

American National Standard

ANSI/AAMI EC13:2002/(R)2007

Cardiac monitors,
heart rate meters, and alarms



Association for the Advancement
of Medical Instrumentation



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The Objectives and Uses of AAMI Standards and Recommended Practices

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

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

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

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

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

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

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

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Cardiac monitors, heart rate meters, and alarms

Developed by
Association for the Advancement of Medical Instrumentation

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Abstract: This American National Standard establishes minimum safety and performance requirements for cardiac monitors, heart rate meters, and alarms that are used to acquire and/or display electrocardiographic signals with the primary purpose of continuous detection of cardiac rhythm.

Keywords: diagnostic, ECG, electromedical equipment, heart rate, medical electrical equipment, monitoring, waveform

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Contents

	Page
Committee representation.....	v
Foreword	vi
1 Scope	1
1.1 Inclusions	1
1.2 Exclusions	1
1.3 Differences in monitors	2
2 Normative references	2
3 Definitions	2
4 Requirements	4
4.1 Labeling requirements	4
4.1.1 Device markings	4
4.1.2 Operator manual	6
4.1.3 Service manual	8
4.1.4 Pacemaker pulse rejection capability	9
4.1.5 Summary	10
4.2 Performance requirements	11
4.2.1 Operating conditions	11
4.2.2 Overload protection	12
4.2.3 Leakage current	12
4.2.4 Auxiliary output	12
4.2.5 Respiration, leads-off sensing, and active noise suppression	12
4.2.6 QRS detection	12
4.2.7 Range and accuracy of heart rate meter	13
4.2.8 Alarm system	13
4.2.9 Special requirements for monitors with ECG waveform display capability	14
4.2.10 Electromagnetic compatibility	17
4.2.11 Summary	18
5 Test methods	22
5.1 Compliance with the labeling requirements	23
5.1.1 Device markings	23
5.1.2 Operator manual	23
5.1.3 Service manual	27
5.1.4 Pacemaker pulse rejection capability	27
5.2 Compliance with the performance requirements	30
5.2.1 Operating conditions	30
5.2.2 Overload protection	30
5.2.3 Leakage current	34
5.2.4 Auxiliary output	34
5.2.5 Respiration, leads-off sensing, and active noise suppression	34
5.2.6 QRS detection	34
5.2.7 Range and accuracy of heart rate meter	35
5.2.8 Alarm system	36
5.2.9 Special requirements for monitors with ECG waveform display capability	37
5.2.10 Electromagnetic compatibility	46
Annexes	
A Rationale for the development and provisions of this standard	48
B Cited references and bibliography	68

C	CMR test fixture design and application notes	70
D	Pacer pulse shaper test circuit and notes	77

Tables

1	Patient electrode connection definitions and color code	6
2	Summary of labeling/disclosure requirements	10
3	Frequency response	16
4	Summary of performance requirements.....	18
5	Lead combinations and number of defibrillator discharge tests	32
6	Patient electrode connections for pacemaker pulse display test	38
A.1	Extreme expected values of impedance (1 electrode) for a typical population	61

Figures

1	Triangular wave signal (for method B)	16
2	Test waveforms for T-wave rejection capability.....	24
3	Test waveforms for verifying heart rate accuracy.....	25
4	Test waveforms for ventricular tachycardia (modified from Lindsay and Budkin, 1970)	26
5	Pacemaker pulse test waveforms	28
6	Test signal simulating the QRS complex of the ECG	29
7	Example of time and amplitude measurement.....	29
8	General test circuit	30
9A	Test circuit for defibrillator overload tests (5.2.2.2.1 and 5.2.2.2.2)	33
9B	Test circuit for operator safety test (5.2.2.2.3).....	33
10	Test circuit for evaluating internal noise and common mode	42
11	Pacemaker overload test circuit	43
12	Electrosurgery test setup	44
13A	Electrosurgery overload test circuit	45
13B	Electrosurgery suppression test circuit	46
A.1	Equivalent circuits for defibrillator discharge.....	56
C.1	CMR test: Line-powered supply and buffer	74
C.2	CMR test: Generator-powered buffer	74
C.3	Expanded offset capability, CMR fixture.....	75
D.1	Pacer pulse shaper circuit.....	78

Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph Committee

This standard was developed by the AAMI Cardiac Monitor and Diagnostic ECG Working Group under the auspices of the AAMI Electrocardiograph Committee. Committee approval of the standard does not necessarily imply that all committee and working group members voted for its approval.

At the time this document was published, the **AAMI Electrocardiograph Committee** had the following members:

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

Foreword

This is the third edition of the American National Standard, *Cardiac monitors, heart rate meters, and alarms*. The first edition of the standard, which was approved in August 1984, was based on the second draft of a standard for cardiac monitors, heart rate meters, and alarms that was developed by the UBTL Division of the University of Utah Research Institute, under the sponsorship of the U.S. Food and Drug Administration's then Bureau of Medical Devices. A second edition was approved in 1992.

Compared to the 1992 edition, this third edition emphasizes changes to EMC requirements; adds tests for electrosurgical interference; clarifies the common mode rejection requirements and testing; and improves pacer pulse testing and reporting by providing methods for obtaining ventricular fibrillation examples, new annexes, and new reference standards. Some definitions were changed to adopt terminology common to the IEC documents (e.g., "peak-to-peak" is equivalent to "peak-to-valley"; "over/undershoot" was reduced to simply "overshoot").

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 cardiac monitors. The waveforms specified in this standard to check QRS detection, pacer, and rate meters can only approximate the physiological signals obtained from the surface of the body. Physiological electrical signals from the heart are complex in shape, amplitude, and rhythm, and may vary drastically from beat to beat. Designing a test waveform sequence that totally represents all electrical signals generated by the heart in health and disease is not possible. Therefore, monitors that conform to this standard could, in some situations, display erroneous heart rate information. Included with this third revision is information about access to a public domain database for providing digital representations of the test signals to simplify testing the instrumentation. This information can be obtained by contacting AAMI through its Web site or national office.

This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. In addition, as other standards pertaining to cardiac monitors are promulgated, they must be incorporated by reference to further ensure safety and efficacy with respect to such characteristics as electromagnetic compatibility and device performance under adverse environmental conditions. To this end, this revision attempts to more closely align this standard with those found internationally.

This standard does not include performance requirements for the detection of ventricular fibrillation (VF) by the cardiac monitor. The testing of VF is described in ANSI/AAMI EC57:1998.

This standard reflects the conscientious efforts of concerned physicians, biomedical and clinical engineers, nurses, 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 to conform to the standard. "Should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others; that a certain course of action is preferred but not necessarily required; or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the recommended practice. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulations.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201.

NOTE—This foreword is not part of the American National Standard, *Cardiac monitors, heart rate meters, and alarms*, ANSI/AAMI EC13:2002.

Cardiac monitors, heart rate meters, and alarms

1 Scope

This standard establishes minimum safety and performance requirements for electrocardiograph (ECG) heart rate and waveform monitors that are intended for use under the operating conditions specified in this standard. Subject to this standard are all parts of such monitors necessary to:

- a) obtain a heart rate indication via noninvasive ECG sensing from the patient's body;
- b) amplify and transmit this signal and display the heart rate and/or ECG waveform; and
- c) provide alarms, based on adjustable alarm criteria, upon the sustained occurrence of the following rate-dependent phenomena: cardiac standstill, bradycardia, and/or tachycardia.

NOTE—The safety and performance criteria defined in this standard are intended principally for use in design qualification or “type” evaluation by the manufacturer. (Type evaluation is the full battery of tests that must be done on a typical instrument or group of typical instruments to verify that all performance design requirements have been met. It is used to officially establish that a product model's design has achieved compliance with all standards to which a manufacturer claims compliance.)

