SLOVENSKI STANDARD

SIST EN 1064:2005+A1:2008

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Zdravstvena informatika - Standardni komunikacijski protokol - Raļ unalniġko podprta elektrokardiografija (vkljuļ no z dopolnilom A1)

Health informatics - Standard communication protocol - Computer-assisted electrocardiography

Medizinische Informatik - Standardkommunikationsprotokoll - Computergestützte Elektrokardiographie

Informatique de santé - Protocole de communication standard - Electrocardiographie assistée par ordinateur

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Foreword

This document (EN 1064:2005+A1:2007) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2007, and conflicting national standards shall be withdrawn at the latest by September 2007.

This document includes Amendment 1, approved by CEN on 2007-01-15.

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1] [A1].

This document supersedes [A1] EN 1064:2005 [A1].

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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. 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 document is to specify a data format for transferring ECG reports and data from any vendor's computerized ECG recorder to any other's vendor central ECG management system. The same standard should also allow standardized transfer of digitised 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 document, the reader needs some basic understanding of electrocardiology, electrocardiography and signal processing.

This document 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 document has not been designed to handle exchange of such recordings, although future extensions could be made to this end. The standard has also not been designed to exchange specialized recordings of intracardiac potentials or of the so-called Holter or other long-term ECG recordings made for monitoring cardiac rhythm. This document 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 document 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 document.

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

〈A1〉 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. Two Data Format Categories have been defined based on information content as in the following table:

Data Format Categories for Compliance Specifications

Category	Data Sections Required	Content Description
I	0, 1, [2][1], 3, 6, (7)[2], (8)[2], (10)[2]	Demographics, and ECG rhythm data (uncompressed or with lossless compression)
II	0, 1, [2][1], 3, 4, 5, 6, (7)[2], (8)[2], (10)[2]	Demographics, ECG rhythm data (uncompressed, with lossless compression or with high compression), and reference beats

NOTE 1 Square brackets [.] indicate that data section 2 is required if Huffman encoding has been used.

NOTE 2 Parentheses (.) indicate that these data sections are optional for export.

A further category may be added in future versions in order to fulfil the specific needs of ECG devices used in other applications (such as telemedicine or homecare).

All devices stating a SCP-ECG Data Format Category shall import at minimum data sections 0, 1, 3, 6, 7, and 8. All Categories may have additional sections added (e.g. 9, 10, 11). Manufacturer specific data shall be optionally included only in manufacturer specific fields, bytes and data blocks that have been defined in the document. Reserved, unspecified and undefined fields, bytes or data blocks shall not be used for manufacturer specific data.

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 document).

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 document. 〈A1▌

1 Scope

This document specifies 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 document specifies the content and structure of the information which is to be interchanged between digital ECG carts and computer ECG management systems, as well as other computer systems where ECG data can be stored.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 646, *Information technology - ISO 7-bit coded character set for information interchange*

ISO/IEC 2022:1994, *Information technology - Character code structure and extension techniques*

ISO/IEC 8859 (all parts), *Information technology - 8-bit single-byte coded graphic character sets*

ISO/IEC 10646, *Information technology - Universal Multiple-Octet Coded Character Set (UCS)*

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

JIS X 0201-1976, *Code for Information Interchange*

JIS X 0208-1997, *Code of the Japanese Graphic Character Set for Information Interchange*

JIS X 0212-1990, *Code of the Supplementary Japanese Graphic Character Set for Information Interchange*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 Terms specific to this document

3.1.1
acquiring cardiograph
cardiograph recording the original ECG signal

3.1.2
bimodal compression
use of low pass filtering and sample decimation outside of a protected zone containing the QRS complex, with no decimation or filtering within the protected zone, is called bimodal compression, and is indicated by 5.9.3 byte 6

3.1.3
confirming
process whereby a trained and experienced cardiologist reviews the computer-generated (or overread) interpretation of an ECG in order to confirm the computer-generated (or overread) interpretation or to make the final changes to the interpretation text. The confirmed ECG is the final clinically acceptable version for diagnosis and treatment

3.1.4
CSE Project
project supported by DG XII of the European Commission aiming at the development of Common Standards for (Quantitative) Electrocardiography

3.1.5
downsampling factor
downsampling (or decimation) factor gives the reduction of samples in data sections where the sampling rate is reduced with reference to the original sampling rate.

NOTE This applies for bimodal data compression.

For example original sampling rate 500 S/s (which is equivalent to a sample interval of 2 ms) is reduced to 125 S/s (which is equivalent to a sample interval of 8 ms). The downsampling factor is than 4

3.1.6
interpretive device
device (cart, computer) analyzing the ECG signal

3.1.7
message
textual body of information

3.1.8
overreading
process whereby a cardiologist or a cardiology fellow reviews the computer-generated interpretation of an ECG in order to verify the accuracy or to make changes to the interpretation text

NOTE An overread ECG is generally not the final clinically acceptable version for diagnosis and treatment. Usually, the overreading process precedes the confirming process.

