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Acquisition and use of physiologic waveform databases for testing of medical devices

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Acquisition and use of physiologic waveform databases for testing of medical devices

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Abstract: This report defines the nomenclature, ingredients, and principles needed to develop, annotate, evaluate, and use physiologic waveform databases in developing and testing medical devices.

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Committee representation

Association for the Advancement of Medical Instrumentation

Waveform Testing Committee

The AAMI Waveform Testing Committee developed this technical information report (TIR). 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 Waveform Testing Committee** had the following members:

Cochairs:	Carl A. Pantiskas
	Sandy Weininger
Members:	James J. Bailey, MD, National Institutes of Health
	Don Brodnick, Marquette Medical
	Richard Diefes, ECRI-MSLB
	Robert Donehoo, Critikon/Johnson & Johnson
	Stacy Gehman, Quinton Instrument
	George Moody, Massachusetts Institute of Technology
	William J. Murray, Siemens Medical
	Carl A. Pantiskas, Spacelabs Medical
	Cadathur Rajagopalan, PhD, Datascope Corp.
	William Saltzstein, Medtronic Physio-Control
	Kok-Swang Tan, PhD, Bureau of Radiation & Medical Devices Canada
	Lee Taylor, MD, Protocol Systems
	Sandy Weininger, U.S. Food and Drug Administration
Alternates:	David Browne, Critikon/Johnson & Johnson
	David Daly, U.S. Food and Drug Administration
	David Hengl, Siemens Medical
	William Midgette, 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.

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Foreword

The objective of the *Acquisition and use of physiologic waveform databases for testing of medical devices* technical information report (TIR) is to provide an integrated overview of the methodology, technology, and potential pitfalls of acquiring, annotating, reconstructing, and using databases for the testing of medical devices and algorithms. It reflects the conscientious efforts of a group of concerned health care professionals, biomedical engineers, device manufacturers, and government representatives to develop a reference document for those involved in developing medical instrumentation.

Waveform databases either can be a collection of digital files stored on disk or other media or can be continuous analog data stored directly on tape media. Digital databases are often used to directly test the performance of software algorithms. Both reconstructed digital databases and analog databases are used to test subsystems or complete systems. Both database forms are valuable in the testing of medical instrumentation and algorithms and have unique advantages and disadvantages. Care must be taken to ensure that the database that is acquired or chosen to test the instrument or algorithm is suitable for its intended purpose.

Continuous patient signals can be complex in size, shape, and timing. Designing waveform sequences that totally represent all possible continuous patient signals is not feasible. Therefore, the use of waveform databases that are collected from the clinical environment is a great advantage in verifying the accuracy and performance of medical instrumentation.

This TIR is written primarily for those who collect, annotate, distribute, use, or evaluate the use of databases for developing and testing medical devices. This report is intended as a reference document for anyone involved with waveform database testing. It must be reviewed and updated periodically to integrate progressive technological developments.

Introduction

Physicians and associated health care professionals need to know how diagnostic and monitoring medical devices work for each subpopulation they encounter, including both the healthy and the diseased. Therefore, similar devices from different manufacturers must perform in a similar manner. If these health care professionals understand the common characteristics of different devices, they can predict how devices will work in particular cases and can rely on the validity of the results.

Medical device standards unify such needs and codify relevant device characteristics. A standards group evaluates a device in each aspect of its overall functionality. For standards purposes, devices are classified according to their specific medical purpose (e.g., the diagnostic electrocardiograph). Generally, such standards groups devise tests for multiple, diverse, and often quite subtle characteristics. Each individual test is then designed to quantify one or more particular aspects of the characteristics of that specific class of medical device.

All standards testing is necessarily parametric because each test quantifies some aspect of a device's characteristics. Even verification of a required label is dichotomized as "acceptable" or "not acceptable" if the device is physically inspected for conformity.

Traditional testing of medical devices has focused on certain device characteristics such as input impedance, frequency response, dynamic range, and common mode rejection. Within the confines of traditional engineering, these characteristics are easy to measure. Relevant medical device standards have codified acceptable ranges or limits for such characteristics. Assessing conformance within these limits is relatively straightforward.

