpaceLabs Medical/Burdick
	Prakash C. Deedwania, MD, VA Medical Center, Fresno, California
	Robert Donehoo, MSBME, Johnson & Johnson Medical
	Jacqueline Emery, Siemens Medical Systems
	Charles L. Feldman, SCD, Brigham & Womens Hospital
	Pradeep M. Gupte, MSBME, Westchester County Medical Center
	Randy E. Langston, Providence Hospital
	Robert J. Loring, PhD, Council for Advance Ambulatory Monitoring
	Brian G. McCrea, Quinton Instrument Company
	Gary Mills, Instromedix
	David M. Mirvis, MD, Univ. of Tennessee/VA Medical Center
	George Moody, Massachusetts Institute of Technology
	David Mortara, PhD, Mortara Instrument
	Nancy Pressly, U.S. Food and Drug Administration
	Kay Rutishauser, RN, American Association of Critical Care Nurses
	Brian Skelton, Medical Research Labs
	Richard Sunderland, Protocol Systems
	John Wang, Hewlett Packard
	Brian Young, Marquette Electronics
Alternates:	Richard Avoy, Johnson & Johnson Medical
	John R. Chance, CCPT, Council for Advance Ambulatory Monitoring
	Louis DeMaso, Spacelabs Medical/Burdick
	Michael C. Garrett, Medical Research Labs
	Mark E. Kolnsberg, BSBE, Siemens Medical Systems

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 6

Jack Lohman, Council for Advance Ambulatory Monitoring
Roger G. Mark, MD, PhD, Massachusetts Institute of Technology–Harvard

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.

© 1999 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI EC38:1998

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 7

Foreword

The objective of this standard is to provide minimum labeling, performance, and safety requirements that will help ensure a reasonable level of clinical efficacy and patient safety in the use of ambulatory ECGs. The waveforms specified in this standard to check detection and classification of waveforms (e.g., QRS, P) and determination of shifts in ST segment can only approximate the electrophysiological signals obtained at the body surface. Such signals generated by the heart are complex in shape, size, and rhythm and may vary drastically from beat to beat. Designing test waveform sequences that totally represent all possible electrophysiological signals generated by the heart in health and disease is not feasible. Hence, ambulatory ECG devices that conform only to waveform tests in this standard could, in some situations, display erroneous information concerning rhythm, conduction disturbance, or displacement in the ST segment. Therefore, the need for supplemental tests of an ambulatory ECG device using a documented arrhythmia database becomes evident.

This standard is written primarily for manufacturers of ambulatory monitoring systems to give them clear labeling, design, performance, and test specifications which, if met, should promote patient safety and diagnostic quality of the results. The standard will also be useful to ambulatory monitoring equipment users because knowledge of the standard will give the user a more precise understanding of the characteristics and limitations of the equipment; such understanding is conducive to a safer and more efficacious use of the device.

This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. In addition, as other standards pertaining to ambulatory ECG devices are promulgated, they should be incorporated by reference in order to provide further assurance of safety and efficacy with respect to such characteristics as electromagnetic compatibility and device performance under adverse environmental conditions.

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 recommended practice; 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 suggested revisions should be sent to AAMI, Vice President, Standards, 3330 Washington Boulevard, Suite 400, Arlington, Virginia 22201-4598.

NOTE—This foreword does not contain provisions of the American National Standard *Ambulatory electrocardiographs* (ANSI/AAMI EC38:1998), but it does provide important information about the development and intended use of the document.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 8

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 9

Ambulatory electrocardiographs

1 Scope

1.1 General

This standard establishes minimum safety and performance requirements for long-term electrocardiographic monitoring devices (ECGs), also commonly called ambulatory electrocardiographs (AECGs), that are intended for use under the operating conditions specified in this standard to analyze rhythm and relevant morphology of cardiac complexes. Subject to this standard are all parts of such devices necessary to

a) obtain a signal from the surface of the patient's body;

b) amplify and transmit the signal to recording and display devices;

c) record and display the signal; and

d) provide summaries of rhythms, conduction disturbances, and displacements of the ST segment.

NOTE—The safety and performance criteria defined in this standard are intended principally for use in design qualification or "type" evaluation by the manufacturer.

The referee test methods of section 5 are intended to provide means by which conformance with the standard can be established unambiguously. These tests are not intended for use in verifying the performance of individual devices, either for purposes of quality assurance inspections by the manufacturer or for purposes of routine in-hospital inspections. Referee tests, by definition, allow for the use of alternative methods for design qualification, provided that the equivalence of the methods can be established in terms of comparability of test results with those of the referee methods.

1.2 Inclusions

The three following types of devices fall within the scope of this standard:

a) *Type 1 devices* provide continuous recording and continuous analysis of the ECG. Continuous recording implies that the ECG is recorded in sufficient fidelity that a usable "full-scale" strip could be obtained from any point in the recording or that the data could be re-analyzed to give essentially similar results. Continuous analysis implies that a summation of all ECG activity is available at the end of the process. This type includes, but is not limited to, the following devices:

   1) Conventional AECG monitoring systems that first record the ECG and later process it on a separate analysis station.

      NOTE—The recording mechanism may be of any type that fulfills the requirements of this standard. This includes digital recording utilizing solid-state memory or tape, or analog tape recording. The analysis station may have the capability to review and edit the results.

   2) Real-time AECG monitoring systems that analyze the ECG while it is recorded.

      NOTE—The ECG recording mechanism may be any one of those types described in (1) above. The real-time system may include a separate station that allows review and editing of the analysis.

b) *Type 2 devices* provide continuous analysis but perform recording of the ECG other than that described for Type 1 devices, or no recording of the ECG. This type includes, but is not limited to, the following devices:

   1) Real-time AECG monitoring systems that record only portions of the ECG to provide "full-scale" examples of significant events.

   2) Real-time AECG monitoring systems that record the ECG with fidelity sufficient only to produce a "full-disclosure" report in a time- and amplitude-compressed format.

© 1999 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI EC38:1998

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 10

c) *Type 3 devices* do not perform continuous analysis and record only periods of the ECG, or only enable transmission of the ECG. This type includes “Intermittent Event Recorders” that provide a limited period of patient- or event-initiated data recording (with or without telephone transmission).

NOTE—It is recognized that the quality of telephone line or other means of transmission cannot be controlled by the manufacturer of AECG devices. If the AECG equipment is intended for use with telephone transmission, however, the standard requires that the manufacturer disclose the minimum performance characteristics of the remote transmission system (e.g., allowable error, noise level, frequency response) necessary to ensure that the total system meets the requirements of the standard.

1.3 Exclusions

The following devices are not included within the scope of this standard:

a) devices that collect ECG data from locations other than the external body surface;

b) devices for fetal heart rate monitoring;

c) devices for pressure monitoring;

d) diagnostic electrocardiographic devices covered by the American National Standard, (ANSI/AAMI EC11:1991);

e) cardiac monitors, heart-rate meters, and alarms covered by the American National Standard (ANSI/AAMI EC13:1992);

f) signal-processing devices with special requirements for the analysis of late potentials.

1.4 Partial application

Some portions of the standard may not apply to all AECG devices. For all of these devices, it is required only that they meet the applicable provisions of the standard.

2 Normative references

The following documents contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to use the most recent editions of the documents indicated below.

2.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Cardiac defibrillator devices.* ANSI/AAMI DF2:1996. Arlington (Vir.): AAMI, 1996. American National Standard.

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

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Diagnostic electrocardiographic devices*. ANSI/AAMI EC11:1991. Arlington (Vir.): AAMI, 1991. American National Standard.

2.4 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Disposable ECG electrodes*. ANSI/AAMI EC12:1991. Arlington (Vir.): AAMI, 1991. American National Standard.

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

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

2.7 CENELEC. *Electromagnetic compatibility for industrial process measurement and control equipment*. EN 61000-4 series. Brussels: CENELEC, (Various Publication Dates). European Standard.

EN 61000-4-1:	*General introduction*
EN 61000-4-2:1995	*Electrostatic discharge immunity test*
EN 61000-4-3:1995	*Radiated, radio-frequency electromagnetic field immunity test*
EN 61000-4-4:1995	*Electrical fast transients/burst immunity test*
EN 61000-4-5:1995	*Surge immunity test*
EN 61000-4-6:1995	*Immunity to conducted disturbances induced by radio-frequency fields*
EN 61000-4-8:1993	*Power frequency magnetic fields immunity test*
EN 61000-4-11:1994	*Voltage dips, short interruptions and voltage variations immunity tests*

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 11

2.8 CENELEC. *Electromagnetic compatibility—Generic immunity standard, Part 1. Residential, commercial and light industry*. EN 50082-1:1997. Brussels: CENELEC, 1997. European Standard.

2.9 INTERNATIONAL SPECIAL COMMITTEE ON RADIO INTERFERENCE. *Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific, and medical (ISM) radiofrequency equipment*. CISPR 11 2nd Edition, 1990. (Available from ANSI.)

2.10 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment—Part 2: Particular requirements for the safety of electrocardiographs*. IEC 60601-2-25, 1993. Geneva: IEC, 1993. International Standard. (Available from ANSI.)

3 Definitions

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

3.1 AF: For the purposes of most tests and reports, AF designates either atrial flutter with an irregular RR interval or atrial fibrillation.

3.2 ambulatory electrocardiographic (AECG) monitor: Device or system of devices, including a recording device that is usually worn by the patient and records one or more channels of ECG for a long duration (often 24 h, occasionally longer).

NOTE—The system distinguishes, analyzes, and displays transient electrocardiographic events such as disturbances in rhythm, shifts in the ST segment, or changes in cardiac conduction.

3.3 aspect ratio: For a display, the ratio of the vertical sensitivity (in mm/mV) to the horizontal sensitivity (in mm/s).

3.4 auxiliary output: Accessible connector or terminal providing electrical connection to the circuits of the device for the purpose of displaying, amplifying, or processing the ECG signal or other data.

3.5 bandwidth: Specifies upper and lower frequency cutoffs (3 decibels [db] amplitude attenuation).

3.6 beats per minute (bpm): Unit for heart rate.

3.7 channel: Portion of the recording system comprising the proportionate width of the recording medium and the associated amplifier for one lead.

3.8 common mode voltage: Undesired voltage of identical amplitude and phase applied to both inputs of a differential amplifier.

3.9 common mode rejection: Ability of a differential amplifier to reject common mode voltage.

3.10 crosstalk: Output signal component in any one channel of a multichannel device that does not arise from inputs applied to that channel but rather is induced by signals on other (driven) channels.

NOTE—Crosstalk is usually measured with all channels driven except the channel to be tested, which has its inputs shorted. Power supplies are a common source of such unwanted coupling between channels.

3.11 full disclosure: Ability to provide a miniature hard copy record of a patient's continuous ECG recorded during the entire procedure.

3.12 glitch: Any error or malfunction in data processing (see 4.2.10.2.4).

3.13 infant: Child weighing less than 10 kg (22 lb).