3.1.9
record
entire data file which has to be transmitted, including the ECG data and associated information, such as patient identification, demographic and other clinical data

3.1.10
reference beat
reference/representative ECG cycle computed through any (but not specified) algorithm comprising the P, QRS and the ST-T waves

3.1.11
residual data
remaining original ECG data after "proper" subtraction of the reference beat. The adjective "proper" refers to accurate beat alignment

3.1.12
rhythm data
full original ECG data, or the decompressed and reconstructed ECG data at reduced resolution

NOTE Rhythm data is typically 10 s in length.

3.1.13
section
aggregate of data elements related to one aspect of the electrocardiographic recording, measurement or interpretation

3.1.14
universal statement codes
ECG interpretation codes described in Annex F of this document

3.2 Other technical terms related to this document

See glossary in Annex G.

4 Abbreviations

AAMI	American Association for the Advancement of Medical Instrumentation
AC	Alternating Current
AHA	American Heart Association
AIM	Advanced Informatics for Medicine Programs of the European Commission Directorate General XIII
ANSI	American National Standards Institute
ASCII	American Standard Code for Information Interchange
ASN.1	Abstract Syntax Notation One
AVM	Amplitude Value Multiplier (see 5.8.3)
BS	Backspace (control character)
CCITT	International Telegraph and Telephone Consultative Committee
CEN	Comité Européen de Normalisation - European Committee for Standardisation
CR	Carriage Return (control character)
CRC	Cyclic Redundancy Check
CSE	Common Standards for Quantitative Electrocardiography
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	Europäische Norm (European Standard)
ENV	Europäische Norm 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
LF	Line Feed (control character)
LSB	Least significant bit
MSB	Most significant bit
RMS	Root Mean Square
SCP	Standard Communications Protocol
SCP-ECG	Standard Communications Protocol for Computerized Electrocardiography
TC	Technical Committee
VCG	Vectorcardiogram
VT	Vertical Tab (control character)

5 Definition of the data contents and format

5.1 General considerations

5.1.1

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.

5.1.2

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

5.1.3

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

5.1.4

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

5.1.5

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

5.1.6

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).

5.1.7

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).

5.1.8

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

5.1.9

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.

5.1.10

Sections are numbered starting from 0 (the Pointer Section) to 32 767.

5.1.11

The term "Reference Beat" used in this document refers to an ECG complex which is chosen as representative of a class of such complexes. No specific statistical meaning is implied by this term; for example, it may be an averaged beat, a "Median Beat", a selected or any other representative single cycle taken from the total ECG recording. This "Reference 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.

An ECG may have multiple reference beats. The term "Beat type" used in this document refers to any one of an ordered list of reference beats, starting with reference beat type 0 (zero). Reference beat type 0 is, by definition, the reference beat used for classification of the ECG, and for reference beat subtraction, if reference beat subtraction is used in compression. The ordering of the list of reference beats does not imply a temporal sequence within the rhythm data.

The term "Rhythm Data" is used to indicate the ECG recording over the entire recording time, usually 10 s 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 Clause 6, Annex B, and Annex C.

Reference Beat type 0 data in 5.8 are intended to be used for display, (re)analysis and, if reference beat subtraction has been used for data compression, for Rhythm Data reconstruction.

5.1.12

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

5.1.13

1 KByte = 1 024 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. Blocks of data within a section may contain either odd or even numbers of bytes. Padding occurs only at the end of a section if needed.

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 1 024 are reserved for future use. Numbers 128 to 1 023 are for manufacturer specific sections. The combination of the manufacturer code (see 5.4.4, tag 14) and section numbers 128 to 1 023 uniquely defines the content of the manufacturer-specific sections. There are no specific rules for the layout and format of these sections. However, use of the structure defined in 5.2.7 is recommended.

5.2.3

[A1⟩ Inclusion of Sections 2, 4, 5, 7 to 11 (5.2.7 and 5.2.8) is optional. Any SCP-ECG data record shall contain Section 0 (Pointers), Section 1 (Header), Section 3 (ECG Lead Definition) and Section 6 (Rhythm Data). No other 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. ⟨A1]

5.2.4

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

1) The 2-byte cyclic redundancy check (CRC) is calculated as a CRC-CCITT, the algorithm of which is described in E.5.5, and is calculated over the entire range starting with the first byte following the CRC 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:

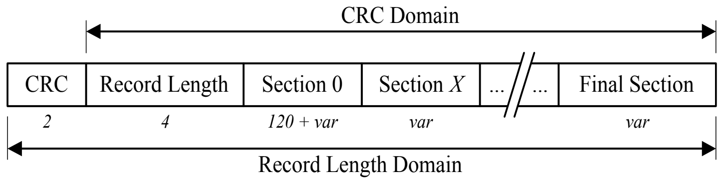

Figure 1 — Record overview

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.