American National Standard

ANSI/AAMI EC57:2012/(R)2020

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

AAMI
Advancing Safety in Health Technology

American National Standard

ANSI/AAMI EC57:2012/(R)2020
(Revision of ANSI/AAMI EC57:1998/(R)2008)

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 and reaffirmed 9 October 2020 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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Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

ISBN 1-57020-478-0

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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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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 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.

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.

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.