

American National Standard

ANSI/AAMI EC13:2002/(R)2007

Cardiac monitors, heart rate meters, and alarms **PREVIEW COPY**

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document,
contact AAMI at (877) 249-8226
or visit www.aami.org.



Association for the Advancement
of Medical Instrumentation

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.

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

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

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

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

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

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

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

Cardiac monitors, heart rate meters, and alarms



This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

Developed by
Association for the Advancement of Medical Instrumentation

Approved 6 May 2002 and reaffirmed 10 December 2007 by
American National Standards Institute, Inc.

For a complete copy of this AAMI document,
contact AAMI at (877) 249-8226
or visit www.aami.org.

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

AAMI Standard

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

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

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.



This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

For a complete copy of this AAMI document,
contact AAMI at (877) 249-8226
or visit www.aami.org.

© 2002 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI at 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1-57020-174-9

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

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at (877) 249-8226 or visit www.aami.org.

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



This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at (877) 249-8226 or visit www.aami.org.

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:

Cochairs: James J. Bailey, MD
David Mortara, PhD

Members: James J. Bailey, MD, National Institutes of Health
David L. Daly, U.S. Food and Drug Administration
Arthur R. Eddy, Jr., ConMed Corp.
Stacy Gehman, Agilent Technologies/Heartstream
Paul Lander, FlowMetrix, Inc.
George Moody, Massachusetts Institute of Technology
David Mortara, PhD, Mortara Instruments
Shankara Reddy, PhD, G.E. Medical Systems
Jonathan Steinberg, MD, St. Luke's Roosevelt Hospital
Roy D. Wallen, PurePulse Technologies

Alternate: Robert Cangelosi, U.S. Food and Drug Administration

At the time this document was published, the **AAMI Cardiac Monitor and Diagnostic ECG Working Group** had the following members:

Chair: Shankara Reddy, PhD

Members: Robert William Bain, CBET, Prince George's Hospital
Richard Diefes, ECRI
Melvin N. Fink, Service Master
David Geraghty, Micro Surgical Technology
David Hernke, G.E. Medical Systems
Charles Ho, U.S. Food and Drug Administration
Cindy Jayne, Medtronic Physio-Control
Michael Kronstadt, Abbott Laboratories
Don Lin, PhD, Cardiac Science, Inc.
William Murray, Siemens Medical Solutions U.S.A.
Cadathur Rajagopalan, PhD, Datascope Corp.
Shankara Reddy, PhD, G.E. Medical Systems
Kay Rutishauser, RN, American Association of Critical Care Nurses
Katherine Stankus, Spacelabs Medical
Richard Sunderland, Welch Allyn Protocol, Inc.
John Wang, Philips Medical Systems

Alternates: George Diller, Philips Medical Systems
Michael Gusel, Datascope Corp.
Charles Sidebottom, Medtronic, Inc.
John Sperinde, PhD, Abbott Laboratories
Kenneth Takaki, U.S. Food and Drug Administration

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 pacemaker 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, pacemaker, 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.



This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document,
contact AAMI at (877) 249-8226
or visit www.aami.org.