1.1 Inclusions

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

- a) portable and battery-powered ECG monitors intended for use within the range of environmental conditions defined in 4.2.1;
- b) operating room and intensive care heart rate monitors based on the ECG;
- c) intensive care and intermediate care ECG monitors using telemetry;
- d) subsystems of more complex devices (such as arrhythmia monitors and defibrillator monitors) that provide the basic information described in the scope of this standard; and
- e) neonatal/pediatric monitors.

1.2 Exclusions

Not included within the scope of this standard are:

- a) devices for fetal heart rate monitoring;
- b) devices for pressure monitoring;
- c) pulse plethysmographic devices;
- d) devices that use invasive catheters or sensors to obtain an indication of heart electrical activity;
- e) instruments or systems for emergency telemetry from ambulances or for out-of-hospital ambulatory monitoring;
- f) devices for ambulatory monitoring that store ECG data for review at a later time, including scanning and readout devices;
- g) telephone transmission devices;
- h) devices intended for use under extreme or uncontrolled environmental conditions outside of a hospital or physician's office;
- i) diagnostic electrocardiographic devices (these devices are covered by the American National Standard, *Diagnostic electrocardiographic devices* [see reference document 2.2]); and

- j) equipment where the monitor-like functions and capabilities are required for trigger acquisition of other instrumentation not intended to be the primary cardiac monitor used for patient management (e.g., intra-aortic balloon pumps, ventricular assist devices).

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

1.3 Differences in monitors

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

2 Normative references

The following standards contain provisions that, 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 investigate the possibility of applying the most recent editions of the standards indicated below. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid AAMI/American National Standards.

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

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Diagnostic electrocardiographic devices*. ANSI/AAMI EC11:1991/(R)2001. Arlington (VA): AAMI, 2001. American National Standard.

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

2.4 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *ECG cables and leadwires*. ANSI/AAMI EC53:1995/(R)2001. Arlington (VA): AAMI, 2001. American National Standard.

2.5 EUROPEAN NORM. *Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment—Radio Disturbance Characteristics—Limits and Methods of Measurement*. EN55011 (European Norm version of CISPR 11).

2.6 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Part 1: General requirements for safety*. 2. *Collateral standard: Electromagnetic compatibility—Requirements and tests*. IEC 60601-1-2:2001.

2.7 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Particular requirements for the safety of electrocardiographic monitoring equipment*. IEC 60601-2-27:1994.

2.8 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Particular requirements for safety. Specifications for electrocardiographs*. IEC 60601-2-25:1993.

2.9 UNDERWRITERS LABORATORIES. *Medical electrical equipment, Part 1: General requirements for safety*. UL 2601.1:2000.

3 Definitions

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

3.1 arrhythmia monitor: Device that distinguishes, analyzes, and displays heart rhythm information in addition to heart rate. A subsystem of an arrhythmia monitor, which essentially performs the functions of a cardiac monitor, providing continuous display of heart rate and alarming when the patient's heart rate exceeds preset limits, is subject to the minimum requirements of this standard.

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

3.3 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.

3.4 band-limited response: Signal or amplifier response limited to a range (band) of frequencies.

3.5 buffer amplifier: Amplifier that has an output voltage equal to its input voltage to a very high degree of accuracy. Its characteristics usually include a high input impedance to minimize noise and errors due to skin-electrode impedance; its output impedance is usually very low.

3.6 central terminal according to Wilson (CT): Terminal at the average potential of the R (RA—right arm), L (LA—left arm), and F (LL—left leg) potentials.

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

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

3.10 defibrillator-monitor: Instrument that combines the functions of a defibrillator and a monitor. The monitor portion of such an instrument is subject to the provisions of this standard.

3.11 diagnostic electrocardiographic (ECG) device: ECG recording and/or display device intended for obtaining a set of conventional or orthogonal ECG signatures that accurately represents the detailed waveforms in each cardiac cycle and the beat-to-beat variability for determining cardiac rhythm. Such devices typically have wider bandwidths and lower reproduction errors than cardiac monitors.

3.12 direct writer: Device that produces a visible, permanent record of the ECG.

3.13 ESIS: Electrosurgical interference suppression. The ability to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used. Without such suppression, the high RF output of an electrosurgical device renders ECG monitoring impossible.

3.14 Frank leads: Vectorcardiographic orthogonal X, Y, and Z signals obtained by summing seven electrode voltages in a manner first proposed by Frank (1956). (See annex B, cited references, and bibliography.)

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, weighing 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 inputs of an amplifier.

3.18 isolated patient connection: Input circuit exhibiting leakage and sink current characteristics that comply with the risk current limits specified for isolated patient connections in the American National Standard, *Safe current limits for electromedical apparatus*.

3.19 lead: For many years, this term has been used in two different senses: (1) a system of conducting wires used to detect body surface potentials; and (2) a single conducting wire which, when attached to the patient by an electrode, is sometimes called a *patient lead*.

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 lead selector: Switch used to select certain leads.

3.22 leakage current: Undesired current, including both resistive and reactive currents, that flows through or across the insulators that separate electrical conductors at different potentials.

3.23 line isolation monitor: Device used in conjunction with a power system isolation transformer, a device that periodically checks that the output of the isolation transformer is still isolated with respect to earth ground. Such a monitor momentarily and periodically attempts to pulse the common mode of the isolation transformer's secondary above ground and back again through a large impedance. Success in moving the common mode voltage sufficiently verifies that the transformer output is still isolated from ground.

3.24 monitor: Device used to acquire and/or display ECG signals with the primary purpose of continuous detection of cardiac rhythm. Although the device may display individual waveforms, morphological accuracy may be compromised in comparison to a diagnostic ECG device.

3.25 multi-channel electrocardiograph: Diagnostic ECG device capable of simultaneous recording from several ECG leads.

3.26 neonatal monitor: Monitor specifically designed to be used with newborn infants up to six weeks of age.

3.27 nonpermanent display: Display that is not permanent, such as the display on an oscilloscope.

3.28 overshoot: Amount of over-travel (plus or minus) of the ECG output trace beyond its final steady deflection when a step voltage is applied at the input leads.

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

3.30 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 to eliminate from the measurement the thickness of the display trace or printed trace.

3.31 pediatric monitor: Monitor specifically designed to deal with ECG signals from newborn infants and children up to eight years of age. Various ECG amplitudes and time durations have ranges that are different for newborns and infants, as compared to adults; these differences gradually disappear with age.

3.32 permanent display: Display of waveforms and/or characters on a medium such as paper that can be retained and filed for indefinite time periods and directly read or interpreted.

3.33 reference electrode: Reference point for differential amplifiers and/or the connection for an ac suppressor-amplifier. The reference electrode, which is not involved in ECG lead combinations, is usually the electrode attached to the RL.

3.34 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.

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

3.36 risk current: Non-therapeutic current that may flow through the patient, medical staff, or a bystander as a result of the use of an electromedical apparatus.

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

3.38 sink current: Current that flows into a device or any part thereof when an external voltage is applied to it.

3.39 source current: Undesirable electrical current that flows from any part of an electromedical apparatus to any other part or to ground when no external voltages are applied.

3.40 sustained: For purposes of this standard and as applied to arrhythmias, a time period of at least 60 seconds.

3.41 time base: Units of the horizontal axis of the display, usually expressed as mm/s. The time base may differ from actual paper speed for devices that do not display the ECG signal in real time.

4 Requirements

4.1 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.

