American National Standard

ANSI/AAMI EC11:1991/(R)2001/(R)2007

Diagnostic electrocardiographic devices

AAMI Association for the Advancement of Medical Instrumentation

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Diagnostic electrocardiographic devices

ANSI/AAMI EC11:1991/(R)2001/(R)2007
(Revision of ANSI/AAMI EC11:1982 and
ANSI/AAMI EC11a:1984)

American National Standard
Diagnostic electrocardiographic devices

Developed by
Association for the Advancement of Medical Instrumentation

Approved 24 October 1991; reaffirmed 4 May 2001 and 24 August 2007 by
American National Standards Institute

Abstract:

This standard establishes minimum safety and performance requirements for electrocardiographic (ECG) systems with direct writing devices which are intended for use in ECG contour analysis for diagnostic purposes.

Committee representation

Association for the Advancement of Medical Instrumentation

This standard was developed by the Diagnostic Electrocardiograph Subcommittee under the auspices of the Electrocardiograph Committee. Committee approval of the standard does not necessarily imply that all committee and subcommittee members voted for its approval.

The AAMI Electrocardiograph Committee has the following members:

Cochairpersons: Stanley A. Briller, M.D.
David Mortara, Ph.D.

Members: James Bailey, M.D., National Institutes of Health
Alan S. Berson, Ph.D., National Heart, Lung and Blood Institute
Stanley A. Briller, M.D., Allegheny General Hospital, Pittsburgh, PA
Francis Charbonnier, Ph.D., Hewlett-Packard Company
David L. Daly, Center for Devices and Radiological Health, FDA
Arthur R. Eddy, Jr., Medtronic, Inc
David Mortara, Ph.D., Mortara Instruments
*Jim Rooks, Medical Data Electronics

Alternates: Robert Cangelosi, Center for Devices and Radiological Health, FDA
Peter Galen, Hewlett-Packard Company
Roy D. Wallen, Hewlett-Packard Company

The committee's Diagnostic Electrocardiograph Subcommittee has the following members:

Cochairpersons: Alan S. Berson, Ph.D.

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Peter Galen, Hewlett-Packard Company
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Ian Rowlandson, Marquette Electronics Inc.

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

This is the second edition of the American National Standard, *Diagnostic electrocardiographic devices*. The standard, which was developed by the AAMI ECG Committee and its Diagnostic Electrocardiograph Subcommittee and first approved in 1983, is based on the fourth draft of a standard for electrocardiographic (ECG) devices developed by the UBTL Division of the University of Utah Research Institute under the sponsorship of the then Bureau of Medical Devices, U.S. Food and Drug Administration.

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 diagnostic ECG devices.

Substantive changes from the original standard appear in this revision. In 1990, the American Heart Association published a new report, updating their recommendations of 1975. The subcommittee carefully considered these recommendations in developing this revision of the AAMI standard. The changes in this revision primarily affect frequency response requirements, direct currents in patient electrode connections, system noise, and defibrillator overload protection.

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

This standard reflects the conscientious efforts of concerned health care professionals, device manufacturers,

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and government representatives to develop a standard for those performance levels that could be reasonably achieved at this time.

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

NOTE—This foreword is not a part of the American National Standard, *Diagnostic electrocardiographic devices* (ANSI/AAMI EC11-1991).

Diagnostic electrocardiographic devices

1 Scope

This standard establishes minimum safety and performance requirements for electrocardiographic (ECG) systems with direct writing devices which are intended for use, under the operating conditions specified in this standard, in the analysis of rhythm and of detailed morphology of complex cardiac complexes. Subject to this standard are all parts of the electrocardiographic system necessary to obtain the signal from the surface of the patient's body, to amplify this signal, and to display it in a form suitable for diagnosing the heart's electrical activity. This standard defines requirements for the electrocardiographic recording system, from the input electrodes[1)] to the output display.

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

The referee test methods of section 4 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 inhospital inspections. Also, 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.

1.1 Inclusions

Included within the scope of this standard are the following devices:

a) direct-writing electrocardiographs;

b) electrocardiographs used in other medical devices (e.g., patient monitors, defibrillators, stress testing devices), when such devices are intended for use in obtaining diagnostic ECG signatures;

c) electrocardiographs having a display that is remote from the patient (via cable, telephone, telemetry, or storage media), when such devices are intended for use in obtaining ECG signatures. These devices are subject to the functional performance requirements at the system output-input levels[2)].

