SCP-ECG V3.0: An Enhanced Standard Communication Protocol for Computer-assisted Electrocardiography

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Abstract

The main goal of the SCP-ECG standard is to address ECG data and related metadata structuring, semantics and syntax, with the objective of facilitating interoperability and thus supporting and promoting the exchange of the relevant information for unary and serial ECG diagnosis. Starting with version V3.0, the standard now also provides support for the storage of continuous, long-term ECG recordings and affords a repository for selected ECG sequences and the related metadata to accommodate stress tests, drug trials and protocol-based ECG recordings. The global and per-lead measurements sections have been extended and three new sections have been introduced for storing beat-by-beat and/or spike-by-spike measurements and annotations. The used terminology and the provided measurements and annotations have been harmonized with the ISO/IEEE 11073-10102 Annotated ECG standard. Emphasis has also been put on harmonizing the Universal Statement Codes with the CDISC and the categorized AHA statement codes and similarly the drug and implanted devices codes with the ATC and NASPE/BPEG codes.

1. Introduction

Several authors and task forces have repeatedly emphasized the need for open communication and interlinking of various types of ECG devices and systems and the difficulty of overcoming the lack of interoperability and limitations of different standards and proprietary solutions [1-4].

SCP-ECG is a self-documented international standard for the digital exchange of ECG signals and related metadata. It was initiated and developed within the framework of the AIM#1015 SCP-ECG European Project of the Advanced Informatics in Medicine Program (DGXIII, 1989-91), submitted to CEN/TC251 in 1992, approved as ENV1064 in 1993, and as a European Norm (EN) in 2005. The latter has been slightly revised in 2007 (EN1064: 2005+A1:2007 [5] and adopted as an ISO standard in 2009 (ISO 11073-91064:2009).

In 2014, CEN/TC251 has initiated the revision of the EN1064:2005+A1:2007 standard. To this end, an SCP-ECG revision Project Team lead by Paul Rubel and Alois Schloegl has been nominated, with the mission of keeping the useful and up-to-date parts of the standard more or less intact, removing or revising the outdated parts and extending the standard by including new measurements and recording modalities, viz long-term and stress test recordings.

In the following, we first present the method used by the revision project team to build up SCP-ECG version 3. We then summarize the changes that have been performed on the sections already existing in versions 1.x and 2.x, briefly present the new sections that have been included in version 3.0 and conclude by recalling the medical challenges of SCP-ECG and why it is a unique standard that is much different from other signal-related standards.

2. Methods

The SCP-ECG revision project team has first performed an in depth review of the literature about the SCP-ECG standard [3, 4, 6] and about complementary standards and/or recommendations from leading scientific societies (AHA, ACC, ESC, etc.). A SWOT analysis was presented during the kick-off meeting of the project team held in the CEN/CENELEC meeting center in Brussels, Belgium, in November 2013 and during several follow-up virtual meetings using Webex. SCP-ECG updates and new sections proposals have then been drafted by and circulated within the project team members and some stakeholders in the field of quantitative Electrocardiology, and have been amply discussed during 24 Webex meetings and during a special session on “Standardization” held during the Staff 2015 meeting in Vence, France.

3. SCP-ECG updates

Figure 1 depicts the structure of SCP-ECG V3.0. Sections 0 to 11 already existed in the previous versions. Sections 12 to 18 are new. Section 4 was formerly used to store QRS locations to allow beat subtraction for computing a “residual signal”. This section has been deprecated and is now reserved. It shall no longer be used.

Emphasis has been put on cross-referencing and providing a semantic mapping between the terminology and the methodologies used in SCP-ECG and the ISO/IEEE 11073-10102 Annotated ECG (aECG) and 11073-10101 Nomenclature (Vital signs) standards and on levering the ambiguities and inaccuracies of some of these other than SCP-ECG standards.

3.1. Section 1 and signal sections updates

The major changes in the signal sections 4 to 6 are the deprecation of the lossy bimodal compression scheme and beat subtraction. Only lossless compression (difference and Huffman encoding) of the long-term rhythm data (section 6) and of the reference beat type 0 data (section 5) are now allowed. To simplify decoding, the standard further recommends storing all ECG signal data uncompressed as a series of fixed length, signed integers and reserving difference data calculation and Huffman encoding for mobile and/or wearable devices, when they are intended to be used in poorly served areas with limited wireless connectivity such as GPRS, where significant lossless data reduction strategies are still of importance.

In order to support multiple languages text strings, all text strings are now encoding as UTF-8.

In section 1, SCP-ECG Drugs coding (Tag 10), Medical History codes (Tag 32) and Electrode configuration Codes (Tag 33) have been significantly updated to take account of the evolution of the medical needs, and two new tags have been introduced, respectively aimed at describing Implanted Cardiac Devices (Tag 36, based on the NASPE/BPEG coding systems) and at specifying drugs according to the WHO Anatomical Therapeutic Chemical Classification System (ATC code, Tag 37).

