American National Standard

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Standard communications protocol for computer-assisted electrocardiography

AAMI
Advancing Safety in Medical Technology

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A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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Standard communications protocol for computer-assisted electrocardiography

Developed by
Association for the Advancement of Medical Instrumentation

Approved 11 May 2001 and reaffirmed 19 September 2013 by
American National Standards Institute, Inc.

Abstract: This standard specifies the content and structure of information for interchange between digital electrocardiographs (ECG carts) and computer ECG management systems, as well as other computer systems where ECG-related data can be stored. Standard data formats are specified for demographics, ECG rhythm data, reference beats, global measurements, and interpretation. Practical compression of the ECG rhythm data is also standardized. This standard also specifies the two-way digital transmission of remote requests and results between digital ECG carts and heterogeneous computer systems (hosts). It specifies conventions required for cart-to-host and cart-to-cart interchange of patient data. Compliance with this standard is defined separately for data format, query messaging, and data transport.

Keywords: electromedical equipment, diagnostic, monitoring, communications protocol, computer-assisted ECG, ECG

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Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph (ECG) Committee

This standard was developed by the ECG/Standard Communications Protocol (SCP) Working Group of the AAMI ECG Committee. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

The **AAMI ECG Committee** has the following members:

Cochairs:	James J. Bailey, MD
	David Mortara, PhD
Members:	James J. Bailey, MD, National Institutes of Health
	David Daly, U.S. Food and Drug Administration
	Arthur R. Eddy, Jr., Conmed Corp.
	Stacy Gehman, Quinton Instrument Company
	Paul Lander, University of Oklahoma Health Science Center
	George Moody, Massachusetts Institute of Technology
	David Mortara, PhD, Mortara Instrument
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The committee's **ECG/Standard Communications Protocol (SCP) Working Group** has the following members:

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	Ward Silver, Medtronic – Physio Control
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	Steve Duke, Medtronic – Physio Control

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 document represents work carried out by the Standard Communications Protocol Working Group of the AAMI Electrocardiograph (ECG) Committee, based on CEN's prENV 1064, "Standard Communications Protocol for Computer-Assisted Electrcardiography".

Development of a universal ECG transmission protocol was first started during a series of discussions involving computerized electrocardiograph manufacturers (principal participants included Marquette Electronics, Mortara Instruments, Hewlett-Packard, Compumed, Burdick, and Siemens) and the United States Veterans Administration in 1986 and 1987. The results of these discussions, the so-called "Universal Protocol," were used as the starting point in AIM's SCP-ECG Project.

In 1989, the Advanced Informatics for Medicine (AIM) Project Nr 1015, entitled "A standard communications protocol for computerized electrocardiography" (SCP-ECG) was initiated. The project team consisted of six main SCP-ECG partners (J.L.Willems, Leuven; Chr. Zywietz, Hannover; P. Rubel, Lyon; J. H. van Bemmel, Rotterdam; R. Degani, Padova and P. W. Macfarlane, Glasgow) and representatives from manufacturers of computerized electrocardiographs (including Cardionics, Elettronica-Trentina, ESA-OTE Biomedica, Fukuda-Denshi, Hellige, Hewlett-Packard, Marquette Electronics, Medis, Mortara Instruments, Mortara-Rangoni, Nihon-Kohden, Picker-Schwarzer, Schiller, Siemens-Elema [also representing Burdick]) and a number of program developers, as well as users from different universities. The resulting document, prENV 1064 was prepared by the members of Project Team 007 of CEN/TC 251 (J.L.Willems, Project Team Leader; P. Rubel & Chr. Zywietz, Core Team; and Extended Team members R. Bedini, K. Hedstrœm, P. W. Macfarlane, C. Monroe, F. Pinciroli, L. Rystrœm, and S. Scheirman) and draft version 1.0 was published February 9, 1993.

