Technical Information Report

AAMI TIR23: 1999/(R)2019

Signal averaging

AAMI
Advancing Safety in Health Technology

AVA Documents
Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

Documents
Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

Signal averaging

Approved 15 March 1999 and reaffirmed 19 September 2019 by
AAMI

Abstract: The signal-averaged electrocardiogram (SAECG) facilitates noninvasive recording of low-amplitude cardiac signals such as ventricular late potentials. The SAECG has been used to predict life-threatening ventricular tachyarrhythmias in patients after acute myocardial infarction and with nonischemic dilated cardiomyopathy and to screen for inducible ventricular tachycardia in patients with unexplained syncope and with nonsustained ventricular tachycardia. This technical information report focuses on currently accepted methodology and clinical applications of the SAECG.

Key words: signal-averaged electrocardiogram (ECG), ventricular tachycardia, sudden cardiac death, electrophysiologic study, syncope, myocardial infarction, cardiomyopathy, atrial fibrillation

Documents
Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

Published by

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

Copyright © 2000 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 901 N. Glebe Road, Suite 300, Arlington, VA 22203. Phone:(703) 525-4890, Ext. 239; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1-57020-129-3

Documents
Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

AAMI TECHNICAL INFORMATION REPORT

A Technical Information Report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, there is value in releasing the information because of the immediate need for it by the industry and the professions.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences among these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that although both standards and TIRs are periodically reviewed, a standard must be acted upon—either reaffirmed, revised, or withdrawn—and the action formally approved usually every 5 years but at least every 10 years. For a TIR, AAMI consults with a technical committee about 5 years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI Technical Information Report may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

Documents
Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

Contents

Page

Committee representation vi

1 Scope 1

2 Definitions 1

3 State of the art of current SAECG device design 3
- **3.1** Introduction 3
- **3.2** Architecture 3
- **3.3** Comparative table of specifications 4
- **3.4** Summary of beat alignment and measurement methods 5

4 Selection and alignment of normal sinus rhythm beats for ensemble averaging 5
- **4.1** Overview 5
- **4.2** Selecting a normal sinus rhythm beat as a “template” 5
- **4.3** Beat alignment techniques 6
- **4.4** Rejecting nonsinus rhythm beats 6

5 Ensemble averaging 6
- **5.1** Overview 6
- **5.2** Endpoint of signal averaging: quality control 7
- **5.3** Rejection of adversely noisy beats 7

6 SAECG analysis: digital filtering, lead combination, and measurements 7
- **6.1** Overview 7
- **6.2** Digital filtering schemes 8
- **6.3** Butterworth IIR filter, applied in a bidirectional mode 8
- **6.4** Spectral window filter 8
- **6.5** FIR filter 8
- **6.6** Lead combination: vector magnitude waveform 8
- **6.7** SAECG measurements of late potentials 9

7 Clinical applications of SAECG 9
- **7.1** SAECG methodology 9
- **7.2** Clinical application of the SAECG 11
  - **7.2.1** Predischarge risk stratification after acute MI 11
  - **7.2.2** Using the SAECG in combination with other noninvasive test results to predict serious ventricular arrhythmias after MI 12
  - **7.2.3** Clinical limitations of the SAECG after MI 13
  - **7.2.4** Interaction of invasive risk stratification with programmed ventricular stimulation and the SAECG 15
  - **7.2.5** The clinical utility of the SAECG in the thrombolytic era 16
  - **7.2.6** Prognostic value of the SAECG in patients with idiopathic dilated cardiomyopathy or with advanced heart failure 18
  - **7.2.7** Predicting electrically induced ventricular tachycardia in the electrophysiology laboratory of patients with unexplained syncope 20
  - **7.2.8** Predicting inducibility of sustained VT in patients with nonsustained VT 21

8 Emerging areas in signal-averaged ECG 22
- **8.1** Frequency domain analysis 22
- **8.2** P-wave signal averaging and analysis methods 22
- **8.3** Application of P-SAECG to measurement of atrial activation 23