3.2 Measurements sections updates

The global and per-lead measurements sections have been significantly extended. The terminology used and the measurements and annotations provided have been harmonized with the aECG standard and with the different recommendations and consensus papers (viz the need for introducing new measurements describing the early repolarization patterns) found in the scientific literature.

(Section 0) POINTERS TO DATA AREAS IN THE RECORD
(Section 1) HEADER INFORMATION - PATIENT DATA/ECG ACQUISITION DATA
(Section 2) HUFFMAN TABLES USED IN ENCODING OF ECG DATA (IF USED)
(Section 3) ECG LEADS DEFINITION
(Section 4) RESERVED FOR LEGACY SCP-ECG VERSIONS
(Section 5) ENCODED TYPE 0 REFERENCE BEAT DATA (IF REFERENCE BEAT IS STORED)
(Section 6) LONG-TERM ECG RHYTHM DATA
(Section 7) GLOBAL ECG MEASUREMENTS
(Section 8) TEXTUAL DIAGNOSIS FROM THE "INTERPRETIVE" DEVICE
(Section 9) MANUFACTURER SPECIFIC DIAGNOSTIC AND OVERREADING DATA FROM THE "INTERPRETIVE" DEVICE
(Section 10) PER LEAD ECG MEASUREMENTS
(Section 11) UNIVERSAL STATEMENT CODES RESULTING FROM THE INTERPRETATION
(Section 12) LONG-TERM ECG RHYTHM DATA
(Section 13) STRESS TESTS, DRUG TRIALS AND PROTOCOL-BASED ECG RECORDINGS METADATA
(Section 14) SELECTED ECG SEQUENCES REPOSITORY
(Section 15) BEAT-BY-BEAT ECG MEASUREMENTS AND ANNOTATIONS
(Section 16) SELECTED ECG BEATS MEASUREMENTS AND ANNOTATIONS
(Section 17) SPIKES MEASUREMENTS AND ANNOTATIONS
(Section 18) ADDITIONAL ECG ANNOTATIONS

Figure 1. SCP-ECG V3.0 Sections List

All measurements have been precisely defined, viz the example displayed in Table 1, with the aim of unifying the way ECG measurements are performed and of serving as a reference for scientific work. Manufacturers using methods other than those recommended in SCP-ECG Version 3.0 are requested to specify the method they are using in the physician's guide.

Table 1. Excerpt of Section 10 – Per-lead ECG measurements, describing the definition and format of ST-T area measurement.

Byte	Contents
…	…
121 to 122	ST-T Area ((µV x ms)/100) (Area of the ST-T segment in the specified lead, computed from the global end of QRS up to the global onset of T) [MDC_ECG_AREA_ST *and/or MDC_ECG_WAVC_STSEG_AREA*] 1) 16)
…	…
NOTE 1: All upper case format aECG REFIDs listed in this section are per-lead ECG measurements REFIDs. Alternatively, several per-lead measurements may also be encoded as 11073-10102 ECG WAVC wave components. The corresponding REFIDs are typed in upper case italic format. NOTE 16: Wave and ST segment Areas are computed in (µVolt x millisecond)/100 by integrating absolute values from the global onset to the global offset of the corresponding waves.	

3.4 Universal statement codes updates

Section 11, which aims to contain the most recent interpretation and overreading data, now allows three different coding schemes (in addition to free text): (1) according to the Universal Statement Codes and Coding Rules defined in SCP-ECG Annex A: (2) based on the categorized AHA statement codes; (3) according to the CDISC (Controlled Terminology. Clinical Data Interchange Standards Consortium) code.

The three different coding schemes may coexist, i.e. an interpretive statement encoded according to the SCP-ECG Universal Statement Codes and Coding Rules may concomitantly also be encoded according to the AHA and/or the CDISC code specifications.

Emphasis has also been put on extending and harmonizing the SCP-ECG Universal Statement Codes defined in Annex A with the AHA and CDISC statement codes and specifications, and with aECG and DICOM.

4. New sections

4.1. Long-term and protocol based ECG recordings - Sections 12 to 14

Starting with version V3.0, in addition to the short duration resting ECG (section 6) and the corresponding type 0 reference beat (section 5), the standard now provides a means of storing long-term ECG rhythm data in section 12, e.g. up to 40 days continuous recording of 3-Lead ECG signals sampled at 200 samples/sec with a 16 bit resolution, in section 14 several selected short to medium duration ECG sequences, and, in section 13, the related metadata and reference beats (or pointers to selected reference beats). These two additional sections have been included to support protocol-based ECG recordings, viz stress tests and drug trials procedures.

The format of section 12 is very similar to the ISHNE format. In order to preserve random access to the record's segments, no compression or encoding is allowed in this section.