The current draft proposal represents the contents of ENV 1064, updated to incorporate the comments and changes recommended by the AAMI SCP-ECG WG. Over the course of three meetings, the first January 27, 1997 in Washington, DC, the second April 24-25 in Palm Coast, Florida, the third June 7, 1997, in Washington DC, the AAMI SCP-ECG Working Group discussed and proposed changes to the CEN prENV 1064 document. These changes, captured in Revision 1.0 of the AAMI draft, reflected the findings of the WG members during implementation of the protocol, and were intended to address shortcomings and inconsistencies in the original document. Comments were reviewed by the AAMI SCP-ECG WG members and the parent AAMI ECG Committee members, and Revision 1.1 of the draft, incorporating these recommendations, was presented to CEN on August 19, 1997. Over the course of three more AAMI SCP-ECG WG meetings in Orlando, Florida, November 6-7, 1997, Keystone, Colorado, April 23-24, 1998, and Cleveland, Ohio, September 12-13 1998, a new version of the then labeled Annex D (Compliance) was prepared and refined. This, plus additional changes resulting from comments on the earlier version, comprised Revision 1.2 of this draft. Revision 1.2 was reviewed at an AAMI-SCP WG meeting in Boston, Massachusetts on June 5, 1999, and recommended changes, including the reordering of the Annexes so that all normative annexes precede any informative annexes, were incorporated into Revision 1.3, dated September 11, 1999.

Current voting members of the AAMI SCP-ECG WG are: Stacy Gehman, Industry Co-Chair, Quinton Instrument Co.; Robert Bain, Johns Hopkins Hospital; Alan Berson, NIH NHLBI; Damon Coffman, Instromedix; Matthew Connell, Burdick; David Geraghty, Fukuda Denshi America; Charles Ho, FDA/CDRH; Peter W. Macfarlane, Univ. of Glasgow; Charles Monroe, Hewlett-Packard; Shankara Reddy, GE Marquette Medical Systems; Johann-Jakob Schmid, Schiller AG; Ward Silver, Physio Control; Christoph Zywietz, Medical School of Hannover.

Other participating members of the WG include: Stig Andersson, Siemens-Elema; James Bailey, NIH; Eric Brinster, Quinton Instrument Co.; Fabrizio Conforti, Elettronica Trentina; Steve Duke, Physio Control; Ronald Fischer, Medical School of Hannover; Kurt Hedstrom, Siemens-Elema; Ed Jones, GE Marquette Medical Systems; Kevin Katzenmaier, 3M Health; Gary Laube, Burdick; Cesare Malossi, Elettronica Trentina; Gordon Neff, Datascope; Paul Rubel, INSERM; Eugene Salber, Braemar; Glenn Sherman, Instromedix; Katherine Stankus, Spacelabs Medical.

The AAMI-SCP Working Group gratefully acknowledges the extensive work of Charlie Monroe, of Hewlett-Packard, as editor of the AAMI-WG version of the SCP document.

Note: Participation by the United States of America Food and Drug Administration representatives in the development of this standard does not constitute endorsement by the United States federal government or any of its agencies.

Introduction and field of application

The electrocardiogram (ECG) is a recording of voltage changes transmitted to the body surface by electrical events in the heart muscle, providing direct evidence of cardiac rhythm and conduction, and indirect evidence of certain aspects of myocardial anatomy, blood supply and function. During its propagation to the surface, extracardiac tissues may intervene and influence the ECG.

Electrocardiography has been used for many years as a key, non-invasive method in the diagnosis and early detection of coronary heart disease, which is the leading cause of mortality in Western countries. In 1993, it was estimated that more than 100 million standard ECGs are recorded yearly in the European Community (EC) for routine diagnostic and screening purposes at an estimated cost of more than 1.2 billion ECU per year.

Almost all newer electrocardiographs nowadays use digital recording, interpretation and communication techniques. These stand-alone, microcomputer based machines can be connected to each other, and to larger minicomputer based management servers for long-term storage and serial comparison. To this end, various manufacturers have used different techniques.