3.14 ischemic ST: Means ECG indicated "ischemia."

NOTE—In the European ST database, a consensus of reviewing physicians have labeled certain episodes of ST displacement as typical of "ischemic" changes; these interpretations were supported by the presence of anginal type symptoms, myocardial scintigraphy, or coronary angiography. In the context of this document, ischemic refers to electrocardiographic ischemic.

3.15 hysteresis: Inability of a direct writer's output trace to attain the same position for the same input voltage if that position is approached from one side or the other.

3.16 input circuit: Circuit consisting of, for example, an amplifier input, weighting networks, protection networks, high-frequency filters, and patient cables.

3.17 input impedance: Voltage-to-current ratio measured at any frequency when applied to the differential inputs of an amplifier.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 12

3.18 lead: System of conducting wires used to detect body surface potentials.

3.19 lead connection: Single conducting wire which, when attached to the patient by means of an electrode, is sometimes called a patient lead, an electrode connection, or a lead wire.

3.20 lead electrode: Electrode fastened on a specific part of the body to detect, in combination with other electrodes, heart action potentials.

3.21 monitor: ECG device used to acquire and/or display electrocardiographic signals with the primary purpose of continuous detection of transient cardiac events.

NOTE—Although the device may display individual waveforms, morphological accuracy may not necessarily be equivalent to that required in a diagnostic ECG device.

3.22 nominal supply (mains) frequency: Nominal powerline frequency.

NOTE—In the U.S., this frequency is 60 Hz. In Europe, it is 50 Hz.

3.23 overshoot: Amount of overtravel of the ECG output trace beyond its final steady deflection when a step voltage is applied at the input leads.

3.24 patient electrode connection: Conducting tip of a patient cable making contact with a lead electrode.

3.25 peak-to-valley (p-v): Amplitude of a wave (e.g., sinusoidal or QRS) measured from the upper side of its positive peak to the upper side of its negative peak in such a way as to eliminate from the measurement the thickness of the display trace or printed trace.

3.26 pulses per minute (PPM): Rate at which test waveforms are presented to a device under test.

3.27 real time: Describes an AECG system that analyzes the ECG data while it is being recorded.

NOTE—Also, when applied to VSS, refers to speed that the data is played back.

3.28 referred-to-input (RTI): Term used to describe an output that has been expressed by specifying, independent of the system gain, the equivalent input signal.

NOTE—A 1 mV output signal RTI means a 10 mm or 5 mm output, depending on whether the gain of the ECG device or monitor was set at 10 mm/mV or 5 mm/mV, respectively.

3.29 rise time: As applied to an input or output step, the time required to go from 10% to 90% of the total change.

3.30 sampled system: System that represents a continuous input signal as a series of discrete values of amplitudes and/or times.

NOTE—The output may be a series of discrete values or a continuous signal derived from the discrete values. Sampled systems, often referred to as digital systems, are typically nonlinear in their behavior.

3.31 time base: Units of the horizontal axis of the display, usually expressed as mm/s.

NOTE—The time base may differ from actual paper speed for devices that do not display the ECG signal in real time.

3.32 visual superimposition scanning (VSS): Display of successive ECG complexes, aligned in time, wherein each complex persists for some fixed period and is shown superimposed upon its predecessor.

4 Requirements

4.1 Labeling/disclosure requirements

In addition to federal regulations applicable to the labeling of all medical devices, the requirements of this section shall apply to all devices within the scope of this standard.

4.1.1 Device markings

4.1.1.1 Product identification and characteristics

All devices that are components of an AECG system shall be clearly and permanently marked with the following information:

a) the manufacturer's name, trademark, trade name, or other recognizable identification;

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 13

b) the catalogue, style, model, or other such designation and the AECG device type (Type 1, Type 2, or Type 3);

c) the serial number;

d) the range of supply (mains or battery) voltage and the maximum operating current or power (mains);

e) the nominal supply (mains) frequency;

f) the number of phases, unless the device is intended for single-phase use only;

g) the current carrying capacity of each convenience receptacle and/or identification of the instrument(s) that can be connected to a device if the device provides mains power for other devices.

4.1.1.2 Panel controls and switches

All controls, switches, and connectors shall be clearly and concisely labeled to identify their function.

4.1.1.3 Electrical safety

Where markings are affixed to any component device of an AECG system to warn maintenance personnel of the potential shock hazard from accidental contact with parts or to identify component devices with current ratings that may overload branch circuits that supply the device, the markings shall be placed in locations suitable for the intended use and shall be clearly visible.

NOTE—Markings that are inside the enclosure of the equipment shall be considered clearly visible if they can be viewed when the connections to the supply are being made or inspected. Markings inside the enclosure of cord-connected equipment are considered to be clearly visible if the markings would be seen before a hazard is encountered.

4.1.1.4 Fuse holders

If fuse holders accessible to the operator are provided, they shall be clearly marked with the applicable fuse rating (in amperes) and with the fuse type.

4.1.1.5 Patient electrode connection nomenclature and colors

Colors, if used, shall be associated with either individually colored patient lead conductors and/or, if plug bodies are used, with the bodies at the electrode ends. Permanent cable legends (e.g., engraved) shall also be used for individual patient electrode connection identification. Table 1 provides standard color coding for patient electrode conductors. Although electrode locations for purposes of AECG recording are not now standardized, it is strongly recommended that lead identifiers and color codes for AECG leads come as close as possible to those recommended by the American Heart Association (AHA) (Sheffield *et al*., 1985).

Table 1—Color coding of leads

In the case of bipolar leads as recommended by AHA (1985), each lead shall be clearly and permanently color coded per the following definition:

Channel 1	+	Red
	-	White
Channel 2	+	Brown
	-	Black
Channel 3	+	Orange
	-	Blue
Reference		Green

When only a single channel is provided, the use of black for “+” and white for “-” is permitted.

The leads shall be color coded in such a manner that the proper lead can be directly determined at both the electrode and equipment attachment ends. In addition to color coding, the channel assignment shall be clearly annotated on the equipment for reference. A manufacturer may substitute other words for “channel 1, channel 2, and

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 14

channel 3" such as "channel A, channel B, and channel C," but equivalence to table 1 shall be disclosed. (For devices to be used outside the United States, an alternative color coding scheme specified by the International Electrotechnical Commission [IEC] may be used.)

4.1.2 Operator's manual

An operator's manual containing adequate instructions for the proper installation and safe and effective operation of each component device of the AECG system and for identifying acceptable repair facilities shall be provided with each device (or, in the case of multiple orders for multiple units, as specified in the purchase contract).

4.1.2.1 Disclosure of cautionary information/performance characteristics

a) *Cautionary information:* Cautionary information and prominent labeling shall be provided where possible use or exposure could create a potential hazard or could damage any component device of the AECG system, including, but not limited to, use of the device in the vicinity of explosive anesthetics and use in the presence of electromagnetic interference or input overload.

b) *Replaceable system components:* The manufacturer shall disclose specifications relating to operator-replaceable components (e.g., tapes, batteries, lead wires, electrodes, etc.) sufficient to allow reliable use of the device.

c) *Performance characteristics:* The operator's manual shall include a statement of the type of the AECG device (i.e., Type 1, Type 2, or Type 3). In addition, all claims made by the device manufacturer that affect the applicability of the performance requirements of 4.2 shall be disclosed in the operator's manual. The response of the recording device to out-of-band input signals up to 10 MHz shall be disclosed.

d) *User-adjustable parameters:* The effects of each user-adjustable parameter upon resultant ECG reproduction or waveform analysis and/or adherence to this standard shall be disclosed. A simple description from the viewpoint of the user will suffice (e.g., "the maximum deviation parameter setting defines how many millimeters an ST segment should deviate from the average baseline value before it will be counted as an episode of ST deviation"). The default values of all user-adjustable parameters shall be disclosed in the operating manual or user physician's guide.

e) *Intentionally applied currents:* The manufacturer shall disclose sufficient electrical parameters to characterize any currents intentionally applied to patient electrode connections (e.g., "lead failures are detected by a 10 mV peak 10% duty cycle rectangular pulse, which is applied to each patient electrode connection through a 6.8 megohm resistor at a rate of 1.0 kHz with respect to the reference electrode."). This requirement does not apply to amplifier input bias currents, which cannot be avoided.

f) *Troubleshooting:* Manufacturers are encouraged to disclose recommended operating procedures, and to alert users to possible operational problems or difficulties and their solutions in the operating manual or the physician's guide as appropriate.

4.1.2.2 Application notes

Appropriate information concerning the application of each device of the AECG system shall be provided, including but not limited to the following items:

a) interconnection characteristics between component devices (e.g., auxiliary output and recording devices, telemetry device where used, and analysis/display devices);

b) requirements for human operator (whether and to what extent a human operator is required for determination of fiducial points and/or pattern recognition and recommended training of operator to achieve specified performance shall be specified);

c) time required for signal processing, analysis, and report generation (the minimum time needed for these activities shall be disclosed for an artifact-free, normal sinus rhythm at a heart rate of 60-80 beats per minute);

d) lead placement (the manufacturer shall disclose what lead placement is recommended or required for equipment to produce expected results, and also if the system performance is sensitive to certain ECG parameters [e.g., R wave amplitude]).

4.1.3 Physician's guide

A physician's guide shall be provided with each AECG system that specifies the AECG system's functional capabilities for the following:

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 15

a) analysis of heart rate;

b) analysis of rhythm disturbances;

c) analysis of ST-T alterations;

d) recognition and measurement of QRS morphology and duration (which may be indicative of alterations in intraventricular conduction);

e) measurement and analysis of PR interval (which may be indicative of alterations in atrioventricular conduction); and

f) recognition of paced rhythms.

The physician's guide shall include a disclosure of how each heart rate presented on the display or on the hard copy report is computed. This disclosure shall include an estimate of the percent error and the duration of the error that can be expected for each kind of heart rate calculation in the presence of a single missed beat (false negative) and separately in the presence of a single extra detection (false positive).

Functional capabilities of (c), (d), (e), or (f) may be limited or absent in certain ambulatory monitoring systems. If so, the limitations or absence of these function capabilities shall be clearly stated. Each of the functional capabilities claimed shall be illustrated by examples or, if the system issues reports, a sample report. The physician's guide shall describe the extent to which the above analyses are "computer-aided" as opposed to the extent to which the analyses rely upon human reading/interpretation. If data compression is used and distorts some of the records, product documentation (e.g., physician's guide) should give a brief description of the data compression algorithm and a general indication of the type and magnitude of errors that may result from data compression. Type 3 devices, providing no analysis, need only state in the labeling that no analysis is provided.

4.1.4 Service manual

A service manual containing instructions for adequate care, preventive maintenance, and appropriate repair shall be provided with each AECG system (or in the case of multiple patient unit orders, as specified in the purchase contract). When feasible and appropriate, the instructions should include items such as electronic circuit schematics and/or block diagrams, test points, waveforms, wiring diagrams, user-replaceable parts lists, and component values. This information shall be complete enough to allow a skilled technician to accomplish calibration and other maintenance needed to ensure conformance of the device with the manufacturer's specifications, and to accomplish field repair when such repair is feasible and appropriate. In addition, the instructions shall identify acceptable repair facilities (for repairs that are not made in the field) and include recommendations concerning

a) test methods that can be used for verification of device performance; and

b) the frequency with which preventive maintenance procedures should be implemented.

