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Medicinska informatika ï Standardni komunikacijski protokol ï Raļ unalniġko podprta elektrokardiografija

Medical informatics - Standard communication protocol - Computer-assisted electrocardiography

Medizinische Informatik - Standardkommunikationsprotokoll - Computergestützte Elektrokardiographie

Informatique médicale - Protocole de communication standard pour l'électrocardiographie assistée par ordinateur

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Contents list **Page**

0	INTRODUCTION	4
1	SCOPE AND FIELD OF APPLICATION	5
2	REFERENCES	6
3	DEFINITIONS	7
4	ABBREVIATIONS	8
5	DEFINITION OF THE DATA CONTENTS AND FORMAT WITHIN THE STANDARD ECG COMMUNICATIONS PROTOCOL	9
6	MINIMUM REQUIREMENTS FOR ENCODING AND COMPRESSION OF THE ELECTROCARDIOGRAPHIC SIGNAL DATA	44
7	DEFINITION OF A MINIMUM SET OF CONTROL AND QUERY MESSAGES FOR THE INTERCHANGE OF ECG DATA	49
8	A STANDARD LOW-LEVEL ECG-CART TO HOST TRANSPORT PROTOCOL	60
Annex A	Encoding of the Alphanumeric Electrocardiographic Data in a Multi-Lingual Environment (Normative)	71
Annex B	Universal Electrocardiographic Interpretive Statement Codes (Informative)	84
Annex C	Methodology and Conformance Testing of the Recommended Electrocardiographic Signal Compression Technique (Informative)	100
Annex D	Definition of Compliance Levels with the Standard (Normative)	130
Annex E	Glossary (Informative)	132
Annex F	Additional References (Informative)	135
Annex G	Subject Index (Informative)	138

FOREWORD

This communications protocol for computerised electrocardiography has been worked out within the Advanced Informatics for Medicine (AIM) Project Nr 1015, entitled "A standard communications protocol for computerized electrocardiography" (SCP-ECG).

The SCP-ECG project was executed from June 1989 until December 1990, with the support of DGXIII/F of the European Commission.

The preparation of this standard was undertaken by Project Team 007 of CEN/TC 251 "Medical Informatics" and covered by the European Commission order voucher BC-IT-215.

The European Prestandard had been approved for submission to the formal vote by CEN/TC 251 during its 11th plenary meeting on 26th of January 1993.

This European Prestandard was submitted for formal vote by the CEN Central Secretariat to the members of CEN/CENELEC on 1993-03-29 with the deadline of 1993-06-01. The result of the formal vote was positive.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to announce the existence of this European Prestandard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

0 INTRODUCTION

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. It is 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 interconnectivity of 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 the present document. The primary aim of this standard is to ensure that ECG reports and data from any vendor's computerized ECG recorder can be transmitted 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.

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

1 SCOPE AND FIELD OF APPLICATION

The present 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. The current 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 . The current Standard also does not address exercise ECG recordings. The clinical need for transmission of these specialized recordings is indeed very low and has therefore not been considered in this Standard.

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 present standard is confined to the first of these three stages.

Reference databases and standards for the other stages, i.e. ECG measurement and diagnostic programs, are outside the scope of the present document. They have been defined in the European Project entitled " Common Standards for Quantitative Electrocardiography " (abbreviated CSE) with support of the Medical and Public Health Research Programmes of Directorate General (DG) XII of the European Community (EC). References to this work are given in Subclause 2.2.

The present 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.

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

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

A minimum set of control and query messages for cart-to-cart and cart-to-host interchange are defined in Chapter 7.

A low-level transport protocol for the exchange of data between an ECG cart and a host based on an enhanced X-Modem protocol is defined in Chapter 8. If an RS-232 interface is used then the enhanced X-Modem Protocol can be used.

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 the current Standard.

2 NORMATIVE REFERENCES

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-8859-1	Information Processing - 8-bit single-byte coded graphic character sets - Part-1: Latin alphabet No. 1 (1986) complement to the ISO 2022 Standard shall be used as the default character set in the Standard defined in the current Document.
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.
IEC 62D(CO6)	Performance Requirements for Single Channel and Multichannel Electrocardiographs, 1977
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

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

3 DEFINITIONS

3.1 Description of terms specific to this standard

3.1.1 **Acquiring Cardiograph:** Cardiograph recording the original ECG signal.

3.1.2 **CSE Project:** Project supported by DG XII of the European Commission aiming at the development of Common Standards for (Quantitative) Electrocardiography.