Once the standard engineering parameters are measured, a device can be subjected to signals and loads that simulate actual applications to real patients, and the results can be evaluated. This process is the basis of operational testing. Even though such tests are parametric, they use simulated reality to assess actual clinical utility. Common operational tests include tests for accuracy, sensitivity and specificity of event detection, noise stress testing, and defibrillation protection and recovery.

Computerized medical devices that run diagnostic and classification algorithms on sampled analog signals are becoming increasingly prevalent. Tests for such devices demand careful extensions to the already established principles of traditional test design. For example, devices that actively sense and interpret a patient's condition must be tested for their ability to recognize certain clinical patterns (e.g., a cardiac monitor must sense the onset of ventricular fibrillation (VF) and respond with its highest priority alarm). Synthesizing waveform sequences that totally represent all possible continuous patient signals is not feasible. Hence, the need for properly documented databases of representative waveforms for testing medical devices becomes evident. For example, electrocardiogram (ECG) rhythm annotations can be determined by consensus review (e.g., MIT-BIH databases), whereas left ventricular hypertrophy requires non-ECG clinical evaluation (e.g., CSE database).

Waveforms that are used for assessment of such responses must be documented clinically or validated by expert medical opinion, according to established medical practice. Specific procedures used in validating such waveforms should be based on standards of medical practice for that purpose. Thus, if consensus review of computer-interpreted patient waveforms were medically accepted, it would be inappropriate to demand independent blind validation by isolated physicians who would be deprived of the preliminary computerized scan and interpretation. The same would be true for the CSE diagnostic database that was documented by non-ECG means, namely angiography, echocardiography, or cardiac enzyme studies.

All tests have characteristic associated costs and information yields, which are determined by the nature of each device and its intended use. Good medical device standards specify tests that appropriately evaluate the characteristics under scrutiny, yield repeatable and clinically relevant results, and impose reasonable costs on those who perform the tests.

Acquisition and use of physiologic waveform databases for testing of medical devices

1 Scope

This document is intended to define the nomenclature, ingredients, and principles to develop, annotate, evaluate, and use physiologic waveform databases for developing and testing medical devices. The TIR identifies issues that should be addressed in the design and development of a physiologic database. It discusses many major pitfalls that must be avoided. Annexes are included that describe several databases in detail. The database profiles that are presented here are intended to serve as a guide in the design, development, acquisition, and documentation of future waveform databases that may be used in the development and evaluation of medical devices and algorithms.

This report considers continuous electrophysiologic signals such as the electrocardiogram and electroencephalogram, as well as nonelectrophysiologic signals such as invasive blood pressure and respiratory tachograms. Medical devices that deal with intermittent data such as thermodilution cardiac output or oscillometric noninvasive blood pressure are not covered in this initial report, but may be included in a later report.

2 Normative reference

2.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms.* AAMI EC57. Arlington (Vir.): AAMI, 1998. American National Standard.

3 Definitions

For purposes of this AAMI Technical Information Report, the following definitions apply:

3.1 ADC: Analog-to-digital converter.

3.2 aliasing: The source of distortion that may result when a signal is sampled at less than the Nyquist rate.

NOTE—Energy from higher-frequency signal components—higher than one-half the Nyquist rate—are folded into frequency components of less than one-half the Nyquist rate.

3.3 CSE: Common standards for quantitative electrocardiology.

3.4 DNRi: See instantaneous dynamic range.

3.5 FFT: Fast Fourier transform.

3.6 impedance: A measurement (in ohms) of electrical opposition to the flow of current in a given circuit.

3.7 instantaneous dynamic range (DNRi): The ratio of the largest signal a system will see to the smallest signal, usually the noise floor.

3.8 LSB: Least significant bit.

3.9 loop area: The actual surface area of a planar loop encircled by the signal pickup leads and the signal source.

NOTE—The amount of noise electromagnetically induced is directly proportional to the area of this loop. Therefore, its minimization is critical. This phenomenon applies to magnetic field coupling only.

3.10 morphology: The appearance of a waveform when viewed in the time domain or, more simply put, the waveform's shape.

3.11 Nyquist rate: The sample rate required to preserve signal content without distortion; at least two times the highest frequency component of the signal.