4.1.1 Device markings

4.1.1.1 Identification of product characteristics

Cardiac monitors shall be clearly and permanently marked with the following information:

- a) the manufacturer's name and address (reference UL2601.1, Section 6.1);
- b) the catalogue, style, model, or other type designation;
- c) the serial number;
- d) power requirements (reference UL2601.1, Section 6.1);
- e) the nominal supply (mains) frequency (reference UL2601.1, Section 6.1);
- f) the number of phases, unless the device is intended for single phase use only (reference UL2601.1, Section 6.1);

- g) the current-carrying capacity of each convenience receptacle and/or identification of the instrument(s) that can be connected to it if the device provides mains power for other devices (reference UL2601.1, Section 6.1); and
- h) if equipped, battery type and disposal method as disclosed by the manufacturer.

4.1.1.2 Panel controls and switches

All controls, switches, and connectors shall be clearly and concisely labeled to identify their function. Identification of the modality in use must be indicated if a change is provided between monitor and diagnostic equipment.

4.1.1.3 Electrical safety

The monitor may have markings that warn maintenance personnel of potential shock hazards from accidental contact with parts. Other markings may be used to identify current ratings that may overload branch circuits. Any such markings shall be placed in locations suitable for the intended use and shall be clearly visible. (See UL 2601.1, Section 6.2.)

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. (See UL 2601.1, Section 6.1.)

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 or molded) also shall be used for individual patient electrode connection identification. Table 1 provides, for both diagnostic 12-lead electrocardiography and Frank vector leads, the standard color code for patient lead conductors and the standard electrode placement. Although electrode locations for monitoring are not now standardized, it is recommended that lead identifiers and color codes for monitor leads conform as closely as possible with those for diagnostic electrocardiographs.

Table 1—Patient electrode connection definitions and color code

System	Patient electrode connection identifier	Color code	Position on body surface
Conventional ¹⁾	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 horizontal level of V4
	RL	Green	Right leg
Frank vector	I	Orange/red	At the right midaxillary line ²⁾
	E	Orange/yellow	At the front midline ²⁾
	C	Orange/green	Between front midline and left midaxillary line at a 45 degree angle
	A	Orange/brown	At the left midaxillary line ²⁾
	M	Orange/black	At the back midline ¹⁾
	H	Orange/violet	On the back of the neck or on the forehead
	F	Red	On the left leg

¹⁾ Requirements for IEC compliance are specified in IEC 60601-2-47, clause 6.1 aa, Table 101.

²⁾ Located at the transverse level of the ventricles (i.e., fifth interspace at the left sternal border).

NOTE—Refer to EC11 for details on conventional lead and Frank vector lead system. (Conventional is AHA in the United States.)

4.1.1.6 Warnings and precautions

Labeling should include cautions and warnings to indicate any harm to the patients or operators that is likely to be caused by their exposure to the monitor. Such a labeling requirement generally is limited to known harmful exposures. Device markings and operator's manuals should have these cautions and warnings clearly identified and easily understood.

4.1.2 Operator manual

An operator manual, which contains adequate instructions for the proper installation and the safe and effective operation of the device and identifies acceptable repair facilities, shall be provided with each unit (or, in the case of multiple orders, as specified in the purchase contract). The following minimum information shall be supplied.

4.1.2.1 Disclosure of performance specifications

- a) **Electrosurgery protection.** Cautionary information must be provided if electromagnetic interference or power overload caused by electrosurgical instruments will damage or otherwise affect the operation of the monitoring device. Monitors that claim protection from damage due to electrosurgery interference must, when used with high-frequency electrosurgical equipment, return to their previous operating mode within 10 seconds after removal of exposure to the high-frequency signals and field, without loss of any permanently stored data.

The means of coupling to the monitor and the fraction of electrosurgical machine output for this requirement are defined respectively by Figures 12 and 13A. The high-frequency electrosurgical equipment used shall have a minimum power cut mode capability of 300 W, a minimum power coag mode of 100 W, and a working frequency of 450 kHz (± 100 kHz).

- b) **Respiration, leads-off sensing, and active noise suppression.** For cardiac monitors designed to intentionally apply a current to the patient for respiration sensing, leads-off sensing, or active noise suppression, the manufacturer shall disclose the waveforms (in the form of voltage, current, frequency, or other appropriate electrical parameters) that are applied to the patient. (See also 4.2.5.)
- c) **Tall T-wave rejection capability.** Disclosure shall be made of the maximum T-wave amplitude (aT) for which heart rate indication is within the error limits specified in 4.2.7. A QRS test signal of 1 millivolt (mV) amplitude and 100 millisecond (ms) duration (d), with a heart rate of 80 beats per minute (bpm), shall be used; the T-wave duration (dT) shall be 180 ms, and the QT interval (dQT) shall be 350 ms. QRS amplitude is defined as [ar + as] in Figures 2 and 6. A 20 second (s) monitor stabilization period shall be allowed before testing. If the maximum T-wave amplitude that can be rejected is affected by the bandwidth chosen, disclose separately the maximum T-wave amplitude rejected for each bandwidth.
- d) **Heart rate averaging.** The type of averaging done to compute the minute heart rate and, if applicable, the updating rate of the display shall be disclosed.
- e) **Heart rate meter accuracy and response to irregular rhythm.** Disclosure shall be made of the indicated heart rate, after a 20 second monitor stabilization period, for the four types of alternating ECG complexes described in Figure 3.
- f) **Response time of heart rate meter to change in heart rate.** Disclosure shall be made of the maximum time, to the nearest second and including the update time of the device, required for the heart rate meter to indicate a new heart rate for a step increase from 80 bpm to 120 bpm and a step decrease from 80 bpm to 40 bpm. The response time is measured from the time of the first QRS complex of the new rate to the time the heart rate meter first reads 37 percent of the heart rate indication at 80 bpm plus (a) for the step increase, 63 percent of the steady state indication at 120 bpm or greater, and (b) for the step decrease, 63 percent of the steady state indication at 40 bpm or less.
- g) **Time to alarm for tachycardia.** Disclosure shall be made of the time to alarm for the two ventricular tachycardia waveforms shown in Figure 4, following a normal 80 bpm rate with the upper alarm limit set closest to 100 bpm and the lower alarm limit set closest to 60 bpm. Disclosure also shall be made of cardiac monitor failure to alarm on either of these waveforms. In addition, the time to alarm shall be disclosed for these waveforms when their amplitudes are one-half and twice the indicated amplitudes.
- h) **Pacemaker pulse rejection warning label.** The following or a substantially similar warning shall be prominently displayed near the front of the operator manual: "WARNING—PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument."
- i) **Audible alarm disclosure.** If the cardiac monitor has an audible alarm, the manufacturer shall disclose the alarm's location (i.e., central station, bedside, or both) and the frequency or other descriptive characteristics of the sounds.
- j) **Visual alarm disclosure.** If the cardiac monitor has a visual alarm, the manufacturer shall disclose its location, color, size, and modulation (flashing).
- k) **Battery-powered monitors.** For monitors equipped with batteries, the manufacturer shall disclose the minimum operating time of the monitor and of any connected accessories, provided that the batteries are new and fully charged. If rechargeable batteries are provided, the manufacturer shall disclose the battery charge time from depletion to 90 percent charge. In addition, a battery depletion indicator shall be provided and its function described. The battery charging cycle or charging procedure also shall be clearly stated. Any performance reduction as described in this standard due to the battery charge state shall be disclosed.
- l) **Telemetry.** Emergency telemetry from ambulances or for out-of-hospital monitoring is not covered by this standard (see 1.2[e]). The following requirements apply only to in-hospital patient monitoring using telemetry.
 - 1) *Electromagnetic compatibility.* Disclosure shall be made of the radio frequency (RF) transmitter carrier frequency and modulation, as well as the current level and frequency of any RF signal intentionally applied to the patient.

