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

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.

Keywords: waveform, physiologic, algorithms, arrhythmia

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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:

<i>Cochairs:</i>	Carl A. Pantiskas Sandy Weininger
<i>Members:</i>	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
<i>Alternates:</i>	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.

3.12 oversampling: An analog I/O (input oversampling) technique whereby samples are either read in or reproduced at a rate equal to some constant (the interpolation factor) times the fundamental sample rate.

NOTE—This technique is used to suppress input and output aliasing and has no bearing on ratios between signal frequency components and the recording's sample rate. It can be more clearly stated as either input oversampling or output oversampling.

3.13 quantization error: One-half the analog value range associated with the least significant bit in a system.

NOTE—For example, a 12-bit converter has 4,096 discrete states possible. If it is applied to a signal with a ± 5 -volt range, there is a step size equal to 10 times the total voltage range divided by 4,096, for nearly 2.44 mV per step. Thus, any analog voltage within ± 1.22 mV of the center of each value range will be associated with exactly the same digital representation. This uncertainty is associated with finite precision quantization. Its range is twice the quantization error and is sometimes referred to as the uncertainty bit size.

3.14 power spectrum: A representation of the energy content per unit frequency. The accuracy of the estimation of a population's power spectrum depends on an ensemble average.

3.15 SNR: Signal-to-noise ratio.

3.16 sample rate: The rate at which the instantaneous value of an analog signal is quantized to one of the N discrete voltage levels an ADC can resolve.

3.17 VF: Ventricular fibrillation.

4 Database requirements

The following requirements have implications for database development and the use of databases use in assessing medical device performance, and should be considered when planning to build a database.

4.1 Intended use of database

The intended use of a waveform database determines its requirements and system specifications. For example, a database that is intended for training purposes needs only enough fidelity so that users can interpret the waveforms. A higher-fidelity recording system may be needed for a database that will be used for algorithm testing without reconstruction to the analog domain. If the database is used for system verification testing, then the demands on the fidelity of the recording and simulation system may be much higher. In a similar manner, the requirements for database annotation may be quite different for each intended use. A mismatch between the intended use and the resultant requirements may produce a system whose testing results are invalid or whose costs far exceed the benefits derived.

4.2 Clinical requirements

It is impractical to collect data until every expected event has been captured. Many times, it is sufficient to synthesize waveforms to augment the recorded physiologic data. This approach should be discussed before database development to facilitate appropriate decisions at each stage.

4.2.1 Population

Inclusion and exclusion criteria must be established for each clinical variable and must be traceable to the database's intended use. For example, using a database of adult signals to assess the performance of infant monitors is incorrect.

4.2.2 Study design

The study design depends on how the patients are stratified with respect to risk or disease categories. An important design problem is how to collect a sufficient number of cases in each category so that classification algorithms can be expected to achieve reasonable statistical power and accuracy. Further, if the design cannot identify signals that are pathognomonic for each category, then signal characteristics must, at least, be distinctive enough to separate the categories of patients, again, with reasonable statistical power. The design should anticipate whether parameters that are extracted from the signals will be used in a stepwise, discrete fashion or as continuous variables.

4.3 Engineering requirements

The characteristics of each signal (e.g., dynamic range, resolution, mode floor, measurement precision, and precision of temperature measurement) to be collected must be specified. The duration of data collection must be specified. Special needs in the clinical setting that may affect the architecture of the equipment must be identified.

4.4 Annotation requirements

There must be a set of rules for analyzing the recorded physiological signals, a method of administering the rules, and a system for incorporating the results into a waveform database. These rules guide the referee annotators to mark and characterize events of interest in the recorded data; these *a priori* rules must be specifically tailored to the database. The data in the database should not be used to determine the rules. The annotation methodology and implementation may place constraints on the engineering of the signal acquisition system and must be established in the planning stage before any development.

4.5 Archive requirements

The methodology for archiving the data should be considered in the planning stage before any data collection. The archive should also contain documentation of the software and hardware data acquisition systems, data formats, and methods for recovering data. Additionally, the archive database storage, maintenance, and ownership should also be addressed.

5 Waveform acquisition and synthesis

This section describes the procedures for recording waveforms within the database and developing a system to play back the waveforms.

5.1 Overview

Any database use strongly depends on the quality of the equipment that is used to record (acquire), store, and reproduce the physiological signals of interest. At each step of the process, care must be taken to ensure that the signal's integrity is maintained, particularly for databases that ultimately will be used to simulate a patient. In short, the signal that is recorded and stored in a database must be reproducible with sufficient accuracy to ensure that the device or algorithm to be tested is presented with an adequate representation of the original physiologic signal.

