Enhanced Integrated Format and Content Checking for Processing of SCP ECG Records

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Abstract

Interoperability between medical devices and host systems is a key requirement for establishing an electronic patient health record. A pre-requisite for interoperability is standardization of data formats and messaging protocols. We report on the development of enhanced testing tools for compliance checks of the SCP-ECG interchange format within the specifications of the CEN standard EN 1064. The presented tools are important for development as well as compliance testing of SCP formatted ECG records and they are necessary to promote the interoperability of important non-invasively gathered cardiac information. Cardiac information is more and more integrated into the electronic patient health record and interchanged between various health care providers. We have conducted practical tests in our laboratory and on two public databases of our own and external SCP implementations.

1. Introduction

Interoperability between medical devices and host systems is a key requirement for establishing an electronic patient health record. A pre-requisite for interoperability is standardisation of data formats and messaging protocols.

For computer assisted electrocardiography a specific standard SCP-ECG was developed and approved by CEN as a pre-Standard ENV 1064 in 1993 [1]. This standard specifies the interchange format and a messaging procedure for ECG cart-to-host communication and for retrieval of SCP-ECG records from the host (to the ECG cart).

The SCP standard specifies that the information in the interchange format has to be structured in data sections as shown in Table 1. The SCP standard was implemented by a couple of European and American manufacturers. Practical experience during implementation and in the field revealed it's usability, e.g. for telemetric applications as well as for data volume effective storage and retrieval (e.g., in the OEDIPE project [2]).

Table 1. Structure of SCP-ECG records.

Mandatory	**2 BYTES - CHECKSUM - CRC - CCITT OVER THE ENTIRE RECORD (EXCLUDING THIS WORD)**
Mandatory	**4 BYTES - (UNSIGNED) SIZE OF THE ENTIRE ECG RECORD (IN BYTES)**
Mandatory	**(Section 0) POINTERS TO DATA AREAS IN THE RECORD**
Mandatory	**(Section 1) HEADER INFORMATION - PATIENT DATA/ECG ACQUISITION DATA**
Optional	**(Section 2) HUFFMAN TABLES USED IN ENCODING OF ECG DATA (IF USED)**
Optional	**(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**
Optional	**(Section 6) "RESIDUAL SIGNAL" AFTER REFERENCE BEAT SUBTRACTION IF REFERENCE BEATS ARE STORED, 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**

There have been several revised versions of the SCP standard published and the current SCP standard is version 2.1 [3]. The aim of our work was to develop tools for verification of the compliance of SCP interchange format implementations within the specifications given by the SCP standard

In 2004, the first version of the Integrated Content and Format Checker tool was developed and published [4]. This tool is available on the Internet [5] and has been used frequently by manufacturers and SCP users.

2. Methods

Comparison of SCP records from different devices of different manufacturers revealed differences in the SCP-implementations, which made these records not fully interoperable. To identify which of the records match the SCP specifications, compliance testing is necessary. Essentially the compliance tests have to cover the following aspects:

- Content of the SCP record.
- Format and structure of the SCP record.
- Messaging mechanisms if records are exchanged according to the SCP specifications.

But the technological progress, since the standard first development in 1993, has changed the communication interfaces and protocols and thus the previous messaging mechanisms are not used anymore in today's ECG devices and have been superseded in the last version of the SCP standard.

Related to the content and format, there are three format options for storing ECG data within the SCP standard:

- Storage of "original" ECG data.
- Redundancy reduction of ECG data.
- SCP "high" compression using reference beat subtraction and sample decimation, which allows quality assured ECG signal compression [6].

Because the basis of the SCP record testing and some aspects of the SCP format checking have been published already [4], this work is focused on the enhanced features of the SCP Format Checker:

- Additional SCP section dependent tests.
- Section interdependent tests.
- Checking SCP recommendations for sample decimation and reference beat subtraction.

There is interdependence between content and format checking. Because of this interdependence an integrated testing is recommended. We have developed software tools written in ANSI C for integrated content and format checking. There is a "Test-Driver" for file input/output operations, the analysing libraries and a common GUI. This system differentiates between different SCP versions 1.0 (CEN), 1.3 (AAMI), 2.0 (CEN) and 2.1 (CEN). Since records to be tested may completely deviate from the SCP format throughout all test phases basic plausibility checks have been implemented to avoid crashes of test functions.

2.1. Additional SCP section dependent tests

The enhanced version of the SCP Format Checker contains new tests for SCP sections 7 (global measurements), 8 (textual diagnosis), 10 (lead measurements) and 11 (universal statement code).