- 2) *Special electrodes, cables, or skin preparation requirements.* Disclosure shall be made of any special electrode connection cables or skin preparation recommended by the manufacturer to reduce the possibility of motion artifact during patient monitoring.
 - 3) *Leads-off, out-of-range, and battery depletion.* Disclosure shall be made of any indication the user will have of the following faults: detached leads, patient out-of-range, transmitter failure, and transmitter battery depletion. The expected battery life and recharging time (if applicable) for new transmitter batteries also shall be disclosed. If device conformance with the performance requirements of this standard is contingent upon battery voltage, then a battery depletion indicator shall be provided and its function described.
- m) **Line isolation monitor transients.** Cautionary information shall be provided, warning that line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. Methods for minimizing this problem, including instructions for proper electrode placement and cable arrangement, also shall be provided.
 - n) **Special disclosure requirements for monitors with nonpermanent ECG waveform display.** The available time bases and full adjustment range of the aspect ratio shall be disclosed.
 - o) **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 (reference IEC 60601-2-27, Section 6.8.2).
 - p) **Auxiliary output.** Disclosure shall be made regarding proper connection of other devices to the auxiliary output, if provided, with particular attention to maintaining risk current limits. In addition, the manufacturer shall disclose all auxiliary outputs' bandwidth, gain, and propagation delay. Manufacturers also shall disclose how internal pacemaker pulses are represented in the auxiliary output (their inclusion or absence, and whether enhanced pace pulses are summed with the ECG signal).
 - q) **Alarm silencing.** Disclosure shall be made of the time required for reactivating the alarm after it has been silenced. If this time is adjustable, the range of time intervals also shall be disclosed.
 - r) **Battery disposal.** If equipped with a battery, adequate disposal instructions shall be provided.

4.1.2.2 Application notes

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

- a) a description of the device's intended application and available functions;
- b) the procedures for checking proper functioning of all controls and indicators;
- c) the following information concerning electrodes and cables used to sense the ECG:
 - the number of electrodes required (reference IEC 60601-2-27, Section 6.8.2);
 - an indication, at the electrode end, of polarity if other than a standard cable is used;
 - a description of any special cable characteristics (or a specification of the part number of the cable(s) permissible for use) if needed for the system to conform to this standard (reference IEC 60601-2-27, Section 6.8.2); and
 - a clear warning that electrodes of dissimilar metals should not be used unless the cardiac monitor can handle polarization potentials as high as 1 volt (V);
- d) disclosure of the settings necessary for pediatric and/or neonatal use (if applicable).

4.1.3 Service manual

A service manual containing adequate care, preventive maintenance, and repair instructions consistent with the manufacturer's requirements 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, logic and/or block diagrams, wiring diagrams, and manufacturer's part numbers, consistent with field repairable units as determined by the manufacturer. This information shall be complete enough to allow a skilled technician to accomplish reasonable field repair, calibration, or other maintenance as specified by the manufacturer. If units cannot be repaired in the field, it shall be clearly disclosed. In addition, the instructions shall identify authorized

service representatives and acceptable repair facilities, disclose any test equipment requirements, and include recommendations concerning test methods that can be used for verification of device performance. Preventive maintenance will be specified by item, the frequency with which preventive maintenance procedures should be implemented, and verification pass/fail criteria (reference UL 2601.1, Section 6.8.2). Optional training should be offered by the manufacturer or authorized service agents (see also 4.1.4).

NOTE—The operator and service manuals may be combined.

4.1.4 Pacemaker pulse rejection capability

The following information shall be disclosed in the service manual and in the operator manual.

4.1.4.1 Pacemaker pulse rejection without overshoot

Disclosure shall be made of the heart rate indicated by the monitor for pacemaker pulses having amplitudes (a_p) from ± 2 mV to ± 700 mV and pulse widths (d_p) from 0.1 ms to 2 ms. If the monitor cannot effectively reject pulses in this range, disclosure shall be made of the range of pulse amplitudes and widths that the monitor can reject. The monitor's pacemaker pulse rejection capability shall be disclosed for: (a) pacemaker pulses alone of the form shown in Figure 5a; (b) pacemaker pulses with a normally paced QRS-T (Figure 5b); and (c) pacemaker pulses with an ineffectively paced QRS pattern (Figure 5c). In all cases, the overshoot (a_o) shall be less than 5 percent of pacer amplitude ($0.05 a_p$ in Figure 5a) and the settling time of the overshoot must be less than 5 microseconds (μ s). The rise and fall times shall be 10 percent of the pulse width, but not greater than 100 μ s, and the onset of the pacemaker pulse shall occur 40 ms or less before the onset of the QRS complex.

Disclosure of rejection capability also shall be made for (a), (b), and (c) above when a (atrial) pacing pulse with identical amplitude and duration precedes this (ventricular) pacing pulse by 150 ms to 250 ms.

NOTE—The above pulse parameters are intended to encompass the characteristics of both unipolar and bipolar pacemakers. Bipolar pacing pulses are, however, generally of lower amplitude than unipolar pulses, and typically do not exhibit a significant overshoot.

4.1.4.2 Pacemaker pulse rejection with overshoot

Disclosure shall be made of the heart rate indicated by the monitor for pacemaker pulses having amplitudes (a_p) from ± 2 mV to ± 700 mV and pulse widths (d_p) from 0.1 ms to 2 ms. If the monitor cannot effectively reject pulses in this range, disclosure shall be made of the range of pulse amplitudes and widths that the monitor can reject. The monitor's pacemaker pulse rejection capability shall be disclosed for the same pulse characteristics as specified in 4.1.4.1. In all cases, overshoot (a_o) shall have recharge time constants (t_o) between 4 ms and 100 ms; the rise and fall times shall be 10 percent of the pulse width, but not greater than 100 μ s, and the onset of the pacemaker pulse shall occur 40 ms or less before the onset of the QRS complex.

The amplitude of the overshoot (a_o) shall be defined by method A or method B below, and it must be disclosed whether the monitor is specified for method A, method B, or for both.

Method A: a_o shall be within the range $0.025 a_p$ to $0.25 a_p$, independent of time constant choice, but not greater than 2 mV.

Method B: a_o shall be equal to $a_p d_p / t_o$.

NOTE—For method B, it is permissible to have the main pulse not be flat on top, but sag by an amount equal to the overshoot's amplitude, as capacitive coupling would cause. Also, for method B with A-V sequential pacer pulses, the overshoot of the ventricular pulse must include any residual left over from unsettled overshoot of the atrial pulse.

4.1.4.3 Pacer pulse detector rejection of fast ECG signals

Disclosure shall be made in V/s RTI of the minimum input slew rate that will cause approximately 50 percent of Figure 5d's pulses to trigger the device's pacer pulse detector. If the monitor behaves differently in different modes of operation, this also must be disclosed.

4.1.4.4 Pacemaker pulse appearance in auxiliary output

Disclosure shall be made of what conditioning, if any, is done by the monitor on pacemaker pulses that are included in the monitor's auxiliary output. Indicate if only bandpass filtering is done, or if pacemaker pulses are removed and replaced by fixed digital pulses. Indicate the bandwidth of filtering and shape of the substituted pulses as appropriate.

4.1.4.5 Pacer pulse detector disabling

If the operator can disable the pacemaker pulse detector (or cause it to be ignored), disclosure must be made of that mode selection. If certain signal conditions are known to disable the pacemaker pulse detector, those conditions also shall be disclosed.