It is in the general public interest for users not to be restricted in their options by incompatible technical features and services of different systems. ECG processing is increasingly being integrated with various other data processing in health care. This evolution shall have considerable impact on the storage and communication of ECG data. There are many different end-users who for different purposes (support of patient care, management, research and education) want to obtain a copy of the signal data, of the interpretive report and/or measurement results. Being one of the very first systems for medical decision support, computerized ECG interpretation stretches from departments of cardiology in hospitals, to general practitioners in primary care and health care centers. In life-threatening acute myocardial infarction, ECGs are being used in ambulances by paramedical personnel to assess the necessity for administering thrombolytic agents, with long-distance monitoring whenever possible.

To enable the exchange of information between various systems it was of utmost importance that a standard communications protocol for computer-aided electrocardiography (SCP-ECG) had to be established, as defined in this document. The primary aim of this standard is to specify a data format and means for transmitting ECG reports and data from any vendor's computerized ECG recorder on a direct connected serial line to any other's vendor central ECG management system. The same standard should also allow standardized transmission of digitized ECG data and results between various computer systems.

Under the standard communication protocol (SCP) the contents and format of the ECG waveform data and the measurements from ECG devices of different manufacturers are not expected to be identical. As a result, the determination of the suitability of a device and/or system for any particular application remains with the user/purchaser. The following possible uses of ECG records require special attention:

- Serial comparison of ECGs and interpretations
- Plot formats of ECGs
- Maintaining audit trail of edits
- Bi-directional communication and remote query.

The user is cautioned to make sure that the data contents and format of the waveform data, measurements, and the interpretive statements meet his or her specific needs. If more than one type of ECG devices and/or database management systems are interconnected, the user is also advised to verify with the manufacturers that the data from different systems are compatible with each other and with the user’s needs.

In order to understand this standard, the reader needs some basic understanding of electrocardiology, electrocardiography and signal processing.

This standard relates to the conventional recording of the electrocardiogram, i.e. the so-called standard 12-lead electrocardiogram and the vectorcardiogram (VCG). Initially, the electric connections used for recording the ECG were made to the limbs only. These connections to the right arm (RA), left arm (LA), left leg (LL) and right leg (RL) were introduced by Einthoven. The electrical variations detected by these leads are algebraically combined to form the bipolar leads I, II, and III. Lead I, for example records the difference between the voltages of the electrodes placed on the left arm and the right arm. The unipolar electrocardiographic leads (aVR, aVL, aVF and the precordial leads V1 to V6) were introduced much later, starting in 1933. In these leads, potentials are recorded at one location with respect to a level which does not vary significantly in electrical activity during cardiac contraction. The "augmented" limb lead potentials are recorded with reference to the average potential of (L+F), (R+F) and (L+R) respectively. The unipolar chest leads are recorded with reference to the average potential of (RA+RL+LL)/3 which is called the Wilson "central terminal" (CT). In vectorcardiography recordings are made of three mutually perpendicular leads, running parallel to one of the rectilinear

coordinate axes of the body. The axes are the X-axis going right to left, the Y-axis with a top to bottom orientation, and the Z or front to back axis.

In some research centers, so-called body surface maps are obtained by placing many (from 24 to 124 or even more) closely spaced electrodes around the torso. This standard has not been designed to handle transmission of such recordings, although future extensions could be made to this end. The standard has also not been designed to transmit specialised recordings of intracardiac potentials or of the so-called Holter or other long-term ECG recordings made for monitoring cardiac rhythm. This standard also does not address exercise ECG recordings.

ECG computer processing can be reduced to 3 principal stages:

1. Data acquisition, encoding, transmission and storage;
2. Pattern recognition and feature extraction, i.e. ECG measurement;
3. Diagnostic classification.

In each of these stages there are important needs for standardization and quality assurance testing. The scope of the standard is confined to the first of these three stages.

The various data sections that shall be transmitted by means of the standard ECG communications protocol are defined in Clause 5 of this Standard.

Minimum requirements for data encoding and compression are defined in Clause 6.