4.1.5 Summary

Table 2 provides a summary of the labeling/disclosure requirements of this standard.

Table 2—Summary of labeling/disclosure requirements

Section	Requirement/Description
4.1.1/4.1.1.1	*Device markings/product identification and characteristics:* manufacturer's identification; type designation; serial number; range of supply voltage and maximum operating current/power; nominal supply frequency; number of phases; current-carrying capacity of convenience receptacle.
4.1.1.2	*Panel controls and switches:* identification of controls, switches, connectors, and indicators.
4.1.1.3	*Electrical safety:* readily visible markings for shock hazard and/or over-current ratings.
4.1.1.4	*Fuse holders:* fuse ratings in amperes and fuse type.
4.1.1.5	*Patient electrode connection nomenclature and colors:* conformance with table 1.
4.1.2/4.1.2.1	*Operator's manual/disclosure of cautionary information/performance characteristics.*

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 16

Table 2—Summary of labeling/disclosure requirements (cont.)

Section	Requirement/Description
4.1.2.1(a)	*Cautionary information:* cautionary information regarding potential hazards/damage including warnings on use of AECG device in presence of explosive anesthetics and use of device in presence of electromagnetic interference caused by other instruments.
4.1.2.1(b)	*Battery-powered devices:* minimum operating time; battery charge time.
4.1.2.1(c)	*Performance characteristics*: device type; claims affecting performance requirements.
4.1.2.2	*Applications notes*: description of device's intended applications and available functions.
4.1.3	*Physician's guide:* physician's guide for AECG function capabilities; sample reports; extent of reliance upon human reading/interpretation.
4.1.4	*Service manual:* adequate care, preventive maintenance, and appropriate repair instructions; identification of acceptable repair facilities; recommended frequency of preventive maintenance.

4.2 Performance requirements

The tests and/or requirements in this section can be divided into three categories: (1) stationary equipment only, (2) portable equipment only, (3) entire system. The system requirements are concerned with verifying that a particular signal is accurately reproduced on the printed page of the AECG report.

4.2.1 Operating conditions

4.2.1.1 Stationary equipment

Stationary equipment is defined as that equipment that is ancillary to the subject AECG devices under consideration and which falls into either of the following categories:

a) equipment which is generally available on a commercial basis and is not specifically intended for medical use, including such equipment as personal computers, printers, disk drives, internal fax/modems, etc.;

b) custom equipment which has been designed and manufactured specifically for use in AECG medical systems under consideration as part of this standard.

For the stationary equipment described in (a), the full medical device standards such as IEC 60601 are not applicable. However, such equipment shall meet those standards that are applicable, such as IEC 950 (Safety of information technology equipment, including electrical business equipment).

The custom stationary equipment—i.e. equipment which has been designed, manufactured, and/or purchased by the manufacturer of the subject AECG system, as described in (b)—shall meet either the appropriate standards for nonmedical equipment such as IEC 950 or the requirements of this standard. In either case, the manufacturer of the subject AECG system shall clearly state which standard has been adhered to.

For either type of stationary equipment [(a) or (b)], if the AECG system has been designed so that the patient can be connected to the AECG device and the stationary equipment simultaneously, even if indirectly, then the manufacturer of the subject AECG system shall supply a separate isolating device as specified in 4.2.4 or provide adequate isolating means within the supplied stationary equipment meeting the referenced section requirements.

Custom stationary equipment, as described in (b), that is intended to comply with this standard shall do so while operating under the following range of operating conditions:

Line voltage:	Nominal voltage ± 10%
Line frequency:	Nominal frequency ± 1Hz
Temperature:	10° C (50° F) to 32.5° C (90° F)
Relative humidity:	20% or 80%, noncondensing

In addition, the custom equipment shall not be damaged by and shall be capable of operating to full specification after having been stored under the following range of conditions:

Temperature:	-20° C (-4° F) to 65° C (149° F)
Relative humidity:	5% to 90%, noncondensing

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 17

4.2.1.2 Portable equipment

Equipment normally utilized in a portable (patient-worn) environment shall meet all requirements of this standard while operating under the following range of conditions:

Power:	Device dependent, as specified by manufacturer
Temperature:	0º C (32º F) to 45º C (113º F)
Relative humidity:	10% to 95%, noncondensing
Ambient air pressure:	700-1060 millibars
Shock:	75 mm drop on a hard surface on any face, edge, or corner. If unit is normally used with a pouch, the pouch can be used during testing. Data acquisition may be interrupted during shock, but data acquired previous to the shock shall be unaffected by the shock, and normal data acquisition shall resume within 60 s after the shock.
Vibration:	A 10 min vibration on each of three orthogonal axes of 0.3 G rms using a random vibration spectrum as shown in figure 1.

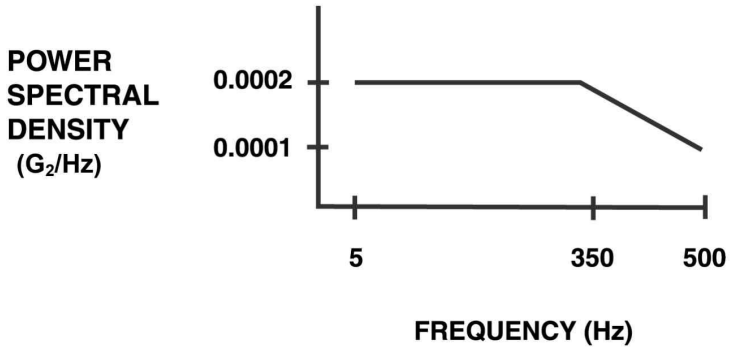


Figure 1—Vibration test for patient-worn AECG using random vibration spectrum (see 4.2.1.2)

In addition, the equipment shall not be damaged and shall be capable of operating to full specification after having been subjected to the following range of conditions:

Temperature:	-20º C (-4º F) to 65º C (149º F)
Relative humidity:	5% to 95%, noncondensing
Shock:	0.8 meter (m) drop on a hard surface (a flooring tile over a concrete surface), in any axis

4.2.2 Lead definition

Ambulatory monitoring is not predicated upon specific, fixed lead definitions as are other devices; however, the following minimum lead requirements shall be met to allow the equipment to function over a wide range of clinical situations.

4.2.2.1 Number of leads

Type 1 and Type 2 devices shall be capable of simultaneously recording and/or analyzing a minimum of two independent ECG channels. The device shall be so constructed that the loss of any one patient electrode connection will not result in the loss of all ECG signals. This results in a total minimum requirement of four patient electrode connections (wires). A separate “ground” reference lead wire, tied directly to electronic circuit common, may also be utilized, resulting in a total of five wires. Additional ECG channels may be provided.

4.2.2.2 Verification of electrode placement

At the time of patient hookup, the equipment shall have the capability for user verification of the acceptability of the electrode placement. This may be accomplished with any of a number of methodologies, provided that the user can determine the acceptability of the signal and the stability of the lead wiring in a clear and effective manner.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 18

4.2.2.3 Safe electrode lead wire connectors

In conformance with the referenced standard on disposable ECG electrodes (ANSI/AAMI EC12—1991), the electrode lead wire connector shall be constructed in such a manner that the pins in the connector used to mate with the AECG recorder cannot contact ground or a possibly hazardous electrical potential. In particular, the connector shall be constructed so as to prevent insertion and electrical connection into a mains outlet or a detachable power cord.

4.2.3 ECG input channels

4.2.3.1 Input dynamic range

Type 1 and Type 2 devices shall be capable of responding to and displaying differential voltages indicated as great as ± 5 mV in amplitude and varying at a rate up to 125 mV/s in the presence of a direct current (dc) offset voltage in the range of ± 300 mV when applied to any lead. The amplitude range shall be ± 3 mV for devices utilizing analog storage.

The indicated time-varying output signal amplitude referred-to-input (RTI) shall not change by more than ± 10% or ± 50 μV, whichever is greater.

Type 3 devices shall be capable of responding to and displaying differential voltages indicated as great as ± 2 mV p-v in amplitude and varying at a rate up to 95 mV/s from a dc offset voltage in the range of ± 150 mV when applied to any lead. The time-varying output signal amplitude RTI shall not change by more than ± 10% or ± 50 μV RTI, whichever is greater. In the case of nondisposable electrodes that are part of the device, the manufacturer shall state in the operating manual or other labeling areas, the voltage range and offset specifications, if different from these values or if less than ± 150 mV.

4.2.3.2 Input impedance

An electrode-to-skin impedance, simulated by a 0.62 megohm resistor in parallel with a 4.7 nanofarad capacitor, in series with any patient electrode connection, shall not result in a signal reduction of more than 20% of that obtained without the simulated impedance, across the total required device bandwidth (see 4.2.7.3). This requirement shall be met across the total required dc offset range capability.

4.2.3.3 Direct currents in patient electrode connections

The direct current through any patient electrode connection, with all remaining patient electrode connections connected to a common node (e.g., the right leg electrode), shall not exceed 0.1 microamperes (μA) for any patient electrode that serves as an amplifier input or 1 μA for any other patient electrode connection.

4.2.3.4 Common mode rejection

Common mode rejection shall be at least 60 dB for a sinusoidal signal at the line frequency and 45 dB at twice the line frequency. This common mode rejection capability is defined as the ratio of the rms value of the interfering line frequency to the rms value of the resulting signal amplitude in any AECG monitor input channel, referred to input.

4.2.4 Risk currents

Any device that is capable of being simultaneously attached to a patient and to an ac line powered-device, even if indirectly, shall provide patient isolation to meet the specifications of the *Safe current limits for electromedical apparatus* (ANSI/AAMI ES1—1993). This requirement applies even if the normal procedural sequence does not involve simultaneous connection with the patient and the line-powered device.

4.2.5 Overload protection

4.2.5.1 AC voltage

The device shall meet the requirements of this standard within 30 s after a 10 s application of a 1 volt p-v, 60 Hz differential voltage to all possible patient electrode connection pairs.

4.2.5.2 Defibrillator energy shunting

The AECG recorder should incorporate current limiting devices so that the defibrillator energy delivered to the 100 ohm load (which simulates the patient) is reduced by a maximum of 10% relative to the energy delivered to this load with the recorder disconnected. The manufacturer shall disclose whether the recorder can meet this requirement.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 19

This test only addresses current limiting designs within the recorder and shunting between the lead wire connectors into the recorder. It does not address shunting across lead wires that happen to be adjacent to one another during the test. Lead wires must comply with the applicable portions of ANSI/AAMI EC53.

4.2.6 Gain control, accuracy, and stability

Gain requirements pertain to the entire system and describe the ability to control and direct the amplification of the ECG signal in preparing output. The overall accuracy of the reproduced signal relative to the input is specified in sections dealing with device frequency response.