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	<i>Device markings/identification of product characteristics:</i> Manufacturer's name and address, 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, modality identification, battery disposal information.
4.1.1.2	<i>Panel controls and switches:</i> Identification of controls, modality identification, switches, connectors.
4.1.1.3	<i>Electrical safety:</i> Readily visible markings for shock hazard and/or overcurrent ratings.
4.1.1.4	<i>Fuse holders:</i> Fuse ratings in amperes, voltage, and fuse type.
4.1.1.5	<i>Patient electrode connection nomenclature and colors:</i> Conformance with Table 1, if applicable.
4.1.1.6	<i>Warnings and precautions:</i> Cautionary information regarding harm to patient and operator due to exposure to monitor.
4.1.2/4.1.2.1	<i>Operator manual/disclosure of performance specifications.</i>
4.1.2.1 (a)	<i>Electrosurgery protection:</i> Cautionary information if electrosurgical unit overload will damage device.
4.1.2.1 (b)	<i>Respiration, leads-off sensing, and active noise suppression:</i> If applicable, disclosure of waveforms applied intentionally to patient.
4.1.2.1 (c)	<i>Tall T-wave rejection capability:</i> Maximum T-wave amplitude for which heart rate indication is within specified error limits. If performance is affected by low-frequency response, disclose for all choices.
4.1.2.1 (d)	<i>Heart rate averaging:</i> Type of averaging used for computation of minute heart rate.
4.1.2.1 (e)	<i>Heart rate meter accuracy and response to irregular rhythm:</i> Indicated heart rate for waveforms of Figure 3.
4.1.2.1 (f)	<i>Response time of heart rate meter to change in heart rate:</i> Time in seconds for meter to indicate 40 bpm increase and 40 bpm decrease from 80 bpm.
4.1.2.1 (g)	<i>Time to alarm for tachycardia:</i> Time to alarm (or failure to alarm, if applicable) for waveforms of Figure 4.
4.1.2.1 (h)	<i>Pacemaker pulse rejection warning label:</i> Warning of the need for close surveillance of pacemaker patients, since rate meters may count pacemaker rate during cardiac arrest or some arrhythmias.
4.1.2.1 (i)	<i>Audible alarm disclosure:</i> Location of source and frequency of sound.
4.1.2.1 (j)	<i>Visual alarm disclosure:</i> Location, color, size, and modulation.
4.1.2.1 (k)	<i>Battery-powered monitors:</i> Minimum operating time, battery charge time, provision of battery depletion indicator, description of function.
4.1.2.1 (l)	<i>Telemetry:</i> EMC information, special electrode requirements, fault indication (detached leads, patient out-of-range, transmitter battery failure) if applicable, battery life and recharging time.
4.1.2.1 (m)	<i>Line isolation monitor transients:</i> Cautionary information and methods of minimizing interference.
4.1.2.1 (n)	<i>Special disclosure requirements for monitors with nonpermanent ECG waveform display:</i> Available time bases; range of adjustment of aspect ratio.

Section	Requirement description
4.1.2.1 (o)	<i>Electrode polarization</i> : Cautionary statement concerning effect of electrode type on system recovery from overload, especially recovery time after defibrillator pulses.
4.1.2.1 (p)	<i>Auxiliary output</i> : Explanation of proper connection of other devices to auxiliary output, if provided, with special reference to maintenance of risk current characteristics, including bandwidth, gain, propagation delay, and dealing with pacer pulses.
4.1.2.1 (q)	<i>Alarm silencing</i> : Disclosure of time required for reactivation of alarm after alarm silencing and, if alarm reactivation time is adjustable, disclosure of the range of time intervals.
4.1.2.1 (r)	<i>Battery disposal</i> : Adequate instructions for disposal of batteries.
4.1.2.2	<i>Application notes</i> : Description of device's intended application and available functions; procedures for checking controls and functions; information concerning electrodes—number of electrodes needed, polarity of cables (if other than standard AAMI cable); any special cable characteristics needed to ensure conformance with standard; warning about use of electrodes of dissimilar metals; settings necessary for pediatric/neonatal monitoring.
4.1.3	<i>Service manual</i> : Adequate care, preventive maintenance, and repair instructions; electrical specifications complete enough to allow reasonable field repair and that identify acceptable repair facilities; recommended frequency of prevention maintenance.
4.1.4/4.1.4.1	<i>Pacemaker pulse rejection capability/Pacemaker pulse rejection, without overshoot</i> : Disclosure in operator and service manual of pacemaker pulse rejection capability for pacing pulses without overshoot ± 2 mV to ± 700 mV amplitude, 0.1 ms to 2.0 ms duration, overshoot less than .05 a_p (Figure 5a), and settling time less than 5 μ s; pulse onset, rise, and fall time not greater than 100 μ s; pulse onset 40 ms or less before QRS onset; and with an identical pulse preceding this pulse by 150 ms to 250 ms.
4.1.4.2	<i>Pacemaker pulse rejection with overshoot</i> : Disclosure in operator and service manual of pacemaker pulse rejection capability for pacing pulses with same parameters as above except overshoot (recharge) time constants between 4 ms and 100 ms, overshoot defined by choice of two methods. Disclose whether test method A or B or both are used.
4.1.4.3	<i>Pacer pulse detector rejection of fast ECG signals</i> : Disclosure must be made in the operator and service manuals of the minimum typical slew rate in V/s RTI that will trip its pacer detector. See also Figure 5d.
4.1.4.4	<i>Pacemaker pulse appearance in auxiliary output</i> : Disclosure of filtering and any substitution done on pacemaker pulses as they appear in auxiliary output.
4.1.4.5	<i>Pacer pulse detector disabling</i> : Disclosure of operating modes or signal conditions that cause the pacer pulse detector to be disabled or ignored.

4.2 Performance requirements

NOTE—4.2.1 through 4.2.8, and 4.2.10 apply to all monitors, with or without ECG waveform display capability. 4.2.9 applies only to those devices that provide ECG waveform display. Unless otherwise stated, specifications in this section apply to the monitor performance regardless of the mode in which it is set. Any periods of inoperability due to overload or saturation conditions shall be indicated.

4.2.1 Operating conditions

Unless otherwise stated, the performance requirements of this standard shall be met under the following ambient environmental conditions (see UL 2601.1, Section 10.2.1):

Line voltage: 104 Vrms to 127 Vrms (root-mean-square)

Line frequency: 60 ± 1 Hz or 50 ± 1 Hz

NOTE—These ranges of operating conditions do not ensure 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.

4.2.2 Overload protection

4.2.2.1 AC voltage

The device shall meet the requirements of this standard after a 10 second application of a 1 V p-v line frequency differential voltage to any patient electrode connection with any lead selection combination.

4.2.2.2 Defibrillator overload protection

NOTE—Meeting this requirement also dictates using an ECG cable that passes EC53, Section 4.5.3 (applicable document 2.4).

4.2.2.2.1 Recovery

The monitor shall recover within 5 seconds after exposure of any patient electrode connection/lead combination to simulated defibrillator discharges which have a damped sinusoidal waveform conforming to the limits specified in the American National Standard, *Cardiac defibrillator devices* (applicable document 2.3). The source generator shall have a minimum stored voltage of 5000 V and the energy delivered to the test assembly minimally shall be 360 J. The waveforms are to be delivered at 20 s intervals into a 100 ohm load, with 400 ohms interposed between the 100 ohm defibrillator load and one connection of the ECG device. The monitor's leads-off sensing must still function after these tests.

4.2.2.2.2 Reduction in energy delivered to the patient

The monitor 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 monitor disconnected. The number of required discharges is specified in Table 5.