It is important to know that some of the following listed tests depend on the respective SCP version:

a) Section dependent format tests for SCP section 7

—Checking the plausibility of wave fiducials (P onset, P offset, QRS onset, QRS offset and T offset).

—Checking the range of the (P, QRS and T) axes for each QRS measurement block.

—Checking for plausibility of QRS numbers.

—Checking for length and data integrity of the tagged data area.

b) Section dependent format tests for SCP section 8

—Checking the range of the report status.

—Checking the ranges of date and time.

—Checking for correct statement sequence numbers.

—Checking for correct termination of each statement.

—Checking for the correct section length.

c) Section dependent format tests for SCP section 10

—Checking whether the section length is plausible to the lead number.

—Checking for correct lead identifier.

—Checking for the presence of the mandatory measurements.

—Checking for plausible entries of PR-interval, P-duration, QT-interval and QRS-duration.

—Checking the entry sign of P-, QRS-, Q-, R-, S-, R'- and S'- duration's, PR- and QT-intervals, iso-electric segment at onset or end of QRS and intrinsicoid deflection.

—Checking for correct entry of P and T morphology.

—Checking for plausibility of P morphology and entry of P amplitudes.

—Checking for plausibility of T morphology and entry of T amplitudes.

—Checking for correct entries for measurements, which are reserved for future use.

—Checking for the length of the section.

d) Section dependent format tests for SCP section 11

—All tests like in SCP section 8 (see b).

—Checking for correct statement type identifier for each statement.

2.2. Section interdependent tests

Section interdependent tests check for the integrity of data, which are located in several SCP sections. This kind of check is helpful because, e.g., the necessary information for calculating the downsampling factor, which is important for the sample decimation, is located in two different SCP sections (sections 5 and 6).

The Enhanced Integrated Format and Content Checker provide the following section interdependent tests:

a) Section interdependent format tests in case of reference beat subtraction (section 3, byte 2, bit 0)

—Reporting an error, if reference beat subtraction is used and at least one of the sections 4, 5 or 6 is not present.

—Reporting an error, if the start sample for subtraction of the 1st QRS complex within SCP section 4 is less than the start sample number in SCP section 3.

—Reporting an error, if the end sample for subtraction of the last QRS complex within SCP section 4 is greater than the end sample number in SCP section 3.

b) Section interdependent format tests in case of bimodal compression (section 6, byte 6)

—Reporting an error, if SCP section 4 (QRS locations) is not present.

—Reporting an error, if SCP section 5 (encoded reference beat data) is not present.

—Reporting an error, if the sample time interval in section 6 is not a multiple of the sample time interval in section 5.

c) Miscellaneous section interdependent format tests

—Reporting an error, if section 3 is not present , while section 5 and/or section 6 are present.

—Reporting an error, if the number of QRS complexes entered in section 7 is not identical to the QRS number entered in section 4.

—Reporting an error, if the type of each QRS complex entered in section 7 is not identical to the respective QRS type entered in section 4.

—Reporting an error, if the start sample to the protected area of the first QRS complex within section 4 is less than the start sample number in section 3.

—Reporting an error, if the end sample to the protected area of the last QRS complex within section 4 is greater than the end sample number in section 3.

—Reporting an error, if pacemaker spike locations (in section 7) are located outside the rhythm data interval (defined in sections 3 and 6).

2.3. Checking SCP recommendations for sample decimation

In the past, there have been some problems applying SCP "high" compression/decompression using sample decimation (SD) and reference beat subtraction (SUB). In some cases transients occur, which are located at the boundaries of reference beat subtraction. The possible causes for this problem are:

- Baseline drift within the ECG data or use of non offset subtracted reference cycle together with filtering beyond the subtraction boundaries (this is an error within the SCP implementation).
- Variations between compression and decompression algorithm in calculating the protected areas (this problem has been eliminated since SCP version 1.3).
- Inhomogeneous processing of sample numbers, which are not multiples of the decimation factor in SCP compression and decompression software (e.g., the software is from different manufacturers). To avoid or to minimize this problem, additional recommendations have been included into the SCP standard within the normative annex C. Therefore the enhanced SCP Format Checker performs additional tests:

  —Reporting a warning, if the interval between start of sample decimation and start of subtraction is not a multiple of the decimation factor.

  —Reporting a warning, if the interval between start of sample decimation and end of subtraction +1 is not a multiple of the decimation factor.

  —Reporting a warning, if the decimation interval between two protected QRS areas is not a multiple of the decimation factor.

