Communication and Retrieval of