Annexes

A Cited references 24

B Bibliography 30

Documents
Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

Tables

1 Estimated value of the signal-averaged ECG combined with other noninvasive variables for predicting serious arrhythmic events after myocardial infarction 14
2 Prognostic value of the post-MI SAECG in the thrombolytic era 17

Figures

1 Representative architecture of current SAECG devices 3
2 The process of signal-averaged ECG recording and analysis 11
3 Odd ratios for risk of arrhythmic event after MI 14
4 Plot of the proportional distribution of patients relative to filtered QRS (fQRS) duration according to treatment assignment in randomized trial of late thrombolytic therapy 16
5 Survival curves displaying freedom from death or sustained ventricular arrhythmia in heart failure patients with normal or abnormal signal-averaged (SA) ECG and bundle branch block 19
6 Prediction of inducible ventricular tachycardia in patients with unexplained syncope, based on presence of single or combination noninvasive variables 21

© 2000 Association for the Advancement of Medical Instrumentation ■ AAMI TIR No. 23:1999

Documents
Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

Committee representation

Association for the Advancement of Medical Instrumentation
Electrocardiograph Committee

This technical information report (TIR) was developed by the ECG/Signal Averaging Working Group of the AAMI Electrocardiograph Committee. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was balloted, 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 Alan S. Berson, PhD, National Heart, Lung, and Blood Institute Robert E. Bruce, Medicomp David Daly, U.S. Food and Drug Administration Arthur R. Eddy, Jr., ConMed Corp. Stacy Gehman, Quinton Instrument Co. Paul Lander, University of Oklahoma Health Sciences Center George Moody, Massachusetts Institute of Technology David Mortara, PhD, Mortara Instrument Inc. Shankara Reddy, PhD, GE-Marquette Medical Systems William Saltzstein, Medtronic Physio-Control Corp. Jonathan Steinberg, MD, St. Luke's Roosevelt Hospital Roy D. Wallen, Pure Pulse Technologies
Alternates:	Robert J. Cangelosi, U.S. Food and Drug Administration

At the time this document was balloted, the committee's **ECG Signal Averaging Working Group** had the following members:

Cochairs	Paul Lander William Saltzstein Jonathan Steinberg, MD
Members:	Edward J. Berbari, PhD, Indiana University Alan Berson, PhD, National Heart, Lung, and Blood Institute Stacy Gehman, Quinton Instrument Company Paul Lander, University of Oklahoma Health Sciences Center Shankara Reddy, PhD, GE-Marquette Medical Systems William Saltzstein, Medtronic Physio-Control Corp. Craig Sellers, Spacelabs Burdick Mike Simson, MD, University of Pennsylvania Jonathan Steinberg, MD, St. Luke's Roosevelt Hospital Jerry Sweeten, Plastics One Inc. Sandy Weininger, U.S. Food and Drug Administration
Alternates:	Carole Carey, U.S. Food and Drug Administration

Acknowledgement

The ECG Signal Averaging Working Group gratefully acknowledges the contributions of former cochair Edward Berbari, PhD, and contributor Eric Chan, PhD.

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

© 2000 Association for the Advancement of Medical Instrumentation

Documents Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

Signal averaging

1 Scope

Signal averaging of the electrocardiogram (SAECG) was devised 25 years ago to reveal low-amplitude cardiac signals in the microvolt range on the body surface. It was originally used to detect His-Purkinje activity (A.1). However, in the next decade the methods for SAECG were refined and developed to determine the full extent of ventricular activation with the object of revealing delays relating to electrical instability of the ventricular myocardium.

The purpose of this report is to provide an understanding of the fundamental principles underlying SAECG methodology, to define terminology, and to review its potential for clinical application. It includes a discussion of some of the major pitfalls that must be avoided. This report is directed partly to those who have an interest in the clinical use of the SAECG but also to those who are considering the development of SAECG methodology in a medical device. The following topics are covered:

a) device architecture for data acquisition and processing;
b) beat selection and alignment;
c) ensemble averaging;
d) filtering, lead combination, and measurement;
e) clinical applications and emerging uses;
f) a list of publications for further reference;
g) terminology.