1.2 Exclusions

Not included within the scope of this standard are:

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

b) devices for interpretation and pattern recognition (e.g., QRS detectors,alarm circuits, rate meters, diagnostic algorithms);

c) fetal ECG monitors;

d) ambulatory monitoring electrocardiographic devices, including ECG recorders and associated scanning and read-out devices;

e) diagnostic electrocardiographic devices utilizing nonpermanent displays;

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f) vectorcardiographs, that is, the display of loops;

g) electrocardiographic devices intended for use under extreme or uncontrolled environmental conditions outside of a hospital environment or physician's office;

h) cardiac monitors, with or without heart rate meters and alarms, that are intended primarily for detecting cardiac rhythm. (These devices are covered by the ANSI/AAMI standard *Cardiac monitors, heart rate meters and alarms.)*

NOTE—Devices that provide selection between diagnostic and monitoring functions must meet the requirements of the appropriate standard—the standard for diagnostic electrocardiographic devices or the standard for cardiac monitors, heart rate meters and alarms—when selected for that function.

2 Normative references

2.1 Applicable documents

The following documents are applicable to the extent specified herein.

2.1.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus.* ANSI/AAMI ES1-1985. Arlington (Vir.): AAMI, 1985. American National Standard. ISBN 0-910275-50-5.

2.1.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Cardiac defibrillator devices*. ANSI/AAMI DF2-1989. Arlington (Vir.): AAMI, 1989. American National Standard. ISBN 0-910275-91-2.

2.2 Reference standards

Reference may be made to the following standards for safety and performance criteria established for other electrocardiographic devices and for components of electrocardiographic recording systems.

2.2.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Cardiac monitors, heart rate meters and alarms.* ANSI/AAMI EC13-1983. Arlington (Vir.): AAMI, 1983. American National Standard. ISBN 0-910275-42-4.

2.2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Disposable ECG electrodes*. ANSI/AAMI EC12-1991. Arlington (Vir.): AAMI, 1991. American National Standard. ISBN 0-910275-61-0.

2.2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Standard for ECG connectors.* ANSI/AAMI ECGC-1983. Arlington (Vir.): AAMI, 1983. American National Standard. ISBN 0-910275-21-1.

3 Requirements

3.1 Labeling 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.

3.1.1 Device markings

3.1.1.1 Product identification and characteristics

Diagnostic ECG devices shall be clearly and permanently marked with the following information:

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

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b) the catalogue, style, model, or other type designation;

c) the serial number;

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

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) which can be connected to it if the device provides mains power for other devices.

3.1.1.2 Panel controls and switches

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

3.1.1.3 Electrical safety

Where markings are affixed to the electrocardiograph warning maintenance personnel of the potential shock hazard from accidental contact with parts, or identifying electrocardiographs with current ratings that may overload branch circuits supplying the electrocardiograph, these 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 that are inside the enclosure of cord-connected equipment are considered to be clearly visible if the markings would be seen before a hazard is encountered.

3.1.1.4 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.

3.1.1.5 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. Cable legends of a permanent type (e.g., engraved) shall also be used for individual patient-electrode connection identification. The standard color code for patient lead conductors, as well as electrode placement, shall conform to the specifications of table 1.

NOTE—See A.3.1.1 for information concerning the differences between the color code specified in this requirement and that recommended by the International Electrotechnical Commission (IEC).

3.1.2 Operator's manual

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

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Table 1—Patient electrode connection definitions and color code			
System	**Patient electrode connection identifier**	**Color code**	**Position on body surface**
Conven-tional	RA	White	Right arm
	LA	Black	Left arm
	LL	Red	Left leg
	V	Brown	Single movable chest electrode
	V1	Brown/red	4th intercostal (IC) space at right border of sternum
	V2	Brown/yellow	4th IC space at left border of sternum
	V3	Brown/green	Midway between V2 and V4
	V4	Brown/blue	5th IC space on left midclavicular line
	V5	Brown/orange	Left anterior axillary line at the horizontal level of V4
	V6	Brown/violet	Left midaxillary line at the horzontal level of V4
	RL	Green	Right leg
Frank vector	I	Orange/red	At the right midaxillary line 1)
	E	Orange/yellow	At the front midline1)
	C	Orange/green	Betweeen front midline and left midaxillary line at angle of 45 degrees
	A	Orange/brown	At the left midaxillary line1)
	M	Orange/black	At the back midline1)
	H	Orange/violet	On the back of the neck or on the forehead
	F	Red	On the left leg

1)Located at the transverse level of the ventricles (i.e., 5th interspace at the left sternal border).

