

# American National Standard



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## ANSI/AAMI EC57: 2012

Testing and reporting  
performance results of  
cardiac rhythm and ST  
segment measurement  
algorithms

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

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

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

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

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

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

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

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**Testing and reporting performance results of  
cardiac rhythm and ST segment  
measurement algorithms**

Developed by  
**Association for the Advancement of Medical Instrumentation**

Approved 18 December 2012 by  
**American National Standards Institute, Inc.**

**Abstract:** This recommended practice establishes a method for testing and reporting the performance of algorithms used to detect cardiac rhythm disturbances, including the ST segment.

**Keywords:** arrhythmia database, arrhythmia monitoring, ST segments, heart rate variability

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# Contents

	Page
Glossary of equivalent standards.....	v
Committee representation.....	vi
Foreword.....	vii
<b>1 Scope.....</b>	<b>1</b>
1.1 General.....	1
1.2 Inclusions.....	1
1.3 Exclusions.....	1
<b>2 Definitions of abbreviations.....</b>	<b>1</b>
<b>3 Algorithm testing.....</b>	<b>2</b>
3.1 Databases.....	2
3.1.1 General description of available databases.....	2
3.1.2 Records to be excluded during testing.....	3
3.2 Testing requirements.....	3
3.3 Test environment.....	3
3.4 Multiple-lead analysis.....	4
3.5 Requirements for the evaluation report.....	4
3.5.1 Required statistics.....	4
3.5.2 Requirements for all arrhythmia algorithms.....	4
3.5.3 Requirements for algorithms with optional capabilities.....	5
3.6 Simulated test patterns.....	7
<b>4 Automated analysis.....</b>	<b>7</b>
4.1 Use of standard databases.....	7
4.2 Use of annotation files.....	8
4.3 Beat-by-beat comparison.....	9
4.3.1 General description.....	9
4.3.2 Method for beat-by-beat comparison.....	10
4.3.3 Heart rate, and heart rate or RR interval variability.....	10
4.3.3.1 Heart rate measurement.....	10
4.3.3.2 Heart rate variability or RR interval variability measurement from databases.....	11
4.3.3.3 Heart rate variability or RR interval variability measurement of test patterns.....	12
4.4 Run-by-run comparison.....	14
4.4.1 General description.....	14
4.4.2 Terms and symbols.....	15
4.4.3 Run sensitivity summary matrix.....	16
4.4.4 Run positive predictivity summary matrix.....	16
4.5 VF and AF comparisons.....	16
4.6 ST comparison.....	17
<b>Annex</b>	
<b>A Rationale and additional guidance.....</b>	<b>22</b>
<b>Tables</b>	
Table 1—Requirements for all arrhythmia algorithms.....	5
Table 2—Requirements for algorithms with optional capabilities.....	6
Table 3—Beat label classifications.....	9
Table 4—AHA and MIT–BIH database labels distributed for use by HRV algorithms.....	12
Table 5—Example of noise floor calculation results.....	13

Table 6—example of HRV test results .....	14
Table 7—Run sensitivity summary matrix.....	15
Table 8—Run positive predictivity summary matrix .....	15
Table A.1—Records to be included in a complete test .....	23
Table A.2—Example of a line-format, beat-by-beat performance report .....	26
Table A.2.1—Condensed beat-by-beat summary matrix containing 11 elements .....	26
Table A.2.2—Summary table (matrix format) of beat-by-beat comparison .....	27
Table A.3—Example of a line-format shutdown report .....	27
Table A.4—Example of a line-format report.....	28
Table A.5—Example of VF performance report .....	29
Table A.6—Example of false VF performance report .....	29
Table A.7—Example of a line-format couplet and run performance report.....	30
Table A.8—Example of results of HRV program run on MIT-BIH database reference annotations.....	31
Table A.9—Example of device measurements of synthetic test patterns .....	31
Table A.10—Example of predicted ideal values for synthetic test patterns .....	32
Table A.11—Example of choice of test patterns.....	32
Table A.12—Example of RMS interval differences .....	34
Table A.13—Example of summary of frequency components .....	35
Table A.14—Example of a line-format report.....	36

## Figures

1	Example of scatter plot of ST amplitude measurement .....	18
2	Example of scatter plot of ST amplitude measurement .....	18
3	Example of scatter plot of ST amplitude measurement (-200 microvolt to + 200 microvolt reference) .....	19
4	Example of scatter plot of ST slope measurement error .....	20
5	Example of scatter plot of ST slope measurement .....	21

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[www.aami.org/publications/standards/glossary.pdf](http://www.aami.org/publications/standards/glossary.pdf)



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## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Electrocardiograph (ECG) Committee

This recommended practice was developed by the ECG Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

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

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Robert E. Bruce  
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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.