2 Definitions

For the purposes of this technical information report, the following definitions apply.

2.1 bandpass filter: A filter that will pass frequencies within a desired range but will attenuate all other frequencies (e.g., a 40– to 250–Hz filter would attenuate frequencies below 40 Hz and above 250 Hz).

2.2 baud rate: The number of bits per second that can be transmitted in a given computer system.

NOTE—When information is transmitted between two computer systems, each must be set to the same baud rate.

2.3 bidirectional filter: A type of digital filter that filters the signal in a forward direction from its beginning to its midpoint and then filters from the end of the signal in a backward direction to the same midpoint.

2.4 Butterworth amplitude filter: A type of filter known for its filter quality on small signals; the filter of choice for the vector magnitude and late potential detection.

2.5 corner frequency: The frequency or frequencies selected to define a filter band (e.g., 40– to 250–Hz Butterworth filter).

2.6 FFT: Fast Fourier Transform is a method by which a segment of time series data can be evaluated for its frequency components.

2.7 fiducial point: A reliable, stable reference point that allows multiple beats to be aligned for averaging.

NOTE—One fiducial point commonly used for SAECGs is the onset of the QRS or the time of maximum slope of the QRS.

2.8 filter: A device or software algorithm that passes information within signals of certain frequencies or frequency ranges while attenuating others.

2.9 finite impulse response (FIR) filter: A type of filter that relies only on previous input to generate its present output.

2.10 high pass filter: A filter that attenuates frequencies below a specified frequency (e.g., a 40–Hz high pass filter would attenuate all frequencies below 40 Hz).

© 2000 Association for the Advancement of Medical Instrumentation ■ AAMI TIR No. 23:1999

Documents
Document Sharing Hub
Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

2.11 high resolution: Having the ability to acquire, resolve, and analyze data in fine increments.

2.12 LAS 40: An abbreviation for low–amplitude signal below 40 uV.

NOTE—It references the duration of the signal below 40 uV measured on the vector magnitude.

2.13 low pass filter: A filter that attenuates frequencies above a specified corner frequency (e.g., a 250–Hz low pass filter would attenuate all frequencies above 250 Hz).

2.14 microvolt (uV): 1 /1,000,000 of a volt or 1/1,000 of a millivolt; represents 100th of a millimeter at standard ECG gain.

2.15 millivolt (mV): 1/1,000 of a volt.

2.16 negative predictive value: The probability that the patient does not have the disease if the test is negative.

2.17 noise: Any signal other than what is wanted.

NOTE—In signal averaging, noise consists of electrical signals, typically between 1 and 20 microvolts, contained in a surface ECG recording which originate primarily from electrode movement, muscular contraction, respiratory movement, and electronic equipment. Since noise signals occur randomly, attenuation occurs with the averaging process. The square root of the number of beats averaged represents the improvement in the signal-to-noise ratio (e.g., if 100 beats are averaged, the signal-to-noise ratio has been improved by a factor of 10).

2.18 orthogonal leads: Leads that are perpendicular to each other.

2.19 positive predictive value: The probability that the patient has the disease if the test is positive.

2.20 root mean square (RMS) voltage: The 'energy' content in microvolts contained under the curve or any selected portion of the curve created by the vector magnitude.

2.21 signal-averaged electrocardiogram (SAECG): The averaging together of multiple ECG cycles (see signal averaging).

NOTE—The cardiac electrical activity may then be processed in a variety of ways (e.g., time domain, frequency domain, etc.) for further analysis.

2.22 signal averaging: Using computer-based processing techniques, multiple R- (or P-) wave samples are averaged together to form one highly refined R- (or P-) wave complex.

NOTE—Nonrepetitive, random signals such as electrical noise are attenuated or eliminated.

2.23 vector magnitude: A graph created by taking the square root of the sum of $X^2 + Y^2 + Z^2$ where X represents the signal-averaged and filtered data from the X lead, Y the data from the Y lead, and Z the data from the Z lead.