4.2.6.1 Gain accuracy

Output at all available gain settings shall be reproduced with a maximum amplitude deviation from the ideal of ± 10%. The ideal is defined as the output obtained at a setting of 10 mm/mV multiplied by the gain factor.

4.2.6.2 Gain stability

The gain change 1 min after energizing the device shall not exceed 0.33% per min. The total change in 1 h shall not exceed ± 3% at any available gain setting.

4.2.6.3 Amplitude calibration

Devices recording on analog media shall have the capability of injecting a standardizing voltage equivalent to 1.0 ± 0.05 mV at the ECG inputs for the purpose of calibrating the system. The signal may be in the form of a step or pulse with a leading edge 10% to 90% rise time of ≤ 5 ms. Systems employing removable media for recording may utilize this calibration voltage to adjust the amplifiers of any playback equipment to meet the amplitude requirements of this standard.

4.2.7 Accuracy of input signal reproduction

These requirements apply to all sections of ECG reproduced regardless of the mechanism of acquisition or storage. New technologies are providing devices that may utilize compression algorithms to store data in digital memories. In some cases, these algorithms may reproduce the ECG with varying degrees of accuracy depending on the analysis performance or signal artifact content. The requirements apply in all cases, regardless of artifact content or analysis error.

A 30 s warm-up period is allowed for the recorder before the following requirements shall apply. The reproducer of the system shall meet all specifications following a warm-up period of one min.

4.2.7.1 System noise

The internal circuit noise referred to input shall not exceed 100 μV p-v over any 10 s period when all inputs are connected through a 51 KΩ resistor in parallel with a 47 nF capacitor in series with each patient electrode connection.

4.2.7.2 Multichannel crosstalk

Any input signal limited in offset, amplitude, and rate of change as per 4.2.3.1, applied to any one channel of a multichannel monitor and with all unused inputs connected to a patient reference through a 51 KΩ resistor in parallel with a 47 nF capacitor, shall not produce an output RTI greater than 5% of the applied signals in those channels where no signal is applied.

4.2.7.3 Frequency response

The overall system frequency response shall meet the specifications described. The input of the system is at the patient electrodes; the output of the system is measured on the system's hard copy ECG record. If special filtering compensation circuits are used in the recorder and/or the reproducer, they shall be disclosed.

a) Amplitude response to sinusoidal signals within the frequency range 0.67 Hz to 40 Hz (30 Hz for Type 3 devices) shall be between 115% and 70% (+1.21 to -3.0 dB) of the response at 5 Hz.

b) Responses to all pulses of a 1.5 mV, 40 ms triangular pulse train (20 ms for infants, refer to 4.2.7.9, 5.2.7.9, A.4.2.7.9), which simulates a series of narrow R wave, shall be within 60 to 110% of the response to a train of 1.5-mV, 200 ms triangular pulses, while the repetition rate of the pulses is slowly varied from 60 bpm to 70 bpm over a 2 min period (30 s period for Type 3 devices).

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 20

c) Response to a 3 mV, 100 ms rectangular pulse (1.5 mV, 200 ms pulse for Type 3 devices) shall meet the following criteria.

   1) Amplitude displacement of the baseline shall not be greater than 0.1 mV from onset to end.

   2) The slope everywhere outside the rectangular pulse shall be less than 0.30 mV/s.

   3) The leading edge overshoot shall be less than 10%.

d) Type 3 devices that do not claim to support S-T segment analysis are permitted to have a reduced low-frequency response (0.5 Hz to 30 Hz). Testing of these devices shall result in an amplitude displacement of the baseline of no greater than 1.0 mV in test 1 above and a slope of 2.0 mV/s in test 2 above.

4.2.7.4 Hysteresis and minimum feature size

Hysteresis shall not exceed 50 μV after a deflection of 1.5 mV in either direction from the baseline. In addition, the device shall exhibit a "response to minimum signal." A 10 Hz, 50 μV p-v sinusoidal signal shall yield a visible recorded deflection at a time base of 25 mm/s and a gain setting of 10 mm/mV.

4.2.7.5 Overall system error

Input signals (such as shown in figure 7) limited in amplitude to ± 3 mV (gain set to allow 10 mV p-v display) and varying at rates of up to 125 mV/s shall be reproduced on any hard copy output device with a maximum deviation from the ideal of ± 20% or ± 100 μV, whichever is greater.

4.2.7.6 Special considerations for high speed superimposition display (optional)

The visual superimposition system (VSS) shall meet the following requirements.

a) There shall be available a minimum display of two channels of simultaneous ECG as a default. The system may allow the display of one or more channels to be turned off.

b) The VSS display device should be capable of displaying the ECG signals with minimum scaling factors of 25 mm/s horizontally and 10 mm/mV vertically. Scaling factors exceeding these dimensions shall, by default, retain the 5:2 aspect ratio within 10%.

c) The maximum speed of the visual superimposition display shall be at least 60 times real time.

d) VSS displays shall meet the minimum frequency response and linearity requirements specified in this standard for the rest of the system, as reflected in real time.

e) Interaction capabilities shall be provided to permit the operator to stop and to resume the scanning process at any point during the recorded period. During the suspension of the scan, hard copy printout capabilities shall be provided for examination of suspected arrhythmias or artifact.

f) The system shall have a method for operator validation of beat classification including ectopy and artifact, such as separate windows or color differentiation. If abnormal beats are excluded from VSS display, the exclusion criteria shall be disclosed in the physician's guide.

4.2.7.7 Baseline stability

With the sensitivity set to maximum and all patient lead wires connected together with 25 KΩ resistors inserted in series with any or all of the leads, the baseline drift shall not exceed 1 mV over 24 h (for Type 3 devices, 10 μV/s referred-to-input over any 60 s period, or maximum recording period of the device).

4.2.7.8 Pacemaker pulse tolerance and display capability

The device labeling shall clearly indicate whether or not the device is intended for recording ECG signals in the presence of implanted pacemaker pulses. If indicated as intended for such recording, the device shall suitably record ECG signals in the presence of pacemaker pulses having amplitudes between 2 mV and 250 mV, durations between 0.1 ms and 2.0 ms, with rise times equal to 10% of the pulse width but not greater than 100 μs, and a frequency of up to 100 pulses per min.

If the manufacturer states that the device is suitable for use in analyzing pacemaker functioning, then for pacemaker pulses having durations between 0.5 ms and 2.0 ms (and amplitudes, rise times, and frequency parameters as specified above), an indication of the pacemaker pulse shall be visible on the hard copy (as defined in 4.2.8.3). This indication shall have an amplitude of at least 0.2 mV RTI.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 21

4.2.7.9 Special infant requirements

The device labeling shall clearly indicate whether its use is intended for infants weighing less than 10 kg (22 lbs). If so indicated, the amplitude response shall be extended to 60 Hz, and the response to the triangular wave (1.5 mV x 20 ms) shall be tightened to within 80% to 100% of the 1.5 mV x 200 ms triangle, while the repetition of the 20 ms triangles is slowly varied from 60 bpm to 70 bpm over a 2 min period, and the overall system error shall meet the requirements detailed in 5.2.7.5.

4.2.7.10 Patient event marks

The major value of the AECG is the capability of correlating transient ECG events with patient symptoms. A patient-activated marker shall be provided. This permits more accurate correlation of brief symptoms with transient ECG phenomena than is possible with only time-of-day logging.

Type 3 devices that are patient activated are not required to provide a unique patient-activated event marker.

4.2.8 Time base selection, accuracy, and stability

4.2.8.1 Timing accuracy

For Type 1 and Type 2 devices, the overall system shall have a cumulative error over a 24 h period of not more than ± 60 s.

4.2.8.2 Hard copy time base

This paragraph applies to the hard copy of the system when operating from the specified power source. The time base of 25 mm/s shall be available.

Specifically, the time base accuracy shall allow time measurements with an error no greater than ± 5% or ± 10 ms, whichever is greater.

4.2.8.3 Hard copy grid standard

The system shall have the provision of printing the ECG with a rectilinear grid that measures 5 cm in height and 25 mm/s of ECG. The manufacturer may provide additional time and amplitude selections as an option. For Type 3 devices, 4 cm paper may be used.

The hard copy shall be ruled with 1.0 mm divisions along both the time (horizontal) and voltage (vertical) axes. Every fifth ruling shall be accented. When the horizontal scale factor is 25 mm/s, a very desirable feature is to accent a vertical grid or otherwise mark consecutive 3 s intervals. Both the voltage and the time axis grid rulings shall be accurate within ± 2% over the humidity conditions specified in 4.2.1.1.

When the scale factors are other than 25 mm/s or 10 mm/mV, the chart record shall preferably be ruled distinctly from that described above. If the scale factors are significantly less than 25 mm/s and 10 mm/mV, then it is acceptable that no grid rulings be utilized (e.g., full disclosure). When the scale factors are different from 25 mm/s or 10 mm/mV, the actual scale for each axis shall be clearly indicated on the record.

4.2.8.4 Full disclosure (miniature displays)

A claim of full disclosure capability requires that a hard copy record of all recorded data for 24 h be available; any gaps in the recorded data shall be indicated in a consistent manner occupying the same space on the hard copy as if the real-time ECG had been recorded during that time. The hard copy record may be at compressed time and voltage scales. The voltage scale shall not be less than 1 mm/mV, and the time scale not less than 2.5 mm/s. Total time to print the 24 h disclosure shall be less than 2 h. Patient identification, date, and time of day shall be present on each page of the record. Indications of patient-activated marks aligned to the coincident ECG are preferred.

4.2.8.5 Gain settings and switching

The system shall support three fixed gain settings of 20 mm/mV, 10 mm/mV, and 5 mm/mV. One of these three gain settings shall be selected (automatically or manually) on a per-procedure and per-channel basis at the beginning of ECG analysis, and that gain setting shall be used to generate the resultant ECG for that procedure. Other gain settings may be provided by the equipment.

The recorded output shall indicate the gain employed.

NOTE—For analog tape, the gain may be reported as “uncalibrated.”

For an analog (tape) AECG procedure, the system shall show the actual calibration pulse(s) on an ECG grid that is included in the report and to the operator on the display so that accuracy of the calibration can be verified.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 22

4.2.9 Temporal alignment

The system shall provide channel-to-channel temporal alignment of the various ECG signals. When the amplifiers for all channels are set to the same frequency response limits, the channel-to-channel skew shall be less than 20 ms or ± 0.5 mm (at 25 mm/s time axis scale). This applies to the recorder, reproducer, and the system collectively.

Skew is an indicator of the accuracy of the alignment of the record and playback heads of an analog tape AECG system. Skew is measured at the start of the patient procedure by determining the relationship of the times of the calibration pulses for each of the ECG channels.

When independent filtering of channels results in channel skew exceeding the above limit, then a suitable warning shall be included in the record to indicate that channel-to-channel temporal comparison is not advised.