The compliance categories defined in ANNEX B provide users and manufacturers of ECG devices and/or systems with a relatively simple codification of SCP-ECG related features and information content that may be provided by a specific device. Compliance is defined separately for data format, query messaging, and data transport. Four Data Format Categories have been defined based on information content as follows:

Category	Data Sections Required [1]	Content Description
I	0, 1, 7, 8	Demographics, global measurements and interpretation
II	0, 1, 2, 3, 6, (7), (8)	Demographics and ECG rhythm data [2]
III	0, 1, 2, 3, 5, (7), (8)	Demographics and reference beats [2]
IV	0, 1, 2, 3, 4, 5, 6, (7), (8)	Demographics, ECG rhythm data, and reference beats [2]

Note 1: All devices stating a SCP-ECG Data Format Category import data sections 0, 1, 7, 8. All Categories may have additional sections added (e.g. 9, 10, 11). A device may export at more than one Category. Manufacturer specific data shall be optionally included only in manufacturer specific fields, bytes and data blocks that have been defined in the standard. Reserved, unspecified and undefined fields, bytes or data blocks will not be used for manufacturer specific data.

Note 2: (7) and (8) mean that these data sections are optional for export.

For a particular device, a SCP-ECG compliance statement lists Data Format Category(ies) for export (i.e. acquiring and making available a SCP-ECG record) and import (i.e. accepting, and making available to a user, a SCP-ECG record). A device may also state its ability to transfer (i.e. making available a SCP-ECG record without changing its data format, for example, exporting a record that was previously imported). (These terms are precisely defined in ANNEX B for the purpose of this standard).

Clause 7 specifies query messaging, and Clause 8 specifies data transport. A device should state one of three options: “Query Messaging and Data Transport not supported”, “Query Messaging supported”, or “Query Messaging and Data Transport supported”. It is recognized that other mechanisms for transfer of a SCP-ECG formatted file exist. This standard neither restricts nor supports use of any mechanism other than SCP-ECG Query Messaging and Data Transport defined in Document Clauses 7 and 8.

The selection and definition of ECG specific high-level syntaxes for transfer of messages and data between host-to-hosts, such as EDIFACT or ASN.1, are beyond the scope of this standard.

Standard communications for computer assisted electrocardiography

1 Scope

This standard covers the two-way digital transmission of remote requests and results between digital electrocardiographs (ECG carts) and heterogeneous computer systems (hosts). It documents the common conventions required for the cart-to-host as well as cart-to-cart interchange of specific patient data (demographic, recording...), ECG signal data, ECG measurement and ECG interpretation results.

This standard specifies the content and structure of the information which is to be interchanged between digital ECG carts and computer ECG management systems (ECG DBMS), as well as other computer systems where ECG data can be stored. It enables any two such systems to establish a logical link for communicating ECG related data in a standard and interpretable form.

2 Normative references

CCITT Blue Book, ed. 1988, Volume VIII.2., Recommendations for X.25 and Specifications for the CCITT-CRC Calculations

CCITT Blue Book, ed. 1988, Volume VIII.1., Specifications for the V series, including XMODEM

GB 2312-80 Code of Chinese Graphic Character Set for Information Interchange - Primary Set

ISO 2022 Information Processing - ISO 7-bit and 8-bit coded character sets- With code extension techniques (1986) . For all text fields the limited conformance to the ISO 2022 standard shall be applied, as described in ANNEX A.

ISO-8859 Information Processing - 8-bit single-byte coded graphic character sets.

ISO 2375 Data processing - Procedure for registration of escape sequences.

ISO 646 Information processing - ISO 7-bit coded character set for information interchange

ISO 4873 Information processing - ISO 8-bit code for information interchange – Structure and rules for implementation.

ISO 6429 Information processing - ISO 7-bit and 8-bit coded character sets – Additional control functions for character-imaging devices.

ISO 60646 Unicode

IEC 601-1 Safety of Medical Electrical Equipment, Part 1. General Requirements - 1979

IEC 601-2 The Particular Requirements for Safety, Part 2. (Electrocardiographs), 62D(CO17) –1979

JIS X0201-1976 Code for Information Interchange

JIS X0208-1998 Code of the Japanese Graphic Character Set for Information Interchange

JIS X0212-1990 Code of the Supplementary Japanese Graphic Character Set for Information Interchange

KS C5601-1987 Code for Information Interchange