4.2.2.2.3 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 monitor disconnected from any ac wall outlet and the power switch turned off and on, shall not make available more than 100 microcoulombs (μC) of charge to operator-accessible chassis points or controls of the monitor. In the case of a device that may be operated from battery power or from the line, the device also shall meet this requirement while disconnected from any ac wall outlet. For a device that may be operated from ac line or battery power, this requirement shall be met with the power line cord disconnected from any power source. After this test, the device shall meet the requirements of 4.2.3 through 4.2.10.

The above paragraph notwithstanding, whether a monitor is powered by ac mains or by battery, if the ECG cable supplied by the monitor's manufacturer contains any exposed metal on the plug that mates with the monitor, that exposed metal shall be connected to the charge-measuring circuit during this test. This also applies to a metal shroud on that connector, since such a shroud is somewhat exposed if not fully inserted.

4.2.3 Leakage current

The monitor shall utilize isolated patient connections. The risk currents flowing to or from the patient through the patient electrode connections, chassis, or monitor controls shall not exceed the limits specified in ES1 (reference document 2.1).

4.2.4 Auxiliary output

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

4.2.4.2 The risk current limits specified in 4.2.3 shall not be exceeded upon proper connection of an auxiliary device to the auxiliary output. This proper connection shall be described in the operator manual.

4.2.5 Respiration, leads-off sensing, and active noise suppression

Currents intentionally applied to the patient for purposes of respiration sensing, leads-off sensing, or active noise suppression shall not exceed the maximum risk currents specified in 4.2.3. The direct current through any patient electrode connection, with all remaining patient electrode connections attached to a common node, shall not exceed 0.1 μA for any active patient electrode connection (i.e., any connection that serves as an input to an amplifier for measurement of ECG potentials). This current shall not exceed 1 μA for any other patient electrode connection.

4.2.6 QRS detection

Cardiac monitors shall have the ability to detect heart rate for the ranges of ECG signals and noise specified below.

4.2.6.1 Range of QRS wave amplitude and duration

For a continuous train of simulated ECG pulses (Figure 6), the device shall meet the heart rate range and accuracy requirements of 4.2.7. The minimum range of QRS amplitude ($a_r + a_s$) is 0.5 mV to 5 mV, and the duration of the QRS wave is between 70 ms and 120 ms (40 ms and 120 ms for neonatal/pediatric monitors). For monitors set for adult patients, the heart rate meter shall not respond to signals having a QRS amplitude of 0.15 mV or less, or a duration of 10 ms or less with an amplitude of 1 mV. Response to either or both of these types of signals is permitted in monitors set for neonatal/pediatric patients.

4.2.6.2 Line frequency voltage tolerance

The maximum line frequency peak-to-valley sinusoidal voltage amplitude that can be superimposed on a train of QRS signals without exceeding the error limits specified in 4.2.7 for indicated heart rate accuracy shall be no less than 100 μ V p-v. The QRS signal shall have an amplitude of 0.5 mV, a duration of 100 ms, and a repetition rate of 80 bpm. If equipment is fitted with a line frequency filter, the filter may be turned on during this test.

4.2.6.3 Drift tolerance

The cardiac monitor shall indicate the heart rate within the error limits of 4.2.7 when a 0.1 Hz triangular wave of 4 mV p-v amplitude is superimposed on a train of QRS signals of 0.5 mV amplitude, 100 ms duration, and 80 bpm repetition rate.

4.2.7 Range and accuracy of heart rate meter

The minimum allowable heart rate meter range shall be 30 bpm to 200 bpm, with an allowable readout error of no greater than ± 10 percent of the input rate or ± 5 bpm, whichever is greater. Cardiac monitors labeled for use with neonatal/pediatric patients shall have an extended heart rate range of at least 250 bpm. In addition, input ECG signals at rates less than the disclosed lower limit of the rate meter range shall not cause the meter to indicate a rate greater than this lower limit. Input signals at rates above the disclosed upper limit of the rate meter range, up to 300 bpm (350 bpm for monitors labeled for use with neonatal/pediatric patients), shall not cause the meter to indicate a rate lower than this upper limit.

4.2.8 Alarm system

If provided, the alarm system of a cardiac monitor shall generate a visible and/or audible alarm when the input heart rate is outside of the preset heart rate limits for more than a specified time. This alarm indication shall be given at bedside for units not connected to a central station. If the bedside unit is connected to a central station, the alarms may be located at the central station. In addition, the alarm system shall conform to the following requirements.

4.2.8.1 Alarm limit range

The range of upper alarm limit settings shall extend from 100 bpm or less to 200 bpm or more for adult cardiac monitors, and 250 bpm or more for monitors labeled for use with neonatal/pediatric patients. The range of lower alarm limit settings shall extend from 30 bpm or less to 100 bpm or more.

4.2.8.2 Resolution of alarm limit settings

The resolution capabilities for setting alarm limits shall be ± 10 percent of the nominal setting or ± 5 bpm, whichever is greater.

4.2.8.3 Alarm limit accuracy

The maximum error in the alarm limit setting shall be ± 10 percent of the nominal setting or ± 5 bpm, whichever is greater. The error (e_d) in the alarm limit setting is defined by the equation:

$$e_d = 100 \times \left| \frac{R_d - R_s}{R_s} \right|$$

where:

R_d = the displayed heart rate at which the alarm threshold is reached

R_s = the alarm limit setting

In addition, ECG signals at rates below the disclosed lower limit of the alarm range shall not fail to generate an alarm. If alarms are not disabled, input ECG signals at rates above the disclosed upper limit of the alarm range, up to 300 bpm (350 bpm for neonatal/pediatric monitors), shall not fail to generate an alarm.

4.2.8.4 Time to alarm for cardiac standstill

The time to alarm for a step change in heart rate from 80 bpm to 0 bpm, with the lower alarm limit set closest to 60 bpm, shall not exceed 10 seconds.

4.2.8.5 Time to alarm for low heart rate

The time to alarm for a step change in heart rate from 80 bpm to 40 bpm, with the lower alarm limit set closest to 60 bpm, shall not exceed 10 seconds.

4.2.8.6 Time to alarm for high heart rate

The time to alarm for a step change in heart rate from 80 bpm to 120 bpm, with the upper alarm limit set closest to 100 bpm, shall not exceed 10 seconds.

4.2.8.7 Alarm silencing

Provision shall be made for silencing or resetting audible and visual alarms after activation. Monitors with latching alarms shall provide for resetting of any audible or visual alarm indicators. The manufacturer shall disclose the time requirement for reactivating the alarm; if this time is adjustable, the range of time intervals available also shall be disclosed.

4.2.8.8 Alarm disabling

If the alarm(s) can be disabled at the bedside, this condition shall be apparent on the front of the bedside unit. If the monitor is connected to a remote central monitoring site with no independent alarm settings, the alarm condition of the bedside unit also shall be displayed at the central monitoring station.

4.2.9 Special requirements for monitors with ECG waveform display capability

The following requirements apply only to cardiac monitors that provide ECG waveform display. Unless otherwise indicated, these requirements apply both to devices with permanent ("hard copy") records and those with nonpermanent ("volatile") displays. Waveform measurements shall be made from the output display of the monitor under consideration.

4.2.9.1 Input dynamic range

The device shall be capable of responding to and displaying differential voltages of ± 5 mV varying at a rate up to 320 mV/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 ± 10 percent over the specified range of dc offset. Changes in offset voltages at a maximum rate of 1 mV/s shall not cause discontinuities in the output greater than 30 μ V, referred to the input.

The ECG monitoring equipment also shall be provided with means to indicate that the equipment is inoperable due to an overload or saturation of any part of the amplifier. The amplitude of a ± 5 mV signal shall not be reduced below 50 percent of the initial value at voltages less than ± 300 mV, and the indicating means shall be fully operative before the amplitude of the signal is reduced to 50 percent of the initial value. Absence of a visible trace is an acceptable means of indication.

