

# American National Standard



## ANSI/AAMI EC57:2012/ (R)2020

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



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

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

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**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>  |
| <b>1.1 General.....</b>                                                                            | <b>1</b>  |
| <b>1.2 Inclusions.....</b>                                                                         | <b>1</b>  |
| <b>1.3 Exclusions.....</b>                                                                         | <b>1</b>  |
| <b>2 Definitions of abbreviations.....</b>                                                         | <b>1</b>  |
| <b>3 Algorithm testing.....</b>                                                                    | <b>2</b>  |
| <b>3.1 Databases.....</b>                                                                          | <b>2</b>  |
| <b>3.1.1 General description of available databases.....</b>                                       | <b>2</b>  |
| <b>3.1.2 Records to be excluded during testing.....</b>                                            | <b>3</b>  |
| <b>3.2 Testing requirements.....</b>                                                               | <b>3</b>  |
| <b>3.3 Test environment.....</b>                                                                   | <b>3</b>  |
| <b>3.4 Multiple-lead analysis.....</b>                                                             | <b>4</b>  |
| <b>3.5 Requirements for the evaluation report.....</b>                                             | <b>4</b>  |
| <b>3.5.1 Required statistics.....</b>                                                              | <b>4</b>  |
| <b>3.5.2 Requirements for all arrhythmia algorithms.....</b>                                       | <b>4</b>  |
| <b>3.5.3 Requirements for algorithms with optional capabilities.....</b>                           | <b>5</b>  |
| <b>3.6 Simulated test patterns.....</b>                                                            | <b>7</b>  |
| <b>4 Automated analysis.....</b>                                                                   | <b>7</b>  |
| <b>4.1 Use of standard databases.....</b>                                                          | <b>7</b>  |
| <b>4.2 Use of annotation files.....</b>                                                            | <b>8</b>  |
| <b>4.3 Beat-by-beat comparison.....</b>                                                            | <b>9</b>  |
| <b>4.3.1 General description.....</b>                                                              | <b>9</b>  |
| <b>4.3.2 Method for beat-by-beat comparison.....</b>                                               | <b>10</b> |
| <b>4.3.3 Heart rate, and heart rate or RR interval variability.....</b>                            | <b>10</b> |
| <b>4.3.3.1 Heart rate measurement.....</b>                                                         | <b>10</b> |
| <b>4.3.3.2 Heart rate variability or RR interval variability measurement from databases.....</b>   | <b>11</b> |
| <b>4.3.3.3 Heart rate variability or RR interval variability measurement of test patterns.....</b> | <b>12</b> |
| <b>4.4 Run-by-run comparison.....</b>                                                              | <b>14</b> |
| <b>4.4.1 General description.....</b>                                                              | <b>14</b> |
| <b>4.4.2 Terms and symbols.....</b>                                                                | <b>15</b> |
| <b>4.4.3 Run sensitivity summary matrix.....</b>                                                   | <b>16</b> |
| <b>4.4.4 Run positive predictivity summary matrix.....</b>                                         | <b>16</b> |
| <b>4.5 VF and AF comparisons.....</b>                                                              | <b>16</b> |
| <b>4.6 ST comparison.....</b>                                                                      | <b>17</b> |

## Annex

|                                                 |           |
|-------------------------------------------------|-----------|
| <b>A Rationale and additional guidance.....</b> | <b>22</b> |
|-------------------------------------------------|-----------|

## Tables

|                                                                                    |    |
|------------------------------------------------------------------------------------|----|
| 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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International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

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

## 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:

*Cochairs:* Richard A. Sunderland  
Ahmet Turkmen  
Brian J. Young

*Members:* Robert William Bain, CBET, Baltimore Medical Engineers & Technician Society  
Robert E. Bruce  
Scott Coggins, Covidien  
Prakash C. Deedwania, MD, The VA Medical Center  
Laura Dhatt, Physio-Control  
Sreeram Dhurjaty, Dhurjaty Electronics Consulting LLC  
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Greg Downs, Spacelabs Medical Inc.  
Arthur R. Eddy, Jr.  
James J. Greco, Medapprove Inc  
Richard Gregg, Philips Electronics North America  
Janice M. Jenkins, PhD, University of Michigan College of Engineering  
Carolyn Lall, Draeger Medical Systems Inc  
Dongping Lin, PhD  
Walter G. Lloyd, Childrens Hospital Boston  
Peter W. Macfarlane, Royal Infirmary  
Luis A. Melendez, Partners Healthcare  
George Moody, Massachusetts Institute of Technology  
Cadathur Rajagopalan, PhD SMIEEE, Mindray DS USA Inc  
Linda Ricci, FDA/CDRH  
Johann-Jakob Schmid, Schiller AG  
Jonathan Steinberg, MD, St Lukes Roosevelt Hospital Center  
Richard A. Sunderland, Welch Allyn, Inc.  
Ahmet Turkmen, BS MS PhD, University of Wisconsin-Stout  
Jeffrey Wiser, 3M Healthcare  
Ted Yantsides, Conmed Corp  
Brian J. Young, GE Healthcare