3.1.2.1 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 the electrocardiograph, including, but not limited to, use of the device in the vicinity of explosive anesthetics and use in the presence of electromagnetic interference or power overloads caused by electrosurgical or diathermy instruments.

b) Battery-powered devices. For ECG devices equipped with batteries, the manufacturer shall disclose the minimum operating time of the device and of any connected accessories, provided that the batteries are new and fully charged. For rechargeable batteries, the manufacturer shall disclose the battery charge time from depletion to 90 percent charge. In addition, if a battery depletion indicator is provided, its function shall be described.

c) Accuracy of input signal reproduction. The manufacturer shall disclose the methods used to establish overall system error and frequency response. The system may be tested in either of two ways, as described in 3.2.7.2 and 4.2.7.2. Because of their sampling characteristics and the asynchronism between sample rate and signal rate, digital systems may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings. This phenomenon, which is not physiologic, shall be clearly described in the operator's and service manuals.

d) Electrode polarization. The manufacturer shall describe the need to pay special attention to the type of electrodes used, since some electrodes may be subject to large offset potentials due to polarization. Recovery time after application of defibrillator pulses may be especially compromised. Squeeze bulb electrodes commonly used for diagnostic ECG recording may be particularly vulnerable to this effect.

3.1.2.2 Applications notes

Appropriate information concerning the application of the device shall be provided, including but not limited to:

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a) a description of the device's intended application and available functions;

b) the procedures for checking proper operation of all controls and functions of the device;

c) the manufacturer's recommendations concerning type(s) of electrodes that should be used with the device to ensure conformance of the device with the requirements of this standard, as well as a clear warning that electrodes of dissimilar metals should not be used unless the amplifier can handle polarization potentials as high as 1 volt (V).

3.1.3 Service manual

A service manual, containing adequate care, preventive maintenance, and repair instructions, shall be provided with each unit upon request (or, in the case of multiple orders, as specified in the purchase contract). These instructions shall include items such as electronic circuit schematics, test points, waveforms, logic and/or block diagrams, wiring diagrams, parts lists, and component values. This information shall be complete enough to allow a skilled technician to accomplish reasonable field repair, calibration, and other maintenance needed to ensure conformance of the device with the manufacturer's specifications. In addition, the instructions shall identify acceptable repair facilities 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. A copy of the operator's manual shall be available to service personnel.

NOTE—The operator's and service manuals may be combined if desired.

3.1.4 Summary

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

3.2 Performance requirements

3.2.1 Operating conditions

Unless otherwise stated, the performance requirements of this standard shall be met under the following ambient environmental conditions:

Line voltage:	104 to 127 volts (V) rms
Line frequency:	60 ± 1 Hz
Temperature:	25 ± 10°C
Relative humidity:	50 ± 20 percent, noncondensing
Atmospheric pressure:	7 x 10^4 to 10.6 x 10^4 Pa (700 to1060 mbar)

NOTE—These ranges of operating conditions are not intended to provide assurance of the safety and effectiveness of devices intended for use under extreme or uncontrolled environmental conditions outside of a hospital environment or physician's office. Such devices are excluded from the scope of this standard.

3.2.2 Lead definition

The definitions of lead sets employing the 12 conventional or orthogonal (Frank) leads shall conform to table 3. The voltage difference is defined algebraically in the second column of the table (see 3.2.7.4 for coefficient tolerances). Single-channel ECG devices shall provide lead selection of at least the first seven leads in table 3. Three-channel devices shall provide selection of at least the first 12 leads of table 3.