4.2.9.2 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 the injected frequency of more than 20 percent of that obtained without the simulated impedance, within the bandwidth of 0.67 Hz to 40 Hz. This reduction shall not be exceeded with dc offset potentials as specified in 4.2.9.1. These requirements shall be met at all appropriate settings of the lead selector. A single-ended input impedance of at least 2.5 megohms over this entire frequency range will be needed to meet these requirements.

4.2.9.3 System noise

Noise due to patient cables, all internal circuits, and output displays shall not exceed 30 μ V (p-v RTI) when the manufacturer's recommended cable is used, 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 when the cable is motionless. This test shall be done with any line frequency notch filter on (i.e., enabled).

4.2.9.4 Multichannel crosstalk

Any input signal limited in amplitude and rate of change as per 4.2.9.1, applied to any one lead of a multi-channel monitor, and with all unused inputs connected to patient reference through a 51 kilohm resistor in parallel with a 47 nF capacitor, shall not produce an unwanted output greater than 5 percent of the applied signals (multiplied by the gain) in those channels where no signal is applied.

4.2.9.5 Gain control and stability

- a) **Gain selection.** The device shall provide at least one gain setting no lower than 5 mm/mV. Devices having permanent display capabilities shall provide at least one fixed gain setting (10 mm/mV). This requirement must be met regardless of whether continuously variable gain control is provided.
- b) **Gain control.** Continuously variable gain control may be provided, if this mode is clearly indicated on the device control panel and if, in addition, some indication is provided on the recorded output that this option is being used.
- c) **Gain switching.** If automatic gain change or switching is provided, the recorded output should indicate whenever this mode has been selected. Any automatic gain switching shall have a manual override.
- d) **Gain stability.** The gain change one minute after energizing the device shall not exceed 0.66 percent per minute. The total change in one hour shall not exceed ± 10 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.

4.2.9.6 Time base selection and accuracy

- a) Devices with permanent displays shall provide at least one time base (25 mm/s). The time base accuracy shall allow time measurements with an error no greater than ± 10 percent for time intervals between 0.2 s and 2 s.
- b) For devices with nonpermanent displays, the available time bases shall be disclosed in the labeling. The time base accuracy for any settings shall not vary by more than ± 10 percent over the complete display window.

4.2.9.7 Output display

The output display shall accommodate the signals specified in 4.2.9.1, and the device shall comply with the following additional requirements.

- a) **Channel width.** The span per channel may be programmable with at least one setting of 30 mm per channel. Note that different aspect ratios must follow requirements of 4.2.9.7(b).
- b) **Aspect ratio.** For devices with nonpermanent displays, the aspect ratio shall be 0.4 ± 0.08 s/mV, where aspect ratio is defined as the ratio of vertical sensitivity (in mm/mV) to horizontal sensitivity (in mm/s). For instruments providing several different aspect ratios or adjustable aspect ratios, an aspect ratio of 0.4 ± 0.08 s/mV must be among those provided. At 10 mm/mV and 25 mm/s, for example, the aspect ratio is 0.4.

4.2.9.8 Accuracy of input signal reproduction

- a) **Overall system error.** Input signals limited in amplitude to ± 5 mV and varying at a rate up to 125 mV/s (as per 4.2.9.1) shall be reproduced on the output recording medium (permanent display) with a maximum deviation from the ideal of ± 20 percent or ± 100 μ V, whichever is greater.
- b) **Frequency response.** The monitor shall meet the specifications for two types of input signals, summarized in Table 3. For method A, the output is relative to that obtained with a 5 Hz input signal. For method B, the output response is relative to that obtained for a repetitive, triangular wave input with a base width of 200 ms and a repetition rate of 1 Hz or less. Frequency response testing shall meet both methods A and B (Figure 1).

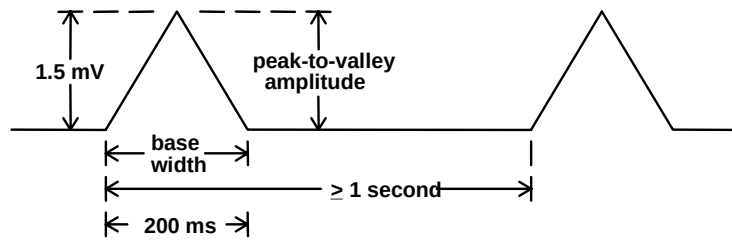


Figure 1—Triangular wave signal (for method B)

Table 3—Frequency response

Method	Input amplitude (mV p-v)	Input frequency and waveform	Relative output response (mm)
A	1.0	0.67 Hz to 40 Hz, sinusoidal	0.67 Hz to 40 Hz bandwidth (3 dB down) Upper limit: 110 % ¹⁾
B	1.5	1 Hz, 20 ms, triangular	11.25 mm to 15 mm ²⁾

¹⁾ Relative to output with 5 Hz sinusoidal input.

²⁾ Relative to output with 200 ms triangular input.

NOTE—The monitor must meet the requirements of both methods A and B.

- c) **Impulse response.** The monitor must be able to operate with an extended low-frequency response equivalent to that of a diagnostic electrocardiograph, as specified in applicable document 2.2 (4.2.7.2, Test method D—Impulse response). These requirements are: a 0.3 mVs (3mV for 100 ms) impulse shall not produce a displacement greater than 0.1 mV, nor a slope exceeding 0.30 mV/s following the end of the impulse. Restrictions on the actual shape of this impulse may apply as discussed in test section.

This impulse response requirement is imposed on all monitors. If it is necessary for the monitor to be placed in a particular mode using an operator-selectable control to achieve this extended low-frequency response, an indication of the mode must appear on the recording medium to inform the operator whether the recording has been made with this extended low-frequency response.

NOTE—Extended low-frequency response operation may require the monitor to operate in a non-real-time mode. If so, the manufacturer must disclose the details of time delays.

- d) **Lead weighting factors.** Cardiac monitors employing standard leads or Frank leads shall utilize weighting factors and exhibit performance characteristics consistent with those specified in the American National Standard, *Diagnostic electrocardiographic devices* (applicable document 2.2).
- e) **Hysteresis.** After a deflection of 15 mm in either direction from the baseline, the hysteresis of the permanent recording system shall not exceed 0.5 mm.

4.2.9.9 Standardizing voltage

A standardizing voltage shall be provided having a value and form that produces a step change in display output whose amplitude is within ± 10 percent of the step change amplitude obtained by applying a 1 ± 0.01 mV signal at the appropriate lead. The standardizing voltage shall exhibit a rise time of less than 10 ms and a decay time constant of at least 100 s. The standardizing signal shall be applied to provide an indication of operator adjustment of the gain. The signal shall be applied to all available channels of multi-channel recorders. An alternative waveform for the standardizing voltage is acceptable, and shall consist of a waveform with peak amplitude within ± 10 percent of the step amplitude obtained by applying a 1 mV signal at the appropriate lead.

NOTE—Devices providing only one fixed gain and devices that always provide a displayed gain indication for each waveform in all permanent and nonpermanent displays are exempt from the requirement to provide a standardizing voltage.

4.2.9.10 Common mode rejection

The cardiac monitor shall have the capability of rejecting line frequency signal mode interfering voltages as encountered on the surface of the body. A line frequency signal, with 10 V_{rms} source and a 200 picofarad (pF) source capacitance, applied from power ground to all patient electrode connections attached to a common node and with a parallel combination of a 51 kilohm resistor and 47 nF capacitor imbalance impedance in series with each patient lead, including the RL or green lead, if supplied (Figure 10), shall not produce an output signal exceeding 1 mV p-v RTI over a 60 s period. The test shall be done while any line frequency notch filter (if provided) is turned off, even if it requires special software or a special method of accessing the control over that filter. 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 4.2.9.1. 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 capacitance may result from shielding components and from patient cable capacitances when the cable is connected to the voltage source. The test method of 5.2.9.10 takes these capacitances into consideration. See annex C for more details on how to properly build, calibrate, and use the CMR test fixture.