3.1.3 **Interpretive Device:** Device (cart, computer) analyzing the ECG signal

3.1.4 **Median Beat:** Reference/representative ECG cycle computed through any (but not specified) algorithm. This comprises the P, QRS and the ST-T waves.

3.1.5 **Message:** A textual body of information.

3.1.6 **Overreading:** The process whereby a cardiologist reviews the computer based interpretation of an ECG in order to verify the report after making changes to the text.

3.1.7 **Record:** The entire data file which has to be transmitted, including the ECG data and associated information, such as patient identification, demographic and other clinical data.

3.1.8 **Residual Data:** The remaining original ECG data after "proper" substraction with the Median cycle. The adjective "proper" refers to accurate beat alignment.

3.1.9 **Rhythm Data:** The full original ECG data.

3.1.10 **Section:** An aggregate of data elements related to one aspect of the electrocardiographic recording, measurement or interpretation

3.1.11 **Universal Statement Codes:** ECG interpretation codes described in Annex B of this document.

3.2 Description of other technical terms related to this Standard

See Glossary in Annex F.

3.3 Description of general Medical Informatics terms

See Vocabulary of Medical Informatics Terms developed by Project Team 001 of CEN/TC 251

4 ABBREVIATIONS

AAMI	American Association for the Advancement of Medical Instrumentation
AC	Alternating Current
A/D	Analog to Digital
AHA	American Heart Association
AIM	Advanced Informatics for Medicine Programme of the European Commission Directorate General XIII
ANSI	American National Standards Institute
AVM	Amplitude Value Multiplier (see 5.8.1)
ASCII	American Standard Code for Information Interchange
ASN.1	Abstract Syntax Notation One
BS	Backspace (control character)
CCITT	International Telegraph and Telephone Consultative Committee
CEC	Commission of the European Communities
CEN	Comité Européen de Normalisation - European Committee for Standardisation
CENELEC	Comité Européen de Normalisation Electrotechnique
CSE	Common Standards for Quantitative Electrocardiography
CR	Carriage Return (control character)
CRC	Cyclic Redundancy Check
CTS	Conformance Testing Service
DG	Directorate General (of the European Commission)
EC	European Community
ECG	Electrocardiogram
ECU	European Currency Unit
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport
EN	Européenne Norme (European Standard)
ENV	Européeene Norme Vorausgabe (European Pre-standard)
ESC	Escape (control character)
FF	Form Feed (control character)
HT	Horizontal Tab (control character)
ICD	International Classification of Diseases
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IMIA	International Medical Informatics Association
ISO	International Organization for Standardisation
JIS	Japanese Industrial Standard
LAN	Local Area Network
LF	Line Feed (control character)
LSB	Least significant bit
MSB	Most significant bit
OSI	Open Systems Interconnection
PT	Project Team
PTT	Post, Telegraph and Telephone Administration
RMS	Root Mean Square
SCP	Standard Communications Protocol
SCP-ECG	Standard Communications Protocol for Computerized Electrocardiography
TC	Technical Committee
TCP/IP	Transmission Control Program / Internet Protocol
VCG	Vectorcardiogram
VT	Vertical Tab (control character)
WG	Working Group

5 DEFINITION OF THE DATA CONTENTS AND FORMAT WITHIN THE STANDARD ECG COMMUNICATIONS PROTOCOL

The data record which is to be interchanged shall be divided into different sections. The contents and format of each of these sections are defined in this document.

5.1 General Considerations

5.1.1 All text data (character strings) shall comply to the limited conformance requirements of ISO 2022, described in Annex A. Latin-1 (ISO-8859-1) shall be the default character set.

5.1.2 All character strings shall be NULL terminated (not part of ISO 2022).

5.1.3 For all signed binary values 2's-complement coding shall be applied.

5.1.4 All single and multiple byte binary values are regarded as unsigned integers, if not otherwise specified.

5.1.5 Binary values spanning more than 1 byte shall be transmitted in ascending order of significance (The least significant byte is transmitted first, the most significant byte last).

5.1.6 Consecutive bytes are numbered from left to right (starting with 1). Bits of a byte are numbered from right to left (0 = LSB, 7 = MSB).

5.1.7 The first byte in the record (i.e. the first byte of the Checksum) is defined as Byte 1.

5.1.8 ECG samples are indexed and numbered starting with sample number 1. Sample index 0 is not used in the present document. The sample index is a ones-based 16-bit index. The first sample starts at time 0. The second sample is at time 0+2 ms in case of 500 samples/s sampling rate.