NOTE—A vector summation of the high-frequency information is obtained from all leads. Squaring any signal always results in its being positive.

2.24 ventricular late potentials: Low-amplitude, high-frequency electrical signals which are found in the terminal portion of the QRS complex and which last a variable time into the ST segment.

NOTE—They appear to correspond to delayed, fragmented ventricular activation which has been observed with epicardial and endocardial electrogram recordings in patients with ventricular tachycardia. It is theorized that late potentials have the same anatomic substrate as reentry tachycardia.

2.25 X lead: A bipolar lead used for signal-averaged ECGs in which X+ is placed in the fourth intercostal space, midaxillary line, left side, and X- is in the same position on the right side.

2.26 Y lead: A bipolar lead used for signal-averaged ECGs in which the Y+ is placed on the proximal left leg and Y- is placed on the manubrium.

NOTE—Alternatively, the standard V-3 position for Y+ and left of the sternum or the suprasternal notch for Y- have been referenced in literature.

© 2000 Association for the Advancement of Medical Instrumentation ■ AAMI TIR No. 23:1999
Documents Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

2.27 Z lead: A bipolar lead used for signal-averaged ECGs in which the Z+ lead is placed in the standard V-2 position and the Z- is in a comparable position on the posterior chest.

3 State of the art of current SAECG device design

3.1 Introduction

All SAECG instrumentation currently being marketed are of similar construction and design. They vary primarily in the techniques used for signal processing, waveform measurements, and noise measurements. This section details a common architecture to be used for comparative purposes and summarizes the attributes of the current state of the art based on this architecture. Information content was contributed from major SAECG vendors.

3.2 Architecture

Figure 1 is a representative architecture of current SAECG devices. Note that it shares many common attributes with standard 12-lead ECG instrumentation.