4.2.9.11 Baseline control and stability

- a) **Reset.** A 1 V p-v line frequency overload voltage shall be applied for at least 1 s to any lead. After removal of this overload voltage, means shall be available for restoring a 1 mV p-v trace to the recording width of the display within 3 s.
- b) **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 a 25 kilohm resistor—the baseline drift rate at output shall not exceed 10 $\mu\text{V/s}$ RTI over any 10 s period. Drift over temperature shall be less than 50 $\mu\text{V}/^\circ\text{C}$. In addition, the total drift of the device shall not exceed 500 μV RTI over a 1 h period at operating temperature.

4.2.9.12 Pacemaker pulse display capability

The device shall be capable of displaying the ECG signal in the presence of pacemaker pulses with amplitudes and durations as specified in 4.1.4, except that the lower limit for pulse duration shall be 0.5 ms. An indication of the pacemaker pulse shall be visible on the display with an amplitude of no less than 0.2 mV RTI.

4.2.9.13 Synchronizing pulse for cardioversion

If a pulse is accessible to serve as an input synchronizing signal to a cardioverter, the time interval from the R wave peak to the start of the synchronization pulse output must be no greater than 35 ms. Other pulse characteristics of amplitude, duration, shape, and output impedance shall be disclosed.

4.2.9.14 Electrosurgical interference suppression

If the manufacturer claims that the monitor has ESIS, then with the monitor's gain set for 10 mm/mV, using any accessories or settings recommended by the manufacturer, and while receiving a 1 mV simulated ECG signal, the ECG trace shall not disappear from the display. The heart rate shall not change by more than ± 10 percent of the rate before electrosurgical interference was activated while the interference is applied for the response time disclosed for 4.1.2.1(f) or 5 s, whichever is longer. This test shall be conducted at a convenient heart rate between 60 bpm and 150 bpm using a simulator whose rate does not vary during electrosurgical interference. This applies during sparking and non-sparking contact of the active electrosurgery electrode. The means of coupling to the monitor and the fraction of electrosurgical machine output for this requirement are defined respectively by Figures 12 and 13B. As in the electrocautery overload tests, the electrocautery unit used must have an operating frequency of 450 kHz $\pm$ 100 kHz, and be set for a pure cut power of 300 W and a coagulation power of 100 W.

4.2.10 Electromagnetic compatibility

4.2.10.1 Electromagnetic emissions

Equipment covered by EC13 shall comply with the requirements of CISPR 11, Group 1 (reference document 2.5). Class A limits apply for equipment that will be used only in hospitals and will be powered only by dedicated supply systems. Class B limits apply for equipment that may be used in domestic environments and doctors' offices (and also are acceptable in hospital environments).

4.2.10.2 Electromagnetic immunity

See IEC 60601-1-2 (reference document 2.6).

4.2.10.2.1 Immunity to radiated electromagnetic fields

The requirements of IEC 60601-1-2 (which specifically refers to EN61000-4-3) apply.

4.2.10.2.2 Immunity to conducted RF interference

The requirements of IEC 60601-1-2 (which specifically refers to EN61000-4-6) apply.

4.2.10.2.3 Immunity to magnetic fields

The requirements of IEC 60601-1-2 (which specifically refers to EN61000-4-8) apply.

4.2.10.2.4 Immunity to electrostatic discharge

The requirements of IEC 60601-1-2 (which specifically refers to EN61000-4-2) apply. ECG spikes, display glitches, or momentary LED flashes are acceptable during an ESD.

4.2.10.2.5 Power line transients

- a) **Fast transients/bursts.** The requirements of IEC 60601-1-2 (which specifically refers to EN61000-4-4) apply. Only transient degradation or loss of functionality is allowed.
- b) **Surges.** The requirements of IEC 60601-1-2 (which specifically refers to EN61000-4-5) apply. The instrument may exhibit momentary loss of functionality, but must recover without user intervention.
- c) **Voltage dips and short interruptions.** The requirements of IEC 60601-1-2 (which specifically refers to EN61000-4-11) apply.

4.2.11 Summary

Table 4 provides a summary of the performance requirements of this standard.

Table 4—Summary of performance requirements

Section	Requirement description	Min/max	Units	Min/max value
4.2.1	Operating conditions:			
	Line voltage	Range	Vrms	104 to 127
	Line frequency	Range	Hz	50/60 ± 1
	Temperature	Range	°C	10 to 40
	Relative humidity	Range	%	30 to 75
	Atmospheric pressure	Range	mbar	700 to 1060
4.2.2	Overload protection			
4.2.2.1	AC voltage: no damage from differential ac voltage, line frequency, 1 V applied for 10 s	Min	V p-v	1
4.2.2.2	Defibrillator overload protection:			
	Over-voltage	Max	V	5000
	Energy	Max	J	360
	Recovery time	Max	seconds	5
	Energy reduction	Max	%	10
	Charge to operator	Max	µC	100
4.2.3	Risk current (isolated patient connection)	As per applicable document 2.1		
4.2.4	Auxiliary output (if provided)			
4.2.4.1	No damage from short-circuit	Min	minute	1

Section	Requirement description	Min/max	Units	Min/max value
4.2.4.2	Risk current (isolated patient connection) auxiliary devices attached	As per applicable document 2.1		
4.2.5	Respiration, leads-off sensing and active noise suppression:			
	Risk current (isolated patient connection)	As per applicable document 2.1		
	Direct current any active lead	Max	µA	0.1
4.2.6	QRS detection			
4.2.6.1	Range of QRS wave amplitude and duration—Meet 4.2.7 for pulses of Figure 6:			
	Amplitude	Range	mV p-v RTI	0.5 to 5
	Duration (adult monitor)	Range	ms	70 to 120
	Duration (neonatal/pediatric)	Range	ms	40 to 120
	No response for signals:			
	Amplitude (except for neonatal/pediatric operation)	Max	mV p-v RTI	0.15
	Duration with amplitude of 1 mV (except for neonatal/pediatric operation)	Max	ms	10
4.2.6.2	Line frequency voltage tolerance	Min	µV p-v RTI	100
4.2.6.3	Drift tolerance (0.1 Hz signal on train of QRS signals:			
	Triangular wave amplitude	NA	mV p-v RTI	4
	QRS amplitude	NA	mV p-v RTI	0.5
	QRS duration	NA	ms	100
	QRS repetition rate	NA	bpm	80
4.2.7	Range/accuracy of heart rate meter:			
	Range (adult monitor)	Range	bpm	30 to 200
	Range (neonatal/pediatric monitor)	Range	bpm	30 to 250
	Error: either ...	Max	%	±10
	... OR (whichever greater)	Max	bpm	±5
	Indicated rate for signal rate < disclosed rate meter min	Max	bpm	Disclosed min limit
	Indicated rate for signal rate = 300 bpm (adult operation)	Min	bpm	Disclosed max limit
	Indicated rate for signal rate = 350 bpm (neonatal/pediatric operation)	Min	bpm	Disclosed max limit
4.2.8	Alarm system requirement			
4.2.8.1	Alarm limit range:			
	Upper range (adult)	Min	bpm	100 to 200
	Upper range (neonatal/pediatric)	Min	bpm	100 to 250
	Lower range (adult and neonatal/pediatric)	Min	bpm	30 to 100