*Alternates:* Mark J. Callahan, Covidien  
Kejian Chen, 3M Healthcare  
Yu Chen, PhD, Draeger Medical Systems Inc  
Steve Duke, Physio-Control  
Charles S. Ho, PhD, FDA/CDRH  
Richard Richardson, GE Healthcare  
Serkan Sezer, Schiller AG  
Donald Stewart, Spacelabs Medical Inc.  
Anna Varlese, Conmed Corp  
John J. Wang, Philips Electronics North America  
Yinqi Zhang, Spacelabs Medical Inc

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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.

- 2.5 HRV:** Heart rate variability.
- 2.6 MA:** Data record identified from the NST (Noise Stress Test) database.
- 2.7 QRS:** The waveform presented in an ECG during ventricular depolarization.
- 2.8 RMS:** Root-mean squared.
- 2.9 RRV:** R-to-R variability.
- 2.10 SVEB:** Supraventricular ectopic beat.
- 2.11 SVTA:** Supraventricular tachycardia.
- 2.12 ST:** Segment of the ECG between the end of the QRS complex and the start of the T-wave.
- 2.13 VEB:** Ventricular ectopic beat.
- 2.14 VF:** Ventricular fibrillation or ventricular flutter.

### 3 Algorithm testing

This section describes what constitutes a complete test of an algorithm. The term “report” refers to the evaluation procedure described in this section and not to the clinical report that the physician receives.

#### 3.1 Databases

##### 3.1.1 General description of available databases

At the time this document was developed, five databases were available for evaluation of cardiac arrhythmia ST algorithms:

- AHA:** The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors (80 records of 35 minutes each), ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462, USA;
- MIT–BIH:** The Massachusetts Institute of Technology–Beth Israel Hospital Arrhythmia Database (48 records of 30 minutes each), <http://physionet.org/physiobank/database/mitdb/>;
- ESC:** The European Society of Cardiology ST-T Database (90 records of 2 hours each), <http://physionet.org/physiobank/database/edb/>;
- NST:** The Noise Stress Test Database (12 ECG records of 30 minutes each plus 3 records of noise only—supplied with the MIT–BIH database), <http://physionet.org/physiobank/database/nstadb/>; and
- CU:** The Creighton University Sustained Ventricular Arrhythmia Database (35 records of 8 minutes each—supplied with the MIT–BIH database with incomplete annotations), <http://physionet.org/physiobank/database/cudb/>.

Sources for these databases include the following:

- ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462, USA (AHA database);
- MIT–BIH Database Distribution, MIT Room E25-505, Cambridge, MA 02139, USA (MIT–BIH, NST, CU databases and the ESC database inside North America—Internet site: <http://ecg.mit.edu>); and
- CNR Institute of Clinical Physiology, Computer Laboratory, via Trieste, 41 56100 Pisa, Italy (ESC database outside North America).

The first four of these databases (AHA, MIT–BIH, ESC, and NST) consist of digitized excerpts of two-channel Holter-type recordings, with each beat labeled. This set of annotation files, in which each beat has been identified by expert cardiologist-annotators, are referred to as “reference” annotations. The CU database contains digitized single-channel ECG recordings with rhythm changes labeled.

Database elements have been referred to as tapes and records. For the purpose of this document, the term “tapes” refers only to physical taped recordings of ECGs. Database elements are referred to as “records.”

This list of standard databases is not intended to exclude others that may become available in the future. It is, however, a list of those that were both adequate and available at the time of this document’s publication.

Databases should be:

- available to the public;
- fully described (standard digital format);
- clearly identifiable by name, version, date, etc.; and
- annexed with utilities and instructions for use.

If any records from a given database are used to fulfill the requirements of 3.5, device performance shall be tested and reported on a record-by-record basis for all records from that database except as excluded by 3.1.2. The first 5 minutes of each record are designated as a learning period. The remainder of each record is the test period. Device performance is measured only during the test period of each record; the entire test period shall be used for this purpose, except as noted in 3.1.2.

### **3.1.2 Records to be excluded during testing**

Of the 80 available records in the AHA database, two are recorded from patients with pacemakers. Of the 48 records in the MIT–BIH database, four are from patients with pacemakers. In these databases, records with paced beats do not retain sufficient signal quality for reliable processing by systems that use special analog circuits for pace artifact detection or enhancement. Such systems shall exclude these six records containing paced beats from the reporting requirements. Performance on these records shall be reported for devices that are intended to analyze paced analog ECG recordings made without pacer artifact detection or enhancement, but aggregate performance statistics shall exclude these records in all cases. This exclusion of records with paced beats applies to arrhythmia algorithms as well as to ST-segment measurement algorithms.