3.2.3 Input dynamic range

The ECG device shall be capable of responding to and displaying differential voltages of ± 5 millivolts (mV) varying at a rate up to 320 mV per second (s) from a dc offset voltage in the range of -300 mV to +300 mV, when applied to any lead. The time-varying output signal amplitude shall not change by more than ± 5

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percent over the specified range of dc offset.

3.2.4 Gain control, accuracy, and stability

3.2.4.1 Gain settings and accuracy

The device shall provide fixed gain selections of 20 mm/mV, 10 mm/mV, and 5 mm/mV, with a gain accuracy of ± 5 percent.

3.2.4.2 Gain control

Continuously variable gain control may be provided if this mode is clearly indicated on the device control panel and if the recorded output indicates when this option is in use.

3.2.4.3 Gain switching

If automatic gain change or switching is provided, the recorded output shall indicate whenever the gain is changed. Any automatic gain switching shall have a manual override.

3.2.4.4 Gain stability

The gain change 1 minute after energizing the device shall not exceed 0.33 percent per minute. The total change in 1 hour shall not exceed ± 3 percent of any available fixed gain setting.

NOTE—Devices that provide simultaneous permanent records and nonpermanent displays need not provide the same gain for both.

3.2.5 Time base selection and accuracy

3.2.5.1 Time base selection

The device shall provide at least two time bases: 25 mm/s and 50 mm/s.

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Table 2—Summary of labeling/disclosure requirements	
Section	**Requirement desciption**
3.1.1/3.1.1.1	Device markings/product identification and characteristic: manufacturer's identification name type designation; serial number; range of supply voltage and maximum operating current/power; nominal supply frequency; number of phases; current-carrying capacity of convienience receptacle.
3.1.1.2	Panel controls and switches: identification of controls, switches, connectors.
3.1.1.3	Electrical safety: readily visible markings for shock hazard and/or overcurrent ratings.
3.1.1.4	Fuse holders: fuse ratings in amperes and fuse type.
3.1.1.5	Patient electrode connection nomenclature and colors: conformance with table 1, if applicable.
3.1.2/3.1.2.1	Operator's manual: disclosure of cautionary information/performance characteristics
3.1.2.1a	Cautionary information: cautionary information regarding potential hazards/damage, including warnings on use of device in presence of explosive anesthetics and use of device in presence of electromagnetic interference or power overload caused by electrosurgical or diathermy instruments.
3.1.2.1b	Battery-powered devices: minimum operating time; battery charge time; function of battery depletion indicator, if provided.
3.1.2.1c	Accuracy of input signal reproduction: description of methods used by manufacturer to establish overall system error and frequency response; desciption of modulating effects in digital systems.
3.1.2.1d	Electrode polarization: cautionary statement concerning effect of electrode type on system recovery form overload, especially recovery time after defibrillator pulses.
3.1.2.2	Applications notes: desciption of device's intended applications and available functions; procedures for checking controls and functions; manufacturer's recommendations concerning electrodes.
3.1.3	Service manual: adequate care, preventive maintenance, and repair instructions; electrical specifications complete enough to allow reasonable field repair; identification of acceptable repair facilities; recommended frequency of preventive maintenance.

3.2.5.2 Time base accuracy

The time base accuracy shall allow measurements of time with an error of less than ± 5 percent, for time intervals between 0.2 and 2.0 s.

3.2.6 Output display

3.2.6.1 Input signals

The output display shall accommodate the signals specified in 3.2.3.

3.2.6.2 Channel width

The display width per channel shall be no less than 40 mm.

3.2.6.3 Trace width and visibility

The trace shall be visible at writing rates corresponding to 320-mV/s input signal rates, at a gain no lower than 5 mm/mV. The trace width shall not exceed 1 mm.

NOTE—User adjustment may be provided to fulfill this requirement.

3.2.6.4 Rectangular coordinates/alignment of writing points

ECG devices shall provide recordings in rectangular coordinates. Departure from time axis alignment of the writing points of a multichannel electrocardiograph shall be less than 0.5 mm or indicated 10 ms, whichever is greater.

