

Health informatics - Standard
communication protocol - Computer-
assisted electrocardiography

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ICS 35.240.80

English Version

**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 draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 251.

This draft amendment A1, if approved, will modify the European Standard EN 1064:2005. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN 1064:2005/prA1:2006) has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by NEN.

This document is currently submitted to the Unique Acceptance Procedure.

Forbiede
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1 Modification to Introduction

Replace the last four paragraphs with the following:

“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.”

2 Modification to 5.2.3

Replace 5.2.3 with the following:

“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.”

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3 Modification to 5.2.11

Replace Table 1 with the following:

“Table 1 — SCP-ECG data structure

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

4 Modification to 5.2.12

Replace 5.2.12 with the following:

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

- | | |
|-----|---|
| 0 | This section contains pointers to the start of each of the following sections. This section is required. |
| 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 required. |
| 2 | This section contains all of the Huffman tables used in the encoding of rhythm (or “residual signal”) and reference beat 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 reference beat encoding section to table 2, this shall refer to the second table defined in Section 2. This section is required, dependent upon Huffman encoding being used in the encoding of rhythm (or “residual signal”) and of reference beat (if stored). |
| 3 | This section specifies which ECG leads are contained within the record. This section is required. |
| ... | |
| 6 | This section contains the “residual” signal that remains for each lead after the reference beats have been subtracted, or if no reference beats have been subtracted, the entire rhythm signal. This section is required. |

“

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