It is recommended that a report of the skew of the signal between the ECG channels should be provided for analog tape procedures. Please note that the companion IEC document already requires that this measurement be reported.

4.2.10 Electromagnetic compatibility

In the interest of harmonizing this standard with existing EMC standards and similar works in process, the electromagnetic compatibility requirements and test methods are as stated in the current revisions of the EN 61000-4 series and EN 50082-1 standards except for unique requirements as stated below.

4.2.10.1 Electromagnetic emissions

4.2.10.1.1 Radiated and conducted electromagnetic emissions

The ambulatory portion of the AECG system shall comply with the requirements of CISPR 11, Group 1, Level B, in the worst-case configuration and operating mode. Instrument configurations are to be determined by the manufacturer.

It is recommended that the instrument be tested in a sufficient variety of configurations and operating states that might be used in normal operation so that the worst case may be determined.

4.2.10.2 Electromagnetic immunity

4.2.10.2.1 Immunity to radiated electromagnetic fields

The test methods and instruments, frequency range, and field strength specified in EN 61000-4-3 for Level 2 apply, except as modified in the following text.

The instrument is exposed to a modulated RF field using an 80% amplitude modulation, with the modulation being a sine wave of frequency chosen by the manufacturer to be within the flat passband of its ECG channel, or if this is a multiparameter ambulatory device, frequency should be chosen to be simultaneously within the flat passbands of all parameter channels of the multiparameter ambulatory device, if possible. (If, for multiparameter ambulatory devices, a single modulation frequency that simultaneously falls within the passband of all parameters cannot be selected, then test runs with additional modulation frequencies will be required so that all passbands are tested.)

The ECG cables are terminated in a simulated patient load (51 KΩ in parallel with 47 nF). The instrument is tested with all of its faces sequentially exposed to the RF field.

When exposed to a field strength as defined for Level 2, the instrument shall operate within normal limits of its specifications. No degradation of system performance or loss of functionality is acceptable except for the following:

a) With the ECG patient leads attached, the instrument may not be able to pass its ECG circuit noise specifications under these EMC susceptibility test conditions.

b) For certain equipment and patient cable configurations, it may not be possible to meet these immunity requirements. In such a case, the manufacturer shall disclose the reduced immunity levels that are met.

4.2.10.2.2 Immunity to conducted RF interference

The test methods and instruments specified in EN 61000-4-6 apply with the level of injection being Level 2. When the instrument can be operated from line power, a noise voltage with characteristics as given in the following paragraph is injected into the input power cord (not in the signal input).

An 80% amplitude modulation shall be used with the modulation being a sine wave of frequency chosen by the manufacturer to be within the flat passband of its ECG channel, or if this is a multiparameter ambulatory device, the modulation frequency should be chosen to be simultaneously within the flat passbands of all parameter channels of

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 23

the multiparameter ambulatory device if possible. (If, for multiparameter ambulatory devices, a single modulation frequency cannot be selected that does simultaneously fall within the passband of all parameters, then test runs with additional modulation frequencies will be required so that all passbands are tested.)

The instrument shall operate within normal limits of its specifications when exposed to these noise voltages. No degradation of system performance or loss of functionality is acceptable, except that, with the patient electrodes attached, the instrument may fail its ECG noise specifications.

4.2.10.2.3 Immunity to magnetic fields

The test methods and instruments specified in EN 61000-4-8 apply. Use the Level 3 test levels for continuous fields.

The instrument shall be exposed on all of its faces. The ECG leads are shorted at the instrument or, if a permanently attached ECG cable or lead set is used, it is to be shorted at the electrodes and tightly twisted to minimize loop area.

The instrument shall operate within the normal limits of this standard when exposed to these fields. No degradation of system performance or loss of functionality is acceptable.

4.2.10.2.4 Immunity to electrostatic discharge (ESD)

The test methods and instruments specified in EN 61000-4-2 apply. The test amplitudes shall be as specified for Level 3 of this IEC standard for both positive and negative discharges.

Condition 1: For open air discharges of up to 4 kV and direct contact discharges of up to 2 kV, no change in instrument operation shall be noticeable by the device user. The instrument shall operate within normal limits of its specifications; however, ECG spikes, display glitches, or momentary LED flashes are acceptable during an ESD.

Condition 2: For open air discharges and direct contact discharges of up to the full amplitudes specified by Level 3, the instrument may exhibit momentary loss of functionality but will recover without user intervention.

Isolated equipment must be discharged between applications of direct contact ESD.

4.2.10.2.5 Power line transients

When the AECG system has an analysis and/or display portion and is operated solely from line power, and risk analysis indicates that a power disturbance could result in an unacceptable risk to the patient or user, then items A, B, and C below apply. The AECG manufacturer may directly satisfy the requirements of items A, B, and C or may choose to show compliance indirectly by meeting one or more of the alternatives listed below item C.

A. Test methods and instruments specified in EN 61000-4-4 apply. Mains connectable instruments shall meet the Level 2 immunity level at the mains plug. Only transient degradation of system performance or loss of functionality is allowed. *Do not apply testing to the ECG cable*.

B. Test methods and instruments specified in EN 61000-4-5 apply. Mains connectable instruments shall meet Level 3 immunity requirements. The instrument shall operate within normal limits of its specifications when exposed to these transients. The instrument may exhibit momentary loss of function but shall recover without user intervention.

C. Voltage dips and interruptions. Test methods and instruments specified in EN 61000-4-11 apply for dips and short interruptions only. The percentage of nominal line voltage to which the mains input is reduced and the number of cycles affected are to be listed by the device manufacturer in the device specification. EN 61000-4-11 lists various levels from which to choose. Loss or corruption of data stored in the ambulatory portion (or tape) is not allowed. Component failures, changes in programmable parameters, factory defaults or operating modes in either portion are not allowed. Data loss or corruption in the nonambulatory portion is permissible only if it generates a transient that cannot reasonably be mistaken for a physiological signal, or if the line-operated portion prevents access to the corrupted data and clearly indicates to the user that the data must be retransferred from the ambulatory portion (or tape).

Alternatives to directly meeting parts A through C: If the AECG system is subject to this section and uses line-powered components that meet at least one of the following conditions, then items A, B, and C are not applied.

a) The off-the-shelf stationary equipment has already been shown by its manufacturer to meet the requirements necessary to obtain a CE marking; or

b) the AECG manufacturer provides with the AECG system an uninterruptable power supply (“UPS”) that meets the immunity requirements of EN 50082-1:1997, table 4, parts 4.2 through 4.5; or

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 24

c) the AECG equipment employs a battery backup to maintain operation in the presence of power-line disturbances; or

d) the AECG manufacturer recommends, rather than sells, off-the-shelf stationary equipment and the AECG manufacturer includes a warning substantially equivalent to the following in the AECG system operator's manual:

> "When used as part of an AECG system, line-operated computer devices that do not provide complete battery operation may be subject to loss or corruption of patient data during power line surges or sags. The user of this AECG system is responsible for obtaining and using with this system equipment that either meets the immunity requirements of EN 50082-1:1997, Table 4, parts 4.2 through 4.5, or is responsible for including and using a suitable uninterruptable power supply with that system. Surge suppressors commonly used to protect computers do not provide protection against line voltage dips or sags."

4.2.11 Auxiliary output

4.2.11.1 Shorted auxiliary output

Where an auxiliary output is provided, the reproducer shall meet all specifications after removal of a short circuit applied to the auxiliary output for 1 min.

4.2.11.2 Effect on risk current

The risk current limits specified in 4.2.4 shall not be exceeded upon proper connection of an auxiliary device to the auxiliary output. Such proper connection shall be described in the owner's manual.

4.2.12 Monitoring time and battery capacity

Type 1 and Type 2 devices shall be capable of monitoring for at least 24 h continuously. They shall also be capable of retaining all of the procedure information for a minimum of 72 h after completion of the procedure. Type 3 devices shall be capable of retaining the stored information for a minimum of 24 h after activation of the last event recording. This test shall be conducted with the temperature at the allowable extremes for no more than 4 h of the procedure.

4.2.13 Special requirements for intermittent event recorders (patient- or event-activated)

4.2.13.1 Data retention

An intermittent (patient-operated) event recorder (Type 3 device) with cleared memory and fresh battery shall function continuously for a minimum period as defined by the manufacturer and disclosed in the operating manual or physician's guide. The device shall be capable of retaining information recorded within the manufacturer's specified operational battery lifetime for a minimum period of 24 h after the recording is made.

4.2.13.2 ECG recording intervals

The ECG recording intervals prior to and following the trigger activation shall have either fixed values or be user adjustable. The fixed values or, in the latter case, the default values shall be disclosed in the operating manual or the physician's guide.

4.2.14 Automated analysis (optional)

In 4.2.14, the term "report" refers to the evaluation procedure described in this section and not to the clinical report that the physician receives (described in 4.2.15). Subclause 4.2.14 applies both to human-operated, stand-alone devices that use automated methods to analyze the recorded ECG and to so-called real-time event recorders that use automated methods to select abnormal events for recording. Evaluation of automated methods shall be reproducible.

4.2.14.1 Use of standard databases

Five standard databases are available for evaluating ambulatory ECG analyzers:

AHA DB — The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors (80 records, 35 min each)

MIT DB — The Massachusetts Institute of Technology–Beth Israel Hospital Arrhythmia Database (48 records, 30 min each)

ESC DB — The European Society of Cardiology ST-T Database (90 records, 2 hours each)

NST DB — The Noise Stress Test Database (12 records, 30 min each; supplied with the MIT DB)

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 25

CU DB The Creighton University Sustained Ventricular Arrhythmia Database (35 records, 8 min each; supplied with the MIT DB)

NOTES

1. Sources:
   ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462, USA (AHA DB).
   MIT–BIH Database Distribution, MIT Room E25-505, Cambridge, MA 02139, USA (MIT, ESC, NST, and CU databases).

2. Outside North America, the ESC DB is available from the CNR Institute of Clinical Physiology, Computer Laboratory, Via Trieste, 41, 56100 Pisa, Italy.

The first four of these databases consist of digitized excerpts of two-channel Holter recordings, with each beat labeled. The CU DB contains digitized single-channel ECG recordings with rhythm changes labeled. This list of standard databases is not intended to exclude others that may become available in the future; it is a complete list of those that are both adequate as a basis for evaluation and generally available at present.

If any records from a given database are used to fulfill the requirements of 4.2.14.2, device performance shall be tested and reported on a record-by-record basis for all records from that database, excluding only those with paced beats (see 5.2.14). The AHA DB contains two records with paced beats, and the MIT DB contains four such records. Performance on these records shall be reported for devices that are intended to analyze paced analog ECG recordings made without pacer artifact detection or enhancement, but aggregate performance statistics shall exclude these records in all cases. The NST DB contains three records (‘bw,’ ‘em,’ and ‘ma’) that are noise recordings only and that are not intended for use in standard tests; the remaining 12 records are those on which device performance shall be tested and reported. Segments of data in which ventricular flutter or fibrillation (VF) is present are excluded from beat-by-beat comparisons (5.2.14.3) only; however, other segments of data within the same records shall be included in these comparisons. The first 5 min of each record are designated as a learning period. The remainder of each record is the test period. Device performance is measured only during the test period of each record; the entire test period shall be used for this purpose, except as noted above for VF segments.