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Table 3—Definition of leads		
Lead nomenclature	**Definition**1)	**Name of lead**
I II	I = LA - RA II = LL - RA	Bipolar limb leads
III	III = LL - LA	(Einthoven)
aVR aVL aVF	aVR = RA - 0.5 (LA + LL) aVL = LA - 0.5 (LL + RA) aVF = LL - 0.5 (LA + RA)	Augmented leads (Goldberger)
V1 V2 V3 V4 V5 V6	V1 = V - 0.333 (LA + RA + LL)2) V2 = V - 0.333 (LA + RA + LL) V3 = V - 0.333 (LA + RA + LL) V4 = V - 0.333 (LA + RA + LL) V5 = V - 0.333 (LA + RA + LL) V6 = V - 0.333 (LA + RA + LL)	Unpolar chest leads (Wilson)
X Y Z	X = 0.610A + 0.171C - 0.781l Y = 0.655F + 0.345M - 1.000H -0.374E - 0.231C	Orthogonal vector leads (Frank)3)

1) The definition is given in terms of algerbraic equations, assuming that the electrode identifier represents the voltage sensed by the elctrode. See table 1 for a list of definitions of patients electrode connection identifiers.

2) For the unipolar chest leads, V represents the potential at each respective chest electrode location: i.e., for voltage V1, V represents the potential at wlwctrode location V1; for voltage V2, V represents the potential at electrode location V2; and so forth.

3) By convention, X is oriented horizontally and towards the left arm of the patient, Y points towards the feet, and Z is horizontal and towards the back of the patient.

3.2.6.5 Time and amplitude rulings

Rulings on preprinted recording media shall be in rectangular coordinates, with the time lines perpendicular to the edge of the recording medium with a maximum error of 0.5 percent of the effective recording width of the recording medium (e.g., 0.2 mm for a 40-mm width). Nominal ruling shall be 1 mm, major ruling 5 mm, with a tolerance of ± 2 percent for the environmental operating conditions specified in 3.2.1.

3.2.6.6 Time and event markers

When provided, markers shall not produce unwanted deflections greater than 0.5 mm in any channel at any gain setting. Time marker generation shall be accurate with an error of no greater than ± 2 percent of the timing interval(s) specified by the manufacturer. Recorders (such as photorecorders) that generate the grid markers shall be capable of time marking at 0.1 and 0.2 s, with a maximum error of ± 2 percent.

3.2.6.7 Reduced performance modes

Any operator adjustment or control which allows degrading of performance for any reason shall, when activated, result in an indication on the recording medium of this reduced performance mode.

3.2.7 Accuracy of input signal reproduction

3.2.7.1 Overall system error

Input signals, limited in amplitude and rate of change to ± 5 mV and 125 mV/s, respectively, shall be reproduced on the output recording medium with a maximum instantaneous deviation from the ideal of ± 5 percent or ± 40 microvolts (µV), whichever is greater.

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Table 4—Frequency response			
Method	Nominal input amplitude (mV p-p)	Input frequency and waveform	Relative output response (mm)
A	1.0	0.67 to 40 Hz, sinusoidal	± 10% 1)
B	0.5	40 to 100 Hz, sinusoidal	+ 10%, - 30%1)
	0.25	100 to 150 Hz, sinusoidal	+ 10%, - 30%1)
C	0.5	150 to 500 Hz, sinusoidal	+ 10%, - 100%1)
D	1.5	≤ 1 Hz, 20 ms, triangular	+ 0, - 10% 2)

1) relative to 10-Hz output
2)relative to 200-ms output

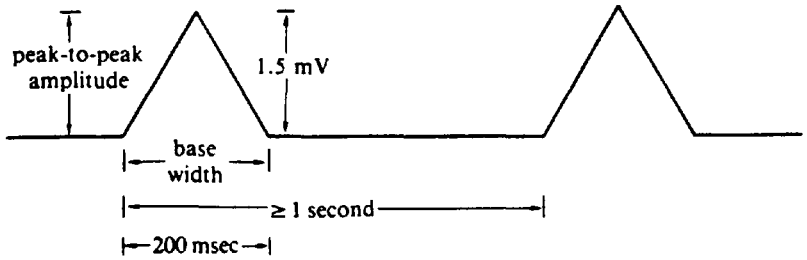

Figure 1—Triangular wave signal (for 3.2.7.2, Method D)

3.2.7.2 Frequency and impulse response

The device shall exhibit a frequency response conforming to the specifications of table 4, at a gain setting of 10 mm/mV.