The NST database contains three records (BW, EM, and MA) that are noise recordings only and are not intended for use in standard tests. The remaining 12 records are those on which device performance shall be tested and reported.

Segments of data in which ventricular flutter or fibrillation (VF) is present are excluded from beat-by-beat comparisons (for QRS and VEB detection) only. Well-defined QRS complexes necessary for a beat-by-beat comparison are not present during these segments, which are marked by rhythm labels in the database annotation files. These segments are included, however, in the tests of consecutive VEB detection and VF detection. Other segments of these records (i.e., those that do contain labeled beats) shall be included in the beat-by-beat comparisons.

## **3.2 Testing requirements**

**3.2.1** The accuracy of QRS detection shall be tested using the AHA DB, the MIT–BIH DB, and the NST DB at a minimum.

**3.2.2** The accuracy of heart rate measurements shall be tested using the AHA DB, the MIT–BIH DB, and the NST DB. If the algorithm is claimed to measure heart rate variability (HRV) or RR interval variability (RRV), its ability to do so shall be demonstrated using the MIT–BIH databases.

**3.2.3** The accuracy of VEB detection shall be tested using the AHA DB, the MIT–BIH DB, and the NST DB at a minimum.

**3.2.4** If the device is claimed to detect ventricular flutter or fibrillation (VF), its ability to do so shall be tested using the CU DB, the AHA DB, and the MIT–BIH DB at a minimum.

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

If the device is claimed to measure ST segment deviations or to detect ST segment changes, its ability to do so shall be tested using the ESC DB at a minimum, unless the characteristics of the database conflict with the algorithm under test.

## **3.3 Test environment**

Algorithm testing using standardized digital databases occurs, by definition, outside the context of the complete monitoring device's clinical setting. Yet, a correlation between algorithm performance and the device's actual clinical performance must be ensured for the results to be meaningful.

To conduct an evaluation that accurately reflects the capabilities of the algorithm as implemented in a monitoring device, it is preferable to perform the test using hardware comparable to the monitoring device although it is

recognized that the nature of the algorithm testing process might require modifications of the hardware or software. Additionally, signals should be presented to the algorithm in a method comparable to the method employed in clinical settings. The computational environment used to perform algorithm testing shall be disclosed.

When algorithm evaluations are conducted under conditions or constraints grossly different from those encountered by the monitoring device in an actual clinical setting, the algorithm results might not represent the true performance of the device. Actual devices can have limited processor speed, computational precision, filtering, and so on. Testing or analysis shall be performed indicating that the algorithm performance in an actual monitoring device can reasonably be expected to correlate with performance in the simulated test environment. This validation shall be disclosed.

Of special concern are monitoring devices intended to monitor more than one patient simultaneously. The algorithm for each patient may be identical and may be tested in isolation to determine the capabilities of the algorithm. In the actual monitoring device, the computing resource provided to each patient is dependent on the computing resources required by all the others. Therefore, validation of algorithm performance in the presence of other patient inputs shall be disclosed.

One method of multipatient monitor performance validation is to provide all patient inputs of the device with the same test waveform. Algorithm performance for all patient inputs shall be reported; the tester is not allowed to choose the best-performing patient input. In the event that a system cannot simultaneously process the same data on all patient inputs, this fact shall be reported, and the number of patient inputs that can be simultaneously processed shall be disclosed.

### **3.4 Multiple-lead analysis**

Any algorithm that analyzes a multiple number of leads simultaneously shall be permitted to report the results as a single test. For any database that has more leads available than can be simultaneously analyzed, the actual combination of channels used shall be disclosed. For any system that can analyze more channels than are available in the database, the disclosure shall state how the data were entered. At no time during the processing of the entire database is the operator allowed to change the combination of leads used. Results shall be reported on a record-by-record basis.

### **3.5 Requirements for the evaluation report**

#### **3.5.1 Required statistics**

For each record, the statistics below shall be reported as required in 3.5.2 and 3.5.3. Aggregate statistics based on the record-by-record reports summarizing the performance of the algorithm under test for each of the databases employed shall be reported as required. Formal definitions of the statistics are provided in the annex as noted.

The following symbols and abbreviations are used in the following tables:

- R = required reporting of this statistic from this database
- O = optional reporting of this statistic from this database
- = no reporting of this statistic required from this database
- ✓ = aggregate statistic required

#### **3.5.2 Requirements for all arrhythmia algorithms**

The requirements for all algorithms are given in Table 1.