The validity of a multiparameter monitor test method depends on the capability to record (acquire) and reproduce high-quality physiologic signals without introducing significant error. As mentioned previously, acquisition fidelity should match the intended use of the database. A high-fidelity acquisition system would be required for reproducing physiologic signals from CD-ROM media to drive the transducer(s) of a monitor under test. However, a lower-fidelity recording system may be designed if the waveforms will be used only for display during training exercises. In either case, care must be taken at each step of the design process to ensure appropriate signal integrity.

The overall architecture of the database's data acquisition system profoundly affects the accuracy of the collected data and the reproduced waveforms during playback. Therefore, two initial tasks required to develop and to use a physiologic database are to determine the general signal requirements and to establish system specifications to meet them.

5.2 Signal issues and requirements

This section discusses the significance of general signal issues, the requirements of system design, and their effect on specifications of the system's signal acquisition, storage, and reproduction subsystems. Sufficient background theory is given where needed to justify the selected implementation.

Four signal acquisition and reproduction issues have been identified as being important for testing physiologic monitors and algorithms: distortion, relative timing (skew), maximum uninterrupted duration, and frequency translation.

5.2.1 Distortion

The most important design goal for a waveform recording and playback system is preserving the signal's waveshape. Knowledge of the distortion introduced by the signal processing system is of primary interest. A distortionless system can be described in the time domain by stating that the waveshapes must be the same between the input and output. The output of a distortionless system can be expressed as shown in equation 1,

$$y(t) = Kx(t - t_d) \quad (1)$$

where t is a term for time, K is a gain term, and t_d is a delay term and $K = 1$ and $t_d = 0$. Equation 1 demonstrates that the input and output waveforms may vary in amplitude and time reference, but the output waveshape is a magnified and time-shifted version of the input waveshape, except in the ideal distortionless case. In realizable systems, some distortion in either amplitude or time always exists. Ideally, the waveform recording and playback system should minimize the effects of these distortions.

Visual checks of waveshape are usually not sufficient to validate that a waveform was recorded and reproduced (played back) with adequate signal fidelity, because the human eye is very tolerant of distortion. A more analytical

measurement technique must be used. Time domain correlation is sometimes used, but the resulting correlation coefficient does not provide sufficient information to assess electronic system performance. The majority of signal acquisition circuits process signals according to their frequency content. Spectral distortion definitions are often used instead because they provide more meaningful information. Frequency domain measurements are sensitive enough to show signal degradation that would otherwise be undetectable using time domain measurements.

In the frequency domain, distortion refers to the alteration of signal amplitude and phase spectral content. To obtain an accurate and meaningful waveform database, the physiological signal's original spectral content must be preserved. This preservation ensures that the database is sufficiently general to test any manufacturer's medical device or algorithm. Similarly, the spectral content of any digitized signal must be preserved as much as possible upon playback in order to produce an accurate test and to obtain a fair measure of monitor performance.

To analyze signal distortion, some sort of spectral analysis must be performed on each channel during the design and testing of the signal acquisition and playback systems. Commercial spectral analyzers are available and work directly on an analog input signal. In practice, the development of signal playback systems typically lags behind development of signal acquisition systems. Thus, signals recorded with the acquisition system cannot be played back in analog form until simulators are developed, so some other means must be used for analysis. Given that the signals exist in digitized form, spectral analysis must be done using digital signal processing techniques (such as a windowed FFT) on a computer. Commercial software exists that can accomplish this task, but care must be taken to apply it properly.

5.2.2 Distortion classifications

Signal distortion can occur by changing the amplitude and phase of existing spectral components. The major types of distortion that affect waveform databases tend to be either linear or nonlinear. The primary difference between these two types of distortion is that linear distortion has a constant effect on the output signal while nonlinear distortion has varying effect on that signal. Other types of distortion (e.g., harmonic) rarely affect waveform databases and are ignored in the following discussion.

5.2.2.1 Linear distortion

Linear distortion occurs when the amplitude or phase of the signal's spectral components alter the output signal's waveshape as described in equation 1. In a distortionless system, the amplitude or phase change that occurs is 0.

Maintaining proper system frequency response is important. This maintenance places restrictions on the shape, magnitude, and phase response characteristics for the system. In particular, distortionless transmission requires flat magnitude and linear phase response within the signal passband of interest. Thus, a linear system can be described by a frequency domain transfer function.

The simplest approach to eliminate linear distortion is to design a signal acquisition system that provides a flat magnitude and linear phase response within the signal's passband of interest. Linear distortion can also be reduced or eliminated through the use of filter networks that provide equalization or spectral balancing. These techniques add complexity and are usually reserved for cases where the transmission medium is distorting and cannot be controlled.

5.2.2.1.1 Amplitude distortion

Amplitude distortion generally results when the spectral magnitude response of the signal processing system is not flat within the passband of interest, effectively filtering the signal. This filtering is commonly quantified by a "flatness" specification that can be determined by applying a swept sinusoid to the system input and by measuring the corresponding output amplitude versus the frequency. Minimizing the passband variation reduces the amount of amplitude distortion that is introduced.