NOTE—The device must meet the requirements of Methods A and D, or alternately, the requirements of all of Methods A, B, and C of table 4. The manufacturer must disclose which of the two sets of requirements (or both) are met (see 3.1.2.1[3]).

For Methods A, B, and C, the output response is relative to that obtained at 10Hz. For Method D, the output response is relative to that obtained for a repetitive, triangular wave signal with a base width of 200 ms and a repetition rate of 1 Hz or less (figure 1).

Additionally, the device shall respond to an impulse as follows:

a) A 0.3 mV-s (3 mV for 100 ms) impulse input shall not produce a displacement greater than 0.1 mV outside the region of the impulse.

b) For a 0.3 mV-s (3 mV for 100 ms) impulse input, the slope of the response shall not exceed 0.30 mV/s following the end of the impulse.

3.2.7.3 Lead weighting factors

ECG devices employing standard lead sets shall use lead weighting factors as specified in table 3. Weighting factors shall be accurate to within ± 5 percent.

3.2.7.4 Hysteresis

The hysteresis of the permanent recording system shall not exceed 0.5 mm, after a deflection of 15 mm in either direction from baseline. In addition, the device shall exhibit a "response to minimum signal": a 10-Hz, 20-µV peak-to-peak (p-p) sinusoidal signal shall yield a visible recorded deflection at a time base of

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25 mm/s and a gain setting of 10 mm/mV.

3.2.8 Standardizing voltage

A standardizing voltage shall be provided having a value and form that produce a step change in display output whose amplitude is within ± 5 percent of the step amplitude obtainable by applying a 1.00 ± 0.01-mV signal at the appropriate lead. The standardizing voltage provided to test this step response shall exhibit a rise time of less than 1 ms and a decay time constant of at least 100 s. The standardizing signal shall provide an indication of operator adjustment of the gain. The signal shall be applied to all available channels of multichannel recorders. An alternate waveform for the standardizing voltage, consisting of a pulsed triangular waveform with peak amplitude within ± 5 percent of the step amplitude obtained by applying a 1.00 ± 0.01-mV signal at the appropriate lead, is acceptable. The base width of this monophasic triangular waveform shall be 100 ± 5 ms.

3.2.9 Input impedance

An electrode-to-skin impedance, simulated by a 0.62-megohm resistor in parallel with a 4.7-nanofarad (nF) capacitor, in series with any patient-electrode connection, shall not result in a signal reduction of more than 20 percent of that obtained without the simulated impedance, within the bandwidth of the ECG device. This reduction shall not be exceeded with dc offset potentials as specified in 3.2.3. These requirements shall be met at all appropriate settings of the lead selector. (A single-ended input impedance of at least 2.5 megohms at 10 Hz will be needed to meet these requirements.)

3.2.10 Direct currents in patient-electrode connections

The direct current through any patient-electrode connection, with all patient-electrode connections connected to a common node, shall not exceed 0.1 µA for any patient-electrode connection that serves as an amplifier input for measurement of ECG potentials, or 1 µA for any other patient-electrode connection.

3.2.11 Common mode rejection

The ECG device shall have the capability of rejecting 60-Hz common mode interfering voltages as encountered on the surface of the body. With all patient-electrode connections connected to a common node through a 51-kilohm resistor and a 47 nF capacitor including RL, if supplied, a 60-Hz, 20-V rms signal applied to the common node through a 100-pF capacitor shall not produce an output signal exceeding 1 mV p-p referred-to-input (RTI) over a 60-s period. This requirement shall be met with sequential shorting of the series-impedance-simulating lead imbalance in each active lead and with a dc offset potential placed in series with any patient-electrode connection, as specified in 3.2.3. The manufacturer's recommended patient cable shall be used for verification testing.

NOTE—In conducting a test to verify this capability, undesirable stray and leakage capacitances may result from shielding components and from patient cable capacitances when the cable is connected to the voltage source. The test method of 4.2.11 takes these capacitances into consideration.