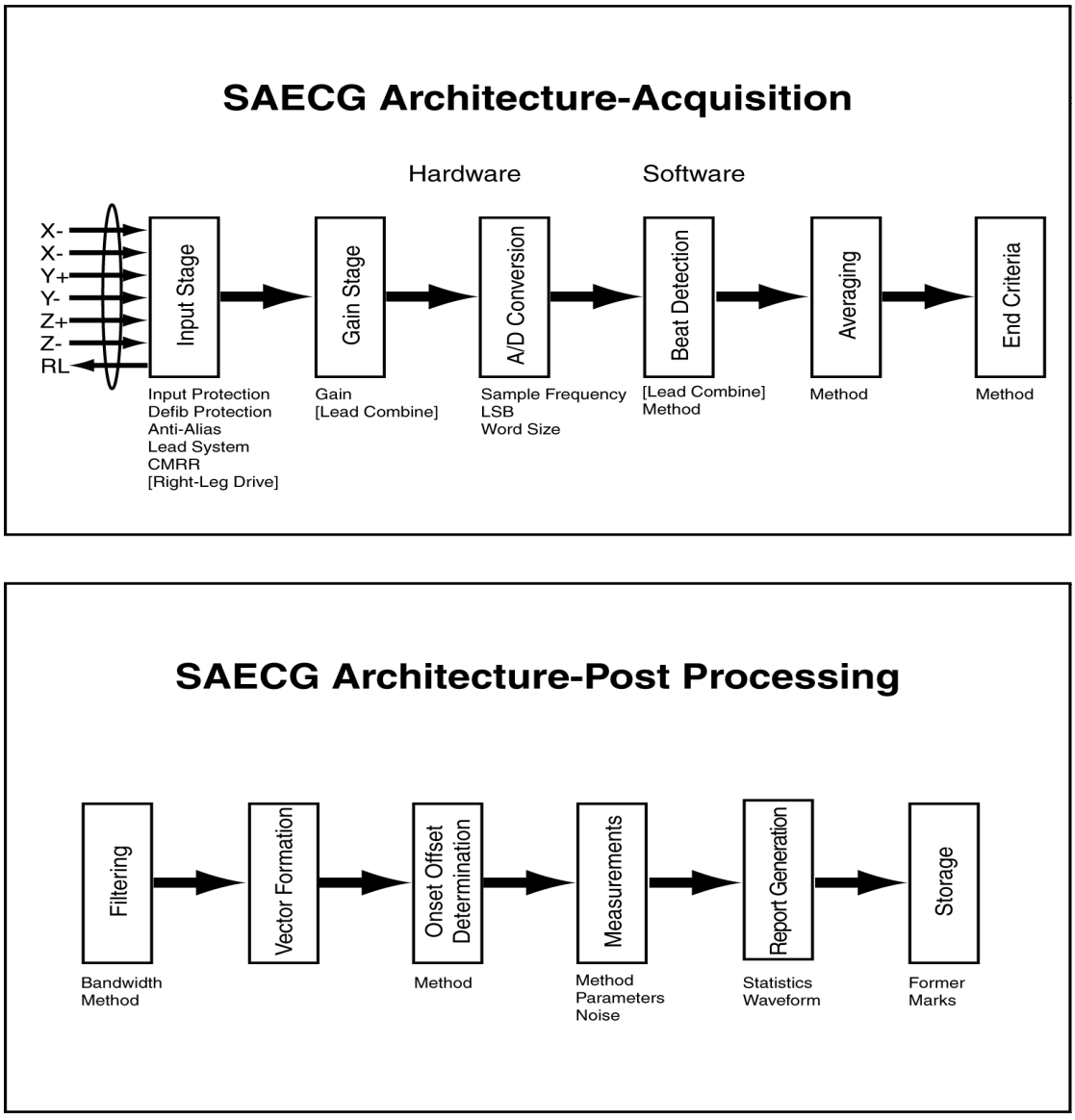

Figure 1—Representative architecture of current SAECG devices

Documents
Document Sharing Hub
Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.

3.3 Comparative table of specifications

Specification	Minimum	Typical	Maximum	Notes
Input Stage				
Input Protection	±6KV		±20KV	ESD, etc
Defibrillation Protection	Yes	360J		
Anti-Alias	Yes	300Hz		
RL Drive	None	Yes		
CMRR	120 dB	150 dB		RTI per AAMI ECG Spec, IEC 601-1, IEC 601-1-2
Electrodes		Ag/AgC1		
Lead System		Bipolar X, Y, Z; Frank X, Y, Z.		
Gain	100	1000	8000	RTI system gain
Lead Combine		Hardware; Software.		
A/D Conversion				
Sample Frequency	1000	1000	2000	Samples/second
LSB	0.3 µV	2.5 µV	2.5 µV	
Word Size	12 Bits	16 Bits	22 Bits	
Interchannel delay	0	10 µS	50 µS	
Signal Averaging				
Beat Alignment*		Correlation of QRS		
Exclusion of beats		Mismatch of QRS	Ectopic beats; Shorter R-to-R intervals; Wider QRS; Excessive Noise	
End Criteria Method		Number of beats	Noise level*	
Measurements/ Late Potential Parameters**		FQRSd, LASd, RMS40		
Report Generation				
Measurements and Statistics		FQRSd, LASd, RMS40; Number of beats; Noise level*.		
Waveforms		Unfiltered X, Y, Z; Filtered X, Y, Z; Vector magnitude		
Storage				
Data Content		Unfiltered X, Y, Z; Filtered X, Y, Z; Vector magnitude; Fiducial points; Statistics; Measurements	Raw Data	
Media		Floppy diskette;	Floppy diskette; Hard disk; Transmit	

* These features are elaborated further in section 3.4.

** ESD = electrostatic discharge; RTI = referred to input; FQRSd = filtered QRS duration; LASd = low-amplitude signal duration under 40 uV from the filtered QRS offset; RSM40 = root mean squared voltage in the terminal 40 milliseconds (ms) of the filtered QRS.

© 2000 Association for the Advancement of Medical Instrumentation • AAMI TIR No. 23:1999
Documents Document Sharing Hub

Full document details: AAMI TIR23:1999/(R)2019 Signal averaging, 1ed.