EESTI STANDARD EVS-EN 1064:2005+A1:2007

Health informatics - Standard communication protocol - Computer-assisted electrocardiography KONSOLIDEERITUD TEKST

Health informatics - Standard communication protocol - Computer-assisted electrocardiography CONSOLIDATED TEXT

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 1064:2005+A1:2007 sisaldab Euroopa standardi EN 1064:2005+A1:2007 ingliskeelset teksti. Käesolev dokument on jõustatud 20.04.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 1064:2005+A1:2007 consists of the English text of the European standard EN 1064:2005+A1:2007. This document is endorsed on 20.04.2007 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: 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.	**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.

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Health informatics - Standard communication protocol - Computer-assisted electrocardiography

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

Medizinische Informatik - Standardkommunikationsprotokoll - Computergestützte Elektrokardiographie

This European Standard was approved by CEN on 17 December 2004 and includes Amendment 1 approved by CEN on 15 January 2007.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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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