3.2.12 System noise

3.2.12.1 Cable, circuit, and output display noise

Noise due to the patient cables, all internal circuits, and output displays shall not exceed 30 µV p-p RTI over a 10-s period, when the manufacturer's recommended cable is used and when all inputs are connected together through a 51-kilohm resistor in parallel with a 47-nF capacitor in series with each patient-electrode connection.

3.2.12.2 Channel crosstalk

Input signals limited in amplitude and rate of change as per 3.2.3, applied to any one lead of a multichannel

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electrocardiograph and with all unused inputs connected to patient reference through a 51-kilohm resistor in parallel with a 47-nF capacitor, shall not produce unwanted output greater than 2 percent of the applied signals (multiplied by the gain) in those channels where no signal is applied.

3.2.13 Baseline control and stability

3.2.13.1 Reset

A 1-V p-p, 60-Hz overload voltage shall be applied for at least 1 s to any lead. After removal of this overload voltage, provision shall be available to restore a 1-mV p-p trace to the recording width of the display within 3 s.

3.2.13.2 Baseline stability

One minute after energizing the device and at least 10 s after activation of the reset function with the patient-electrode connections connected through 25-kilohm resistors, the baseline drift rate at output shall not exceed 10 µV/s RTI over any 10-s period. (The baseline is defined as the trace location 10 s after activation of the reset function.) In addition, the total baseline drift shall not exceed 500 µV RTI in any 2-minute period. The device shall incorporate means to return the output trace to within 3 mm of the baseline within 1 s of switching leads.

3.2.14 Overload protection

3.2.14.1 AC voltage

The device shall meet the requirements of this standard after a 10-s application of a 1-V p-p, 60-Hz differential voltage to any patient-electrode connection with any lead selection combination.

3.2.14.2 Defibrillator overload protection

3.2.14.2.1 Recovery

The electrocardiograph shall recover within 8 s after exposure of any patient-electrode connection/lead combination to simulated defibrillator discharges having a damped sinusoidal waveform conforming to the limits specified in the American National Standard, *Cardiac defibrillator devices* (applicable document 2.1.2). The source generator shall have a minimum stored voltage of 5000 V, and the energy delivered to the test assembly shall be 360 J. The waveforms are to be delivered at 20-s intervals into a 100 ohms load, with 400 ohms interposed between the 100 ohm defibrillator load and one connection of the ECG device.

3.2.14.2.2 Reduction in energy delivered to the patient

The electrocardiograph shall incorporate current limiting devices so that the defibrillator energy delivered to the 100 ohm load is reduced by a maximum of 10 percent relative to the energy delivered to this load with the electrocardiograph disconnected. The number of required discharges shall be as specified in table 9.

3.2.14.2.3 Operator safety

In the case of a device that may be operated from battery power, application of defibrillator pulses in the arrangements described above, but with the electrocardiograph disconnected from any ac wall outlet and the power switch turned off, shall not make available more than 100 microcoulombs (µC) of charge to operator-accessible chassis points or controls of the electrocardiograph. In the case of a device that may be operated from battery power, the device shall also meet this requirement while disconnected from any ac wall outlet. After this test, the device shall meet the requirements of 3.2.3 through 3.2.13 and the requirement of 3.2.15.

3.2.14.3 Pacemaker pulse display capability

The device shall have the capability of displaying the ECG signal in the presence of pacemaker pulses with

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amplitudes between 2 and 250 mV, durations between 0.1 and 2.0 ms, a rise time of less than 100 µs, and a frequency of 100 pulses/minute. For pacemaker pulses having durations between 0.5 and 2.0 ms (and amplitude, rise time, and frequency parameters as specified above), an indication of the pacemaker pulse shall be visible on the recording; this indication shall be visible on the display with an amplitude of at least 0.2 mV RTI.

3.2.15 Risk currents

The device shall utilize isolated patient connections. The risk currents flowing to or from the patient through the patient-electrode connections, chassis, or controls of the electrocardiograph shall not exceed the limits specified in the American National Standard, *Safe current limits for electromedical apparatus* (applicable document 2.1.1).

3.2.16 Auxiliary output

3.2.16.1 Where an auxiliary output is provided, the device shall meet all specifications after removal of a short-circuit applied to the auxiliary output for 1 minute.

3.2.16.2 The risk current limits specified in 3.2.15 shall not be exceeded upon proper connection of an auxiliary device to the auxiliary output. Such proper connection shall be described in the operator's manual.