4.2.14.2 Testing requirements

The accuracy of QRS detection shall be tested using the AHA DB, the MIT DB, and the NST DB.

The accuracy of heart rate measurements shall be tested using the NST DB.

The accuracy of ventricular ectopic beat (VEB) detection shall be tested using the AHA DB, the MIT DB, and the NST DB.

If the device is claimed to detect VF, its ability to do so shall be tested using the CU DB, the AHA DB, and the MIT DB.

If the device is claimed to detect supraventricular ectopic beats, or atrial flutter or fibrillation (AF), its ability to do so shall be tested using the MIT DB and the NST DB.

If the device is claimed to measure ST segment deviations or to detect ST segment changes, its ability to do so shall be tested using the ESC DB.

4.2.14.3 Requirements for the system evaluation report

Record-by-Record Results. Formal definitions of the statistics listed below are provided in A.4.2.14.3.

For each record, the following statistics shall be reported:

QRS sensitivity and positive predictivity;
VEB sensitivity and positive predictivity;
ventricular couplet sensitivity and positive predictivity;
ventricular short (3–5 beats) run sensitivity and positive predictivity;
ventricular long (6 beats or more) run sensitivity and positive predictivity.

For each record, any of the following statistics which are relevant to the device’s claimed capabilities shall also be reported:

VF episode sensitivity and positive predictivity;
VF duration sensitivity and positive predictivity;
SVEB sensitivity and positive predictivity;
supraventricular couplet sensitivity and positive predictivity;
supraventricular short (3–5 beat) run sensitivity and positive predictivity;
supraventricular long (6 beats or more) run sensitivity and positive predictivity;

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 26

AF episode sensitivity and positive predictivity;
AF duration sensitivity and positive predictivity.

4.2.14.3.1 Additional reporting requirements for ST analyzers

If the device incorporates ST measurement or analysis functions, the additional data listed in this section shall be reported.

The resolution of ST segment level and slope measurements, the number of leads analyzed, the number of beats averaged or the time constant characteristic of ST measurement, and the policy with respect to treatment of ectopic and noisy beats by the ST analysis algorithm shall be disclosed.

For each of the 368 reference measurements in the ESC DB, the corresponding algorithm measurement shall be reported. In this report, each measurement shall be identified by record name and elapsed time from the beginning of the record. The percentage of such measurements, which differ from the reference measurements by more than 100 microvolts, shall be reported.

If the AECG system claims ability to distinguish between ischemic and nonischemic origin of ST segment changes, the ischemic ST episode sensitivity and positive predictivity and the ischemic ST duration sensitivity and positive predictivity shall be reported for each of the 90 records in the ESC DB. Devices that perform ST measurement, but not ST episode detection, are exempted from the requirements of this paragraph.

4.2.14.4 Reporting requirements: aggregate statistics

Based on the record-by-record reports required by 4.2.14.3, aggregate statistics summarizing the performance of the device under test on each of the databases used for testing shall be reported in tabular format as shown in 4.2.14.4.1 and 4.2.14.4.2. Symbols and abbreviations used in these tables are:

A average of all single record statistics

G gross statistic (calculated for the entire database)

O optional (no report required)

+P positive predictivity

R required (the statistic shall be reported)

Se sensitivity

W worst case statistic for any single record in the database

— the given performance measure cannot be obtained from the given database (no report required)

4.2.14.4.1 Reporting requirements for standard analyzer outputs

Requirements specified by this section shall apply for all ambulatory ECG analyzers.

Statistic	AHA DB	MIT DB	NST DB	CU DB	ESC DB
QRS Se (G)	R	R	R	—	O
QRS Se (A)	R	R	R	—	O
QRS +P (G)	R	R	R	—	O
QRS +P (A)	R	R	R	—	O
VEB Se (G)	R	R	R	—	O
VEB Se (A)	R	R	R	—	O
VEB +P (G)	R	R	R	—	O
VE Couplet Se (G)	R	R	—	—	—
VE Couplet +P (G)	R	R	—	—	—
VE Short Run Se (G)	R	R	—	—	—

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 27

Statistic	AHA DB	MIT DB	NST DB	CU DB	ESC DB
VE Short Run +P (G)	R	R	—	—	—
VE Long Run Se (G)	R	R	—	—	—
VE Long Run +P (G)	R	R	—	—	—

4.2.14.4.2 Reporting requirements for optional analyzer outputs

Reports specified by this section shall be provided if applicable to the device under test, as defined by section 4.2.14.2.

Statistic	AHA DB	MIT DB	NST DB	CU DB	ESC DB
VF Episode Se (G)	R	R	—	R	—
VF Episode +P (G)	R	R	—	R	—
VF Duration Se (G)	R	R	—	R	—
VF Duration +P (G)	R	R	—	R	—
SVEB Se (G)	—	R	R	—	O
SVEB Se (A)	—	R	R	—	O
SVEB +P (G)	—	R	R	—	O
SVE Couplet Se (G)	—	R	—	—	—
SVE Couplet +P (G)	—	R	—	—	—
SVE Short Run Se (G)	—	R	—	—	—
SVE Short Run +P (G)	—	R	—	—	—
SVE Long Run Se (G)	—	R	—	—	—
SVE Long Run +P (G)	—	R	—	—	—
AF Episode Se (G)	—	R	—	—	—
AF Episode +P (G)	—	R	—	—	—
AF Duration Se (G)	—	R	—	—	—
AF Duration +P (G)	—	R	—	—	—
Discrepant ST Measurements	—	—	—	—	R
Ischemic ST Episode Se (G)	—	—	—	—	R
Ischemic ST Episode +P (G)	—	—	—	—	R
Ischemic ST Duration Se (G)	—	—	—	—	R
Ischemic St Duration +P (G)	—	—	—	—	R

4.2.15 Minimum requirements for clinical report

Any abnormality in the items listed below which an AECG system is capable of detecting shall be reported. The report shall also list all user-selected parameters. The report shall summarize each item at least once per hour during the ambulatory procedure and then as a procedure total at the end of the procedure.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 28

4.2.15.1 Heart rate

Low, mean, and high heart rates shall be reported. The summary information shall also reflect a total number of heart beats detected. The report shall summarize each item at least once per hour of the ambulatory procedure and then as a procedure total at the end of the procedure.

4.2.15.2 Supraventricular ectopy

Totals for SVPBs, single SVPBs, paired SVPBs, runs of SVT, and some form of SVT duration (either beat totals or time duration) shall be reported. Summary information shall include the total number of each event that occurred during the procedure. The report shall summarize each item at least once per hour of the ambulatory procedure and then as a procedure total at the end of the procedure.

4.2.15.3 Ventricular ectopy

Totals of VEBs, single VEBs, paired VEBs, and runs of three or more VEBs, and the duration of runs (either number of beats or time duration) shall be reported. For episodes of ventricular tachycardia, rate and duration (either beat totals or time duration) of each episode shall be reported. The number of minutes (and optionally seconds) which were analyzed on each channel shall be reported (the manufacturer may substitute the amount of time not analyzed).

4.2.15.4 Bradycardia data

Hourly presentation of the total of bradycardia episodes is required, specifying rate and duration of the episodes. Bradycardia episodes (heart rate < 50/min for > 15 s OR manufacturer-selected parameters OR user-defined parameters) shall be reported.

4.2.15.5 Pauses

The total number of pauses detected based upon a user-selectable multiple of the ongoing average RR interval OR a user-selectable absolute threshold OR manufacturer-selected parameter shall be reported.

4.2.15.6 ST segment shifts

If the device is designed to detect and/or measure ST segment shifts, the manufacturer shall disclose in the operating manual or physician's guide the following:

a) whether the ST analysis is performed on all leads using any or all calibration signals;

b) whether there are user-selectable detection criteria for ST segment shifts (such as displacement and slope parameters);

c) how frequently ST segment shifts are summarized in the report (e.g., hourly) and whether numbers of episodes, types of episodes (elevation or depression), and durations of episodes are reported; or whether the report presents this information episode-by-episode;

d) whether ranges of heart rates, ranges of displacements, and/or slope values during each episode are reported.

4.2.15.7 ECG hard copy

User-selectable, 25 mm/s, multichannel ECG strips shall be available with each AECG report in sufficient quantity to support all meaningful clinical conclusions. Lead configuration for each channel shall be provided either with each ECG strip or as part of the procedure settings information. ECG strips shall, minimally, include the following labeling:

a) time of strip;

b) heart rate on strip;

c) strip annotation.

Additionally, each "page" of ECG strips shall contain the patient identification. A "page" in this context might be a single ECG strip from an ECG strip recorder or several strips contained on a "letter" size sheet of paper. Each channel calibration signal shall be present in each AECG report for which a subsequent ST segment analysis is to be done.

Hard copy outputs for Type 3 devices may be single channel and do not require printing of time, heart rate, page, patient, or strip annotations.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 29

5 Tests

This section provides referee test methods and procedures by which compliance of the device with the requirements of section 4 can be verified. The paragraph numbers below correspond with those of section 4, except for the first digit (e.g., conformance with requirement of 4.2.3 can be determined by the test method of 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 tests are not intended for use in verifying the performance of individual devices, either for purposes of quality assurance inspections by the manufacturer or for purposes of routine in-hospital inspections by the device user. General instrumentation and procedural requirements for conducting the tests are provided below.

Test and Recording Conditions: Unless otherwise specified, all measurements and tests shall be performed at the standard operating conditions specified in 4.2.1. During testing of battery-powered units, the battery voltage shall be within the manufacturer's specifications. Measurement tolerances are ± 1.4º C for temperature and ± 5% for humidity.

Test Apparatus: The following test instruments will be required.

a) Oscilloscope with a differential input amplifier must have an input impedance of at least 1 megohm and an amplitude resolution of 10 μV. The 3 dB frequency response shall be at least dc to 1 MHz, with a midband amplitude accuracy of ± 5%.

b) Voltmeter capable of measuring dc voltages in the range of 1 mV to 1 V with an accuracy of ± 1%; and a voltmeter or p-v amplitude detector capable of measuring p-v sinusoidal and triangular signals in the voltage range of 0.1 V to 10 V with an accuracy of ± 1%.

c) Two signal generators capable of generating sinusoidal, square wave, and triangular waveforms with frequencies ranging from 0.05 Hz to 1000 Hz. The signal generators shall have adjustable voltage outputs up to at least 12 V p-v.

d) High voltage power supply and power resistor capable of charging a 32 μF capacitor to 5000 V. A short charging time and prompt discharge are recommended for safety reasons.

Test Circuits: Unless otherwise specified, the circuits described in the tests shall be made with resistors having a ± 5% tolerance (or better) for frequencies of up to 1 MHz. Capacitors shall be nonpolarized, of suitable voltage rating, and have a tolerance of at least ± 5%. Inductors shall also have a ± 5% tolerance.