5.2.2.1.2 Phase distortion

Phase distortion generally refers to the nonlinear spectral phase response within the passband of interest of a signal processing system. In the time domain, the system is often characterized by applying a step function to the input and monitoring the output step (or transient) response. Although the step response is influenced by the amplitude distortion, any overshoot or ringing (which determines the settling time) that occurs is a result of a nonlinear system phase response and, thus, provides a relative indication of the amount of phase distortion.

An alternative method that is often used for design purposes defines phase distortion in terms of delay distortion. Specifically, group delay can be determined from the derivative of the system phase response with respect to frequency:

$$T_g = - \frac{d\phi}{d\omega} \quad (2)$$

Equation 2 shows that a distortionless system with a linear phase response (with a negative slope) also has a constant group delay. This finding means that all spectral components are delayed by the same amount of time as they travel through the system. Minimal spectral phase distortion is desirable so that the relative skew between two signals is not frequency dependent and is a function only of time delays through the system. Having minimal spectral phase distortion allows skew to be corrected after acquisition to within the time resolution of the system.

5.2.2.2 Nonlinear distortion

Nonlinear distortion occurs when spectral components appear at the output of a system but were not present in the input signal. All linear systems have some amount of nonlinearity, so extraneous spectral content is usually present. Nonlinear distortion cannot always be reduced or eliminated once it is created, so system output spectral content must be evaluated during the design process.

The amount of distortion in a nonlinear system is generally analyzed by measuring the magnitudes of all extraneous spectral components that are present at the system output but that were not present in the input signal. This distortion includes spurious (nonharmonic) and harmonic-related components. For test purposes, the input signal that is used usually has simple spectral content so that the input and output components may be easily distinguished. Such signals include single sinusoids (for harmonic distortion testing) or summed sinusoids (for intermodulation distortion testing). Sinusoidal signals are also virtually immune from linear distortion. Note that, in each case, these sinusoidal signals must be monochromatic (e.g., each must be a pure sinusoid composed of a single frequency and without modulation).

Depending on the source of distortion, the maximum allowable magnitude of any extraneous component for each recording channel may be obtained from either the instantaneous or the total dynamic range for the associated physiologic signal. The instantaneous dynamic range refers to the maximum likely AC signal variation, whereas the total dynamic range refers to the maximum possible signal variation (including the DC component). Relative to full-scale range, any extraneous amplitude components must be attenuated below the QLSB (quantization least significant bit) level for the dynamic range of the signal of interest (this assumes that the analog-to-digital (A/D) converter resolution for the channel has been matched to the signal resolution). For example, a signal with a specified dynamic range of 12 bits should ideally have all extraneous components attenuated by at least 78 dB $[(6 \text{ dB/bit} \times 12 \text{ bits}) + 6 \text{ dB} = 78 \text{ dB}]$. Another way of stating this requirement is that the filter's reject band should be at least 78 dB below that filter's passband. Of course, this specification becomes more difficult to meet as the dynamic range increases.

The three principle sources of nonlinear distortion (e.g., amplifier saturation) in digital signal acquisition systems are nonlinear impulse responses, detector or device coupling (e.g., electrodes), and frequency aliasing (inadequate sampling rate).

5.2.2.2.1 Nonlinear transfer characteristic

Nonlinear systems have time domain transfer characteristics that alter the data's amplitude and frequency domain characteristics in a nonlinear fashion. Because of this effect, the output gain and frequency cannot be predicted from the transfer function itself. Recursive systems with feedback mechanisms are examples of this type of nonlinear system.

The amplitude of any extraneous spectral components that are generated by a nonlinear transfer characteristic should not exceed the amplitude of the input test signal. Therefore, the amplitude of all extraneous components should be below the instantaneous dynamic range of the signal of interest.

5.2.2.2.2 Coupling

Stray coupling of unwanted signals into the signal of interest may be considered a type of nonlinear distortion. The coupled signals may be from adjacent system channels (crosstalk) or from extraneous sources (internal clock noise, 60-Hz pickup, etc.). This type of interference can be minimized with proper isolation, shielding, and grounding techniques.

It is possible for the coupled amplitude level from these extraneous sources to exceed the amplitude of the desired signal. Ideally, the amplitude of any unwanted signal's spectral components should be below the total dynamic range of the signal of interest. This result is difficult to achieve for wide dynamic range systems.

5.2.2.2.3 Aliasing

Improper sampling can create nonlinear distortion when any of the rules of digital sampling theory are violated. This type of distortion is impossible to correct with postprocessing once a signal has been digitized, so the use of proper sampling techniques is very important.