3.2.17 Summary

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Table 5 provides a summary of the performance requirements of this standard.

Table 5—Summary of performance requirements

Section	Requirement description	Min/max	Units	Min/max value
3.2.1	Operating conditions:			
	line voltage	range	V rms	104 to 127
	frequency	range	Hz	60 ± 1
	temperature	range	°C	25 ± 10
	relative humdity	range	%	50 ± 20
	atmosphere pressure	range	Pa	7×10^4 to 10.6×10^4
3.2.2	Lead definition	NA	NA	table 3
	Number of leads:			
	single-channel	min	NA	7
	three-channel	min	NA	12
3.2.3	Input dynamic range:			
	range of linear operations of input signal	min	mV	± 5
	slew rate change	max	mV/s	320
	DC offset voltage range	min	mV	±300
	allowed variation of amplitude with DC offset	max	%	± 5
3.2.4	Gain control, accuracy and stability:			
	gain selections	min	mm/mV	20, 10, 5
	gain error	max	%	5
	manual override of automatic gian control	NA	NA	NA
	gain change rate/minute	max	%/min	± 0.33
	total gain change/hour	max	%	± 3
3.2.5	Time base selection and accuracy:			
	time base selections	min	mm/s	25, 50
	time base error	max	%	± 5
3.2.6	Output display:			
	general	NA	NA	per 3.2.3
	width of display	min	mm	40
	trace visibility (writing rates)	max	mm/s	1600
	trace with (permanent record only)	max	mm	1
	departure from time	max	mm	0.5
	axis alignment	max	ms	10
	preruled paper division	min	div/cm	10
	error of rulings	max	%	± 2
	time marker error	max	%	± 2
3.2.7	Accuracy of input signal reproduction:			
	overall error for signals up to ± 5 mV & 125 mV/s	max	%	± 5
		max	µV	±40
	upper cut-off frequency (3dB)	min	mm	13.5
	response to 20 ms, 1.5 mV triangular input	min	mm	13.5
	response to 0.3 mV·s impulse	max	mV	0.1

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	displacement slope	max	mV/s	0.30
	error in lead			
	weighting factors	max	%	5
	hysteresis after 15-mm			
	deflection from baseline	max	mm	0.5
3.2.8	Standardizing voltage:1)			
	nominal value	NA	mV	1.0
	rise time	max	ms	1
	decay time	min	s	100
	amplitude error	max	%	± 5
3.2.9	Input impedance at			
	10Hz (each lead)	min	megohms	2.5
3.2.10	DC current (any input lead)	max	µA	0.1
	DC current (any other patient			
	electrode)	max	µA	1.0
3.2.11	Common mode rejection:			
	allowable noise with 20 V,			
	60 Hz & ± 300 mV dc &	max	mm	10
	51-kilohm imbalance	max	mV	1
3.2.12	System noise:			
	RTI, p-p	max	µV	30
	multichannel crosstalk	max	%	2
3.2.13	Baseline control and stability:			
	retun time 10 s			
	after reset	max	s	3
	return time after			
	lead switch	max	s	1
	Baseline stability:			
	baseline drift			
	rate RTI	max	µV/s	10
	total baseline drift			
	RTI (2-min period)	max	µV	500
3.2.14	Overload protection:			
	No damage from differential			
	voltage, 60-Hz, 1 - V p-p,			
	10-s application	min	V	1
	No damage from sumulated			
	defibrillator discharges:			
	overvoltage	NA	V	5000
	energy	NA	J	360
	recovery time	max	s	8
	energy reduction by			
	defibrillator shunting	max	%	10
	transfer of charge through			
	defibrillator chassis	max	µC	100
	ECG display in presence			
	of pacemaker pulses:			
	amplitude	range	mV	2 to 250
	pulse duration	range	ms	0.1 to 2.02)
	rise time	max	µs	100
	frequency	max	pulses/min	100
3.2.15	Risk current (isolated			
	patient connection)	as per applicable document 2.1.1		
3.2.16	Auxillary output (if			
	provided):			
	no damage from short circuit			
	risk current (isolated			
	patient connection)	as per applicable document 2.1.1		

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