4.2. Beat-by-Beat ECG measurements and annotations – Section 15

In addition to the full set of global measurements (section 7) and the per-lead measurements (section 10) of the type 0 reference beat, starting with version V3.0 the standard now allows the storage, in this section, of several pre-defined global and per-lead beat measurements and annotations, for all or for only some computed or selected beats of the analysed signals (long-term and/or long-term ECGs stored in sections 12 and 14 and/or in section 6). The beats may have been selected one by one by a physician or by a beat typing algorithm (reference beats of different types, etc.), or may refer to the entire set of beats from one or more selected time windows within the long-term ECG stored in section 12 or in the long-term ECGs stored in sections 6 or 14. The data format has been designed to support a large number of use cases, such as selecting and daily analyzing a set of 10 minutes duration time windows from a continuous long-term ECG recording, for example for time windows starting at 2 am and 2 pm, and then storing (P-on, P-off, QRS-on, QRS-off, T-off) and some additional useful annotations for assessing day and night differences and day to day variability of the selected measurements.

In another scenario, one may choose to select and store the measurements and annotations for K preselected, not necessarily consecutive beats, in as much Measurement Blocks (MB) as there are selected beats, for thorough QT studies for example. To facilitate comparison with reference beats measurements, the standard also allows saving, in separate MBs, the measurements and annotations performed on the reference beats stored in sections 5 & 13.

4.3. Additional ECG beats and spikes measurements and ECG annotations – Sections 16 - 18

Although section 15 already provides a means of storing several pre-defined global and per-lead beat measurements and annotations for different subsets of computed or selected (reference) beats of the analyzed signals, there are various scenarios which, for example, require storage of a few measurements and annotations for all beats of the rhythm signals, and a larger set of measurements and annotations for a much smaller number of beats, i.e. for some selected or computed reference beats. One solution would be to extend the number of (optional) additional measurements in section 15 in order to include the additional measurements used for quantifying the selected or computed reference beats, but this could introduce huge overheads as all measurement and annotations arrays in section 15 do have the same MB length which would require the storage of void measurement values for the non-selected beats, even if not computed.

Section 16 provides a solution for storing a different set of measurements and annotations than those stored in section 15 and is thus complementary to section 15. Its structure and format are much the same as for section 15, except that there is no provision for specifying analysis time windows and that there are no reserved fields for systematically storing the PP and RR intervals (the latter can nevertheless be stored, if need be, as optional additional measurements).

Section 16 is the preferred section for storing selected ECG beat measurements and annotations, if no beat-by-beat measurements and annotations are required (section 15 is not present).

Section 17 has been designed to include support for pre-defining and storing (much like the way used for storing beat-by-beat ECG measurements in section 15) large sets of global and/or per-lead spike measurements and annotations, spike-by-spike in one or more spike measurements array(s), one measurement array per analyzed ECG sequence (full long-term ECG record, selected ECG sequence) or reference beat.

The main objective of section 18 “Additional ECG annotations” is to provide a solution for storing any type of manually or automatically produced annotation which has not been stored in a systematic way in sections 7, 8, 10, 11 and 15 to 17, viz the onset (and end) of a bigeminal rhythm or atrial fibrillation, the identification of a pacemaker spike that was not listed in section 17, measurements that were not foreseen in sections 15 and 16 (or a few measurements like QT intervals in drug studies in case neither section 15 nor section 16 have been implemented), manual annotation of complex cases with different types of aberrant QRS complexes (LBBB aberrancy, etc.) and P waves (AV dissociation, etc.), noise annotations in a given lead, etc.

5. Conclusion

The work presented in this paper is a revision of an existing, partly outdated standard EN1064 which is also an ISO standard 11073-91064. The standard aims to define: (1) how to store ECG lead data; (2) the relevant data to be stored in addition to the signals for enabling their medical interpretation; (3) the exact and standardized definition of each piece of stored data and computed measurements; (4) the data encoding format and how to encode data; (5) how to secure the reliability of an SCP-ECG file.

The binary encoding of ECG data within SCP-ECG and the included content self-control capabilities allow for an efficient encoding, an encapsulation of all ECG-related parameters, and a small memory footprint compliant with mHealth scenarios. These features not only provide an advantage in data transmission and archiving, but also when the data need to be encrypted (for protecting the data and the confidentiality), or signed (protection against changes).

The standard is thus expected to: (1) provide a means of setting up interoperability facilities at low cost, thus enabling the interchange of standardized ECG signals, which are the first source of information for an early detection of cardiovascular diseases, and which can be collected anywhere, even at home or in the countryside; (2) promote serial ECG analysis, which is highly recommended by leading international societies (AHA, ACC, ESC, ...) to enhance ECG diagnosis accuracy.

After the completion of the revision of EN1064, the intention is also to revise the corresponding ISO 11073-91064 standard and to set-up a Web site providing SCP-ECG related information, tools and services, viz viewers, V2.x to V3.0 and V3.0 to HL7 aECG and vice versa converters, etc. (http://webimatics.univ-lyon1.fr/scp-ecg).

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