5.1.9 Sections are numbered starting from 0 (the Pointer Section) to 32767.

5.1.10 The term "Median Beat" used in this document should not be interpreted in the strict statistical sense. It is any of an averaged beat, a "Median Beat", a selected or any other representative single cycle taken from the total ECG recording. This "Median Beat" does include the P-wave if present (not in case of atrial fibrillation), the ST-T segment and the T wave of this beat. The term "Rhythm Data" is used to indicate the ECG recording over the entire recording time, usually 10-seconds in most recorders.
A description of these terms and of the recommended data compression methodology, including numerical examples and the methods for conformance testing on the minimum requirements of data compression and signal distortion are given in Annex C.

5.1.11 All indexes or pointers to a field are defined in bytes and are ones-based (start at 1) if not otherwise specified.

5.1.12 One KByte = 1024 bytes.

5.2 Specifications for the data structure

5.2.1 All sections shall start on an odd index (even offset) boundary. This implies that all sections shall contain an even number of bytes. A padding byte has to be added to the end of any section otherwise containing an odd number of bytes. Padding bytes shall always be set to NULL.

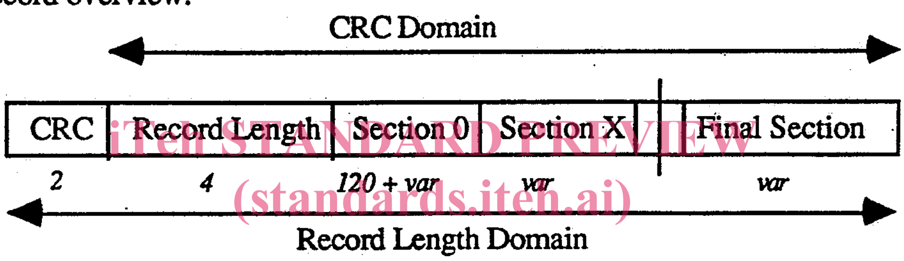
5.2.2 All sections are given Identification numbers. Section ID numbers 0 through 11 are currently defined in the SCP-ECG protocol, numbers 12 through 127, as well as numbers above 1024 are reserved for future use. Numbers 128 to 1023 are for manufacturer specific sections. The combination of the manufacturer code (see 5.4.4, tag 14) and section numbers 128 to 1023 uniquely define the content of these specific sections. There are no specific rules for the lay-out and format of these sections. However, use of the structure defined in 5.2.7 is recommended.

5.2.3 Inclusion of sections 2 - 11 (see 5.2.7 and 5.2.8) are optional. Any SCP-ECG data record shall contain Section 0 (Pointers) and Section 1 (Header). No consistency checking among the presence of different sections is assumed. Specifically, if any of sections 8, 9, or 11 is present, it is not assumed that all three shall be present.

5.2.4 The ECG record starts with a 6-byte record header, consisting of a 2-byte checksum followed by a 4-byte record length. These are defined as follows:

1) The 2-byte checksum is calculated as a CRC-CCITT, the algorithm of which is described in 8.3.5, and is calculated over the entire range starting with the first byte following the checksum and ending with the last byte in the record.
2) The 4-byte record length denotes the number of bytes in the total record, including the 6 bytes of this record header.

5.2.5 Record overview:



5.2.6 The sequence order of the sections of a record is free, with the exception of Section 0 (zero) which shall immediately follow the record header. However, a maximum of one instance of any section is allowed in a SCP-ECG data record.

5.2.7 Each section consists of :

1) A Section Identification Header (Section ID Header)
2) A Section Data Part.

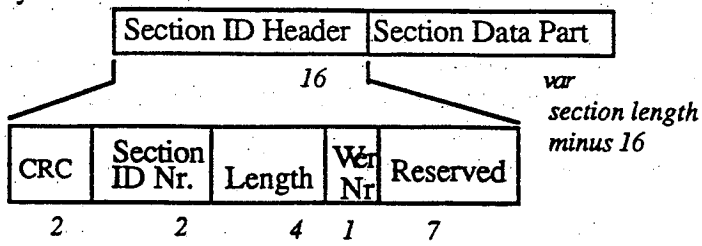
Any section shall start with a "Section ID Header" (16 bytes) defined below:

Bytes	Contents
1-2	16 bit CRC-CCITT **Checksum** over the entire section except these 2 bytes.
3-4	**Section ID number** as defined in 5.2.2 (see also paragraph 5.3.1.1).
5-8	**Section length** in bytes including the "Section ID Header" (see 5.3.1.2).
9	**Version Number of the Section**
10-16	**Reserved.**

Each section shall have a Protocol Version Number (see byte 9) which may be used to specify different levels of compatatibily with the Standard when this is updated in the future (see Annex E).