Test Signals and Output Measurements: Unless otherwise specified, input test signal amplitudes shall be set so that errors do not exceed ± 1% of the specified value for dc voltages or voltage steps. Triangular or sinusoidal test voltages shall be set within ± 2% of the specified p-v value. The measurement of the output signal shall be made from the hard copy or, where appropriate, from a fixed image of the signal on the display screen. When necessary, a photograph or other hard copy of the signal, with a superimposed known graticule in the vertical and horizontal directions, may be used. Where a requirement or test is specified in μV RTI, the corresponding output in mm is obtained by multiplying the μV value by the device gain expressed in mm/mV and dividing by 1000. Distance measurements on the output traces shall be made with a linear enlarger (optical) with a scale accurate to 0.1 mm. Distances shall be expressed to the nearest 0.1 mm. The line thickness of the output trace may be as much as 1 mm; therefore, care shall be taken to measure distance from points on the same edge of the trace. Figure 2 shows an example of amplitude and time measurement.

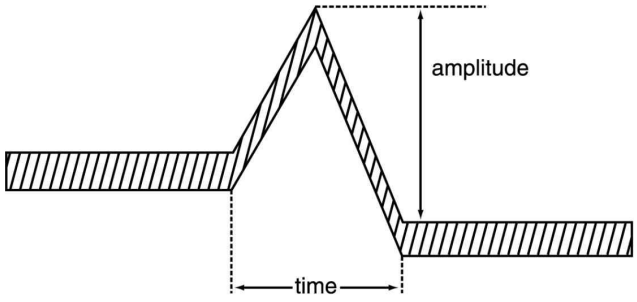


Figure 2—Example of time and amplitude measurement

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 30

Noise Interference: The performance tests shall be conducted so as to minimize extraneous noise interference and pickup, as is good practice in recording electrocardiograms.

5.1 Labeling/disclosure requirements

Compliance with the labeling requirements of 4.1 can be verified by inspection.

5.2 Performance requirements

5.2.1 Operating conditions

Specialized equipment such as environmental test chambers, altitude or pressure chambers, and programmable shake tables are required to perform the environmental tests.

Adherence to performance specifications is verified while the equipment is being subjected to the extreme limits of the range of operating conditions. For testing purposes, the three general categories of environmental conditions (input power, temperature/humidity, and shock/vibration) are considered mutually exclusive. For example, compliance with the specified temperature/humidity range is demonstrated if the device meets all requirements of the standard while operating for a minimum of 4 h at the four possible combinations of temperature and humidity (maximum temperature with minimum humidity, maximum temperature with maximum humidity, etc.) with all other conditions at nominal.

For verification of the ambient air pressure requirement, it will be sufficient to place the equipment in a pressure chamber at the lowest pressure (i.e. 700 millibars) and verify that the equipment shows no loss of functionality at one value of temperature and humidity, e.g., 25º and 50% humidity. (It is not necessary to test over a range of temperatures and humidity levels at reduced pressures.)

Adherence to the shock/vibration requirements is verified by conducting these tests while the portable equipment acquires a signal from any reasonable source (e.g., a battery-operated ECG simulator), playing back the recorded signals on the manufacturer's playback device, and visually noting whether:

a) the applicable shock requirements of 4.2.1.2 are met; and

b) the recording continues uninterrupted while the recorder is undergoing vibration. (An increase of noise levels during vibration may result from the cable microphonic effects and does not constitute a failure.)

Adherence to storage condition requirements is determined by subjecting the equipment to the worst-case conditions long enough to fully affect the equipment, then returning the equipment to the normal operating environment and verifying that performance requirements are still met.

Testing at the extremes of temperature and humidity shall be performed for 4 h total out of the 24 h of monitoring time and 4 h total out of the 24 h of hold time. This test is supposed to simulate the device under test in a normal operating environment. There is no requirement for the device to sustain temperature swings from the maximum to the minimum of the operating range in a short period of time.

5.2.2 Lead definition

Compliance with lead definition requirements is made by inspection.

5.2.2.1 Number of leads

Compliance is made by inspection.

5.2.2.2 Verification of electrode placement

Compliance with the lead placement verification mechanism requirement is determined by demonstrating that any input signal can be visually displayed or printed.

5.2.2.3 Safe electrode lead wire connectors

Compliance with the requirements of 4.2.2.3 can be determined by inspection, with particular consideration given to safety characteristics during use and during attempted forced mating with connectors supplying hazardous energy (e.g., female end of a detachable power cord).

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 31

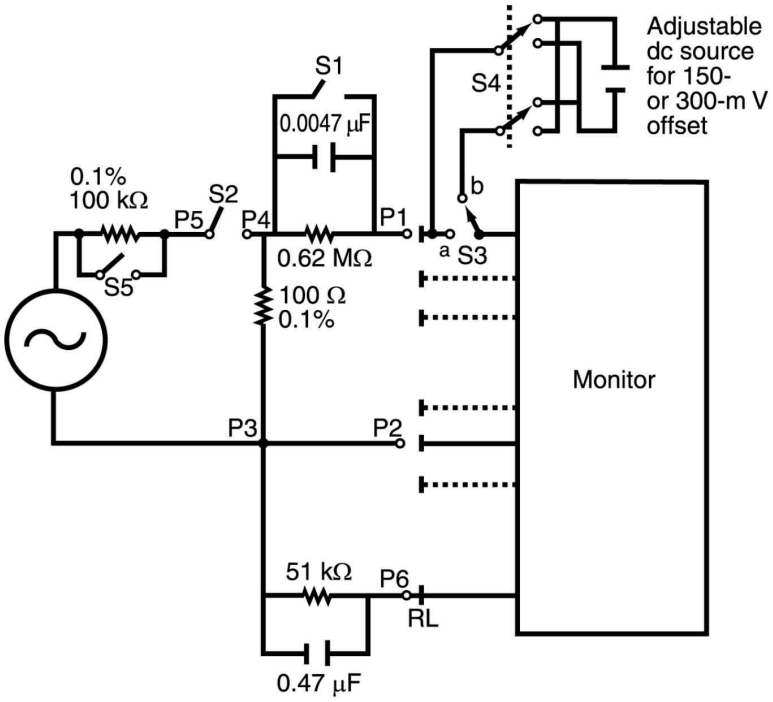


Figure 3—General test circuit—The 100 Ω and 100 kΩ resistors are 0.1% so as to provide an accurate voltage division

5.2.3 ECG input channels

5.2.3.1 Input dynamic range

The test is conducted according to the following procedure.

a) Set the gain to a setting that can represent 10 mV p-v (6 mV p-v for a device utilizing analog storage, 4 mV p-v for a Type 3 device). Connect the recorder to the test circuit of figure 3, with switches S1 and S2 closed, S5 open, S3 in position A, and the positive patient electrode connection for each channel joined to P1. The negative patient electrode connection of each channel is joined via P2 to the reference leadwire through a parallel combination of a 51 KΩ resistor and a 47 nF capacitor.

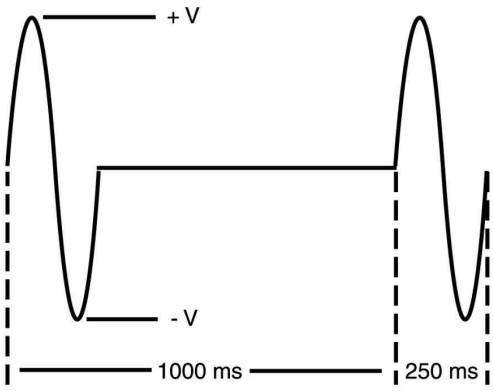
b) Record a 4 Hz (6.7 Hz for a device utilizing analog storage and 7.5 Hz for a Type 3 device) sine wave with a pattern that may be continuous or consist of isolated single cycles repeating once per s as in figure 4. The amplitude of this signal shall be 10.0 + 0.1 mV p-v (6.0 + 0.06 mV p-v for a device utilizing analog storage, 4.0 + 0.04 mV p-v for a Type 3 device).

c) Set switch S3 to position B, use switch S4 to add a 300 mV (150 mV for Type 3 device) offset, wait at least 30 s for device to stabilize, and repeat step (b).

d) Set switch S3 to position B, use switch S4 to subtract a 300 mV (150 mV for Type 3 device) offset, wait at least 30 s for device to stabilize, and repeat step (b).

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 32



Note: V is variable - see the text

Figure 4—Sine wave with pattern of isolated single cycles repeating once per second

e) On playback, in each mode that allows the full display of the recorded signal, confirm that the recorded signals are not distorted or truncated within the indicated range of 10.0 mV p-v (6.0 mV p-v for a device utilizing analog storage, 4.0 mV p-v for a Type 3 device). The output shall not be considered distorted if the waveform is within +10 % or + 50 μV (whichever is greater) of a best fit sine wave.

5.2.3.2 Input impedance

The test is conducted according to the following procedure.

a) The test circuit of figure 3 is configured with switches S1 and S2 closed, S5 open, and S3 in position A. The signal generator is adjusted to generate a sinusoidal signal with a frequency of 1 Hz and a p-v amplitude, across P1 and P2, of 2 mV.

b) Connect the patient electrode connections for channel 1 to P1 and P2. All other patient electrode connections are connected to P6.

c) Measure the output of the signal produced on the manufacturer's playback device. Open switch S1 and measure the change in amplitude at the output. The steady state signal amplitude shall not decrease by more than 20%.

d) Repeat step (c) with frequencies of 1 Hz, 5 Hz, and 20 Hz; verify that opening switch S1 does not decrease the output by more than 20%.

e) Repeat steps (b) and (c) with + 300 mV and - 300 mV dc offsets (± 150 mV for Type 3 devices) imposed on the sinusoidal test signal.

f) Repeat this test sequence for all other ECG channel pairs.

5.2.3.3 Direct currents in patient electrode connections

The test is performed according to the following procedure.

a) Connect together all leads except channel 1+. Attach channel 1+ to the node (formed from the other leads) through a 100 KΩ resistor. It may be necessary to parallel the resistor with a suitable capacitor to minimize AC interference.

b) Measure the voltage across the resistor. To meet the current requirement, the dc voltage shall not exceed 10 mV for any patient input connection or 100 mV for any other patient electrode connection.

c) Repeat steps (a) and (b) for all other input leads.

5.2.3.4 Common mode rejection

The test is performed according to the following procedure.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 33

The manufacturer's recommended patient cable, or equivalent, shall be used in conducting the following test. If user-selectable power-line filters are available, they may be invoked during this test. The AECG unit under test is enclosed in a conductive foil wrap that is connected to earth ground. The foil shall fully enclose the AECG monitor, except where the patient cable enters, and shall conform to the contours of the AECG monitor within 0.1 inch. The patient cable shall be enclosed throughout its entire length by a similar foil shield connected to the shield driven by the simulated line frequency source. This same driven shield encloses the various resistor/capacitor networks, dc offset source, and switches. An additional earth-referenced shield shall enclose the entire test setup described above. The interference signal is initially set at the power line frequency (see figure 5). All switches must be either fully insulated or the test operator must not be in contact with them during the actual CMR tests or the test operator's body capacitance to earth is likely to affect the calibration of the fixture.