Figure 1 depicts the different intervals within the ECG data during SCP "high" compression. The sample decimation interval for each beat is divided into tree parts (two parts with SD and SUB and one part with pure SD). The SCP standard recommends that the length of each of the tree parts is a multiple of the decimation factor.

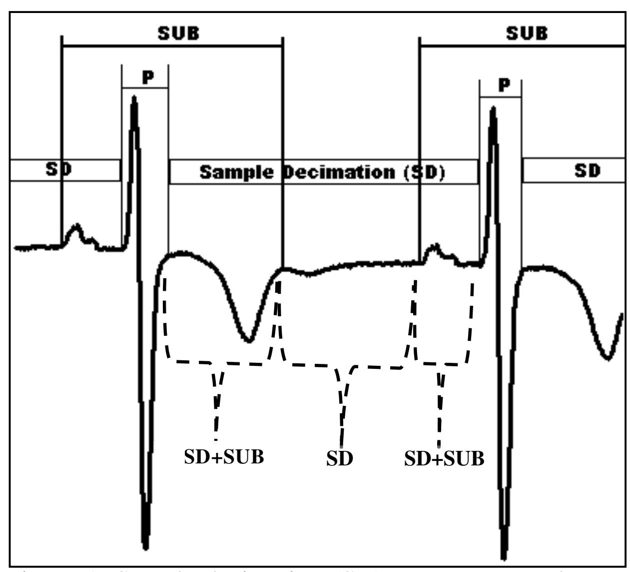

Figure 1. Sample decimation (SD) areas, protected areas (P) and reference beat subtraction areas (SUB).

3. Results

The enhanced integrated SCP Format Checker tool contains several newly implemented tests. The different test classes and numbers of tests are depicted in Table 2.

Table 2. Test classes and number of tests within the SCP Format Checker tool.

Test class	Number of tests
Global tests	5
Common tests for all SCP sections	8
Section dependent test	271
Section interdependent tests	14
Total	**298**

The result of the SCP format checker is a report file containing:

- Title and version of the format checking program.
- Name of the checked SCP file.
- SCP version number (SCP section 1, tag 14, byte 15).
- Detected errors and/or warnings.
- Total number of format tests.
- Number of detected format errors/warnings.

These tools have been applied to two public and one internal databases containing 476 SCP records. Figure 2 depicts the distribution of number of test and number of errors and warnings of 465 records. 11 records have been excluded, because they contain no analysable SCP pointer section. The wide variance of the number of errors and warnings indicate that there are a few SCP implementations not too accurate compared to the standard, but the accumulation of errors and warnings lower than 100 depicts that most of the SCP implementations reside in a level of moderate compliance.

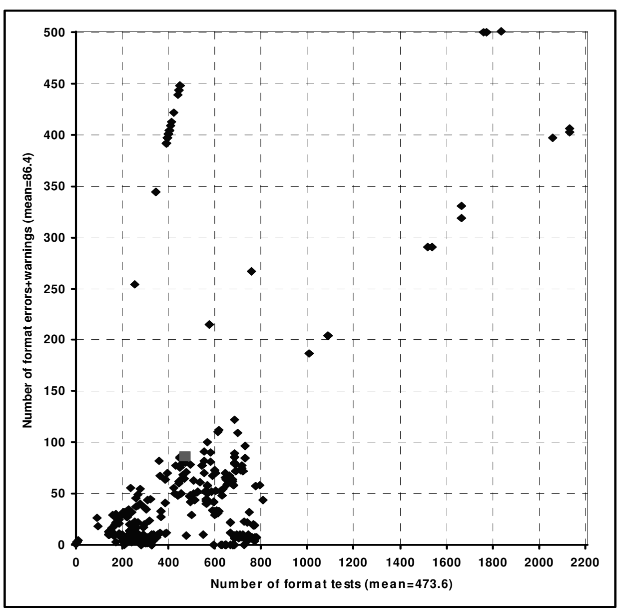

Figure 2. Distribution of number of test and number of errors and warnings of 465 tested SCP records.

4. Discussion and conclusions

The presented tools are important for development as well as compliance testing of SCP formatted ECG records. They are necessary to promote interoperability of important non-invasively gathered cardiac information. This information will be more and more integrated into the electronic patient health record and interchanged between the various health care providers.

The Enhanced Integrated Format and Content Checking tool is available on the Internet [5]. Already a significant number of compliance tests could be supported. For more information about the implementation of SCP, please refer to [7-8].

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