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## Foreword

This recommended practice was developed by the Arrhythmia Monitoring Working Group of the AAMI Electrocardiograph (ECG) Committee. It reflects the conscientious efforts of health care professionals, in cooperation with manufacturers of arrhythmia monitoring devices, to develop recommendations for testing and reporting performance results of algorithms for cardiac arrhythmia detection and ST segment measurement.

The first edition of this document was issued in 1987 under the title *Recommended practice for testing and reporting performance results of ventricular arrhythmia detection algorithms* (AAMI ECAR:1987). The document was developed to assist in the comparison of ventricular arrhythmia detection algorithm performance through the promulgation of a generally accepted method for testing and reporting such performance. Major changes were incorporated into this revision, retitled *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms* (ANSI/AAMI EC57:1998), including updated references to databases that have become available since 1987 and the addition of mechanisms for testing and reporting ST measurement and heart-rate variability performance along with supraventricular ectopic performance statistics. As with cardiac ventricular rhythm measurements, these additional parameters are intended to benefit users who are comparing algorithm performance. This current revision makes minor changes to the 1998 standard and updates the information for the databases.

It is not intended that these recommendations be construed as universally applicable to all circumstances. It is also recognized that these recommendations may not be achievable in all situations.

This recommended practice must be reviewed and updated periodically to assimilate progressive technological developments. The concepts incorporated in this recommended practice should not be considered inflexible or static.

As used within the context of this recommended practice, “shall” indicates requirements strictly to be followed to conform to the recommended practice; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action is discouraged but not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the recommended practice; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards Dept., AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633. Comments may also be e-mailed to: [standards@aami.org](mailto:standards@aami.org).

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NOTE—This foreword is not a part of the AAMI Recommended Practice, *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms* (ANSI/AAMI EC57:2012), but it does provide important information about the development and intended use of the document.

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# Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms

## 1 Scope

### 1.1 General

The availability of annotated arrhythmia and ST databases has permitted different automated arrhythmia detection algorithms to be tested on the same data. This recommended practice provides a protocol for a reproducible test with realistic clinical requirements, and emphasizes record-by-record presentation of results that reflect an algorithm's ability to detect events of clinical significance. Beat-by-beat comparisons are used to measure performance in QRS (see 2.7), ventricular ectopic beat (VEB), and supraventricular ectopic beat (SVEB) detection. Run-by-run comparisons are used to measure an algorithm's ability to detect consecutive VEBs and SVEBs. Detection of ventricular flutter, atrial flutter, ventricular fibrillation, and atrial fibrillation are addressed. The evaluation of heart-rate variability measurement algorithms and ST segment measurement algorithms are also examined.

Although this document seeks to establish clinically relevant measures of performance for the comparison of algorithms, it must be recognized that certain clinical concerns cannot be addressed within the context of this recommended practice. Available databases do not yet contain a representative sample of nonventricular arrhythmias, paced patients or artifacts typical of a very significant portion of ECG signals originating in the clinical setting. In addition, these databases have a limited bandwidth and should be used with caution when testing algorithms designed for full ECG diagnostic bandwidth devices. Therefore, the clinical implications of a test are necessarily limited by the size, scope, and characteristics of the databases used for testing. Performance measures derived from such testing should be regarded as uncertain indicators of performance in clinical settings.

This recommended practice has been developed for testing algorithms, not entire systems. It is not a performance standard, but rather a set of recommendations for testing cardiac rhythm and ST measurement and reporting the results of those tests. The intent of this recommended practice is that automated testing methods be reproducible.

### 1.2 Inclusions

This recommended practice applies to algorithms implemented in devices or systems that use automated methods to analyze the ECG.

This document applies both to human-operated, stand-alone devices that use automated methods to analyze the recorded ECG, and to so-called real-time event recorders that use automated methods to select abnormal events for recording.

### 1.3 Exclusions

Testing methodologies other than beat-by-beat techniques, specified rhythm analysis, and ST segment analysis are outside the scope of this document. The evaluation of systems that rely on intensive interaction by a skilled user is also outside the scope of this document. However, if beat-by-beat evaluations are performed, the results of such testing should conform to this recommended practice.

## 2 Definitions of abbreviations

NOTE—Definitions for beat labels (N, V, F, S, Q, U, X, O) are provided in 4.2.

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

**2.1 AF:** Atrial fibrillation or atrial flutter.

**2.2 BW:** Data record identified from the NST (Noise Stress Test) database.

**2.3 DB:** Database.

**2.4 EM:** Data record identified from the NST (Noise Stress Test) database.