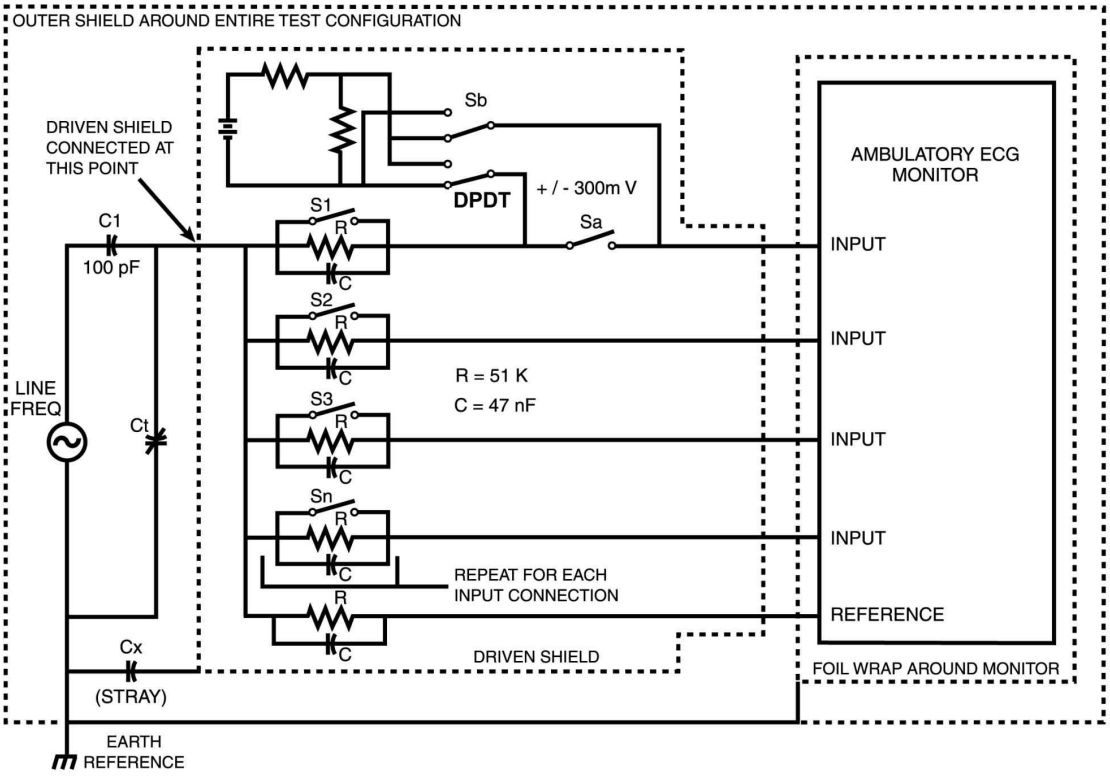


Figure 5—AECG unit under test as in 5.2.3.4—Unit is enclosed in conductive foil wrap

a) To calibrate the fixture, while the AECG unit and its ECG cable, if any, are entirely removed from the fixture and the fixture's outer shield is in place, adjust Ct so that Ct + Cx = 100 pF. The resulting test voltage across Ct will then be one-half of the generator value. Connect all patient electrode leads to a common node, each one in series with a parallel combination of a 51 KΩ resistor, a 47 nF capacitor, and a single pole, single throw (SPST) switch. Connect any common or reference electrode, if supplied, through a 51 KΩ resistor in parallel with a 47 nF capacitor to the same common node. Apply the interference test signal to the common node through a 100 pF capacitor. The negative side of the generator is connected to earth ground. Switches S1 through Sn are open; switch Sa is closed. Once Ct is calibrated, connect the AECG unit, its cable and the foil wrap for that cable. Then record sufficient duration of signal to allow measurement of worst-case interference, taking into account any possible aliasing and the reproducer's maximum operator selectable playback speed.

b) Repeat the above test with a plus and minus 300 mV dc offset (150 mV for Type 3 devices) in series with the imbalance impedance by opening Sa and testing with the double pole, double throw (DPDT) switch Sb

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 34

in each of its two positions. Repeat test with offset in series with each input. (The source impedance of the dc offset source must be small compared to 51 KΩ.)

c) Repeat the above tests with each of the switches S1 through Sn closed, in turn.

d) Repeat the above tests at two times power line frequency.

Recover the data from the AECG monitor and verify that the measured rms output during each recording test period does not exceed - 60 dB at power line frequency and - 45 dB at two times power line frequency compared to the interference test signal rms value for each available lead setting. If necessary, adjust the magnitude of the interference test signal to prevent clipping the resulting recorded waveform. For purpose of calculation, consider the interference signal's magnitude to be defined as one-half the signal fed by the generator to the 100 pF input capacitor.

5.2.4 Risk currents

The test methodology for determining risk current levels is provided in the referenced standard ANSI/AAMI ES1: 1993.

5.2.5 Overload protection

5.2.5.1 AC voltage

The test is conducted according to the following procedure.

a) The test circuit of figure 3 is configured with switches S1 and S5 closed, S2 open, and S3 in position A. The signal generator is adjusted to generate a sinusoidal signal with a frequency of 60 Hz and a p-v amplitude, across P3 and P5, of 1 V.

b) Connect the patient electrode connections for channel 1 to P1 and P2.

c) Close switch S2 for 10 s.

d) Repeat step (c) two more times within a 5 min period.

e) Repeat steps (c) and (d) for all other ECG channel pairs.

f) Verify that the device has not suffered any damage and still meets the requirements of this standard.

5.2.5.2 Defibrillator energy shunting

For test purposes, the simulated defibrillator discharge shall have a damped sinusoidal waveform conforming to the limits specified in the *Cardiac defibrillator devices* (ANSI/AAMI DF2:1996). The source generator shall have a minimum stored voltage of 5000 V, and the energy delivered to the test assembly shall be 360 Joules (J). The waveform shall be delivered into a 100 ohm load (simulating the patient), with 400 ohms interposed between the 100 ohm defibrillator load and one connection of the AECG recorder, as shown in figure 6. For this test, the AECG manufacturer's recommended patient cables shall be used.

a) Connect P1 and P2 to the AECG patient electrodes for channel 1.

b) Charge the capacitor to 5000 V, with switch S1 in position A.

c) Discharge the test circuit by actuating switch S1 to position B and measure the energy E1 delivered to the defibrillator tester (i.e. 100 ohm load).

d) Remove the connections from the AECG recorder to P1 and P2, discharge the test circuit, and measure the energy E2 delivered to the tester.

e) Verify that the energy E1 is at least 90% of E2.

f) Repeat the procedure for the other channel(s) of the AECG monitor.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 35

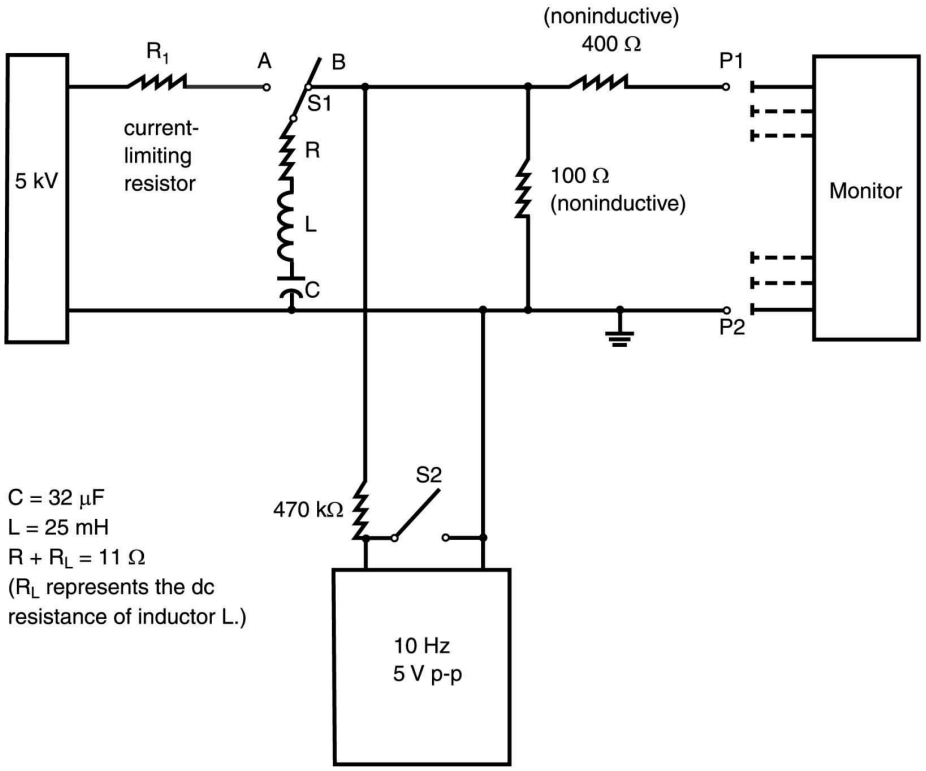


Figure 6—Test circuit for defibrillator energy-shunting test (5.2.5.2)—Switch S1 must withstand peak current of 60 A in the closed position and not break down for voltages up to 5000 V in the open position

NOTES

1. The values of R, C, and L may be varied as long as the waveform conforms to the limits specified in ANSI/AAMI DF2:1996.

2. The AECG recorder's patient cables shall be used.

3. The test circuit shown in figure 6 for producing simulated defibrillator pulses shall be constructed and used with great caution so as to avoid danger to test personnel. It may be necessary to connect two 50 ohm resistors in series to obtain a test load of 100 ohms. This shall be done carefully as the node connection of the resistors is at or near one-half of the full defibrillator voltage.

5.2.6 Gain control, accuracy, and stability

5.2.6.1 Gain accuracy

To test the accuracy of the gain settings, the device is operated with a train of 1.0 mV (± 0.05 mV), 100 ms rectangular pulses repeated at a rate of 1 Hz injected into all ECG input channels. The system gain is changed to each allowable setting, and the output is verified as being within the requirements for each setting.

5.2.6.2 Gain stability

To test gain stability, the device is operated with a train of 1.0 mV (± 0.05 mV), 100 ms rectangular pulses repeated at a rate of 1 Hz injected into all ECG input channels for the length of a normal usage period (typically 24 h). Measurements are made of the amplitude of the output at the points of 1 min, 15 min, 30 min, and 60 min after the device has been energized and each hour thereafter until 24 h have elapsed. For Type 3 devices, the test will be terminated at the end of the recording period, as specified by the manufacturer.

Licensed to Lynn Brazil. ANSI store order # X_1068169. Downloaded 12/11/2024. Single user license only. Copying and networking prohibited.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1041
Page 36