5.2.8 Reserved fields shall always be set to NULL (zero)

5.2.9 Section lay-out overview:



5.2.10 The numbers in italic in the lay-out overviews (in 5.2.5, 5.2.9 and below) indicate the length in bytes of the corresponding field or indicated block (*var* = variable length).

5.2.11 A global overview of the SCP-ECG data structure is presented in the Table below:

Manda-tory	2 BYTES - CHECKSUM - CRC - CCITT OVER THE ENTIRE RECORD (EXCLUDING THIS WORD)
Manda-tory	4 BYTES - (UNSIGNED) SIZE OF THE ENTIRE ECG RECORD (IN BYTES)
Manda-tory	(Section 0) POINTERS TO DATA AREAS IN THE RECORD
Manda-tory	(Section 1) HEADER INFORMATION PATIENT DATA/ECG ACQUISITION DATA
Optio-nal	(Section 2) HUFFMAN TABLES USED IN ENCODING OF ECG DATA (IF USED)
Optio-nal	(Section 3) ECG LEAD DEFINITION
Optio-nal	(Section 4) QRS LOCATIONS (IF MEDIANS ARE ENCODED)
Optio-nal	(Section 5) ENCODED MEDIAN DATA IF MEDIANS ARE STORED
Optio-nal	(Section 6) "RESIDUAL SIGNAL" AFTER MEDIAN SUBTRACTION IF MEDIANS ARE STORED, OTHERWISE ENCODED RHYTHM DATA
Optio-nal	(Section 7) GLOBAL MEASUREMENTS
Optio-nal	(Section 8) TEXTUAL DIAGNOSIS FROM THE "INTERPRETIVE" DEVICE
Optio-nal	(Section 9) MANUFACTURER SPECIFIC DIAGNOSTIC AND OVERREADING DATA FROM THE "INTERPRETIVE" DEVICE
Optio-nal	(Section 10) LEAD MEASUREMENT RESULTS
Optio-nal	(Section 11) STATEMENT CODES RESULTING FROM THE INTERPRETATION

5.2.12 The following remarks apply to the data areas identified above:

Section nr. Contents

(0) This section contains pointers to the start of each of the following sections. This section is **mandatory**.

(1) This section contains information of general interest concerning the patient (e.g. patient name, patient ID, age, etc.) and the ECG (acquisition date, time, etc.). This section is **mandatory**.

(2) This section contains all of the Huffman tables used in the encoding of rhythm (or "residual signal") and median data. The tables shall be referenced by Sections 5 and 6 by their numerical order in this section. Thus, when reference is made in the median encoding section to table 2, this shall refer to the second table defined in Section 2. This section is **optional**.

(3) This section specifies which ECG leads are contained within the record. This section is **optional**.

(4) If medians are encoded, then this Section shall identify the position of these medians relative to the "residual" signal contained in Section 5 below. This section is **optional**.

(5) Median ECG complexes for each lead are encoded if the originating device has generated those complexes. This section is **optional**.

(6) This section contains the "residual" signal that remains for each lead after the median QRS complexes have been subtracted, or if no medians have been subtracted, the entire rhythm signal. This section is **optional**.

(7) This section contains global measurements for each beat type or for each QRS contained in the record and a list of possible pacemaker spikes in the record. This section is **optional**.

(8) This section contains the latest actual text for the legal document of the diagnostic interpretation of the recorded ECG data, including all overreadings if performed. Only the text of the most recent interpretation and overreading shall be included in this section. No manufacturer specific codes should be used in the text. Mnemonic codes as listed in the Universal statement codes may be used if necessary.
The data contained in this section shall be consistent with the data in Section 9 and Section 11. This section is **optional**.

(9) This section contains the manufacturer specific diagnostic statements of the analyzing device and overreading trails of the interpretations. The source of the analyzing device and the name of the overreading physician (or device) are defined in the "Header section" (Section 1). The data contained in this section should enable a similar device of the same manufacturer to exactly re-compile Sections 8 and 11. This section is **optional**.

(10) A set of basic measurements and manufacturer specific measurements (if any) for each recorded lead are presented in this section. This section is **optional**.

(11) This section contains the most recent interpretation and overreading data, coded according to the Universal Statement Codes and Coding rules (Annex B).The data contained in this section shall be consistent with the data in Sections 8 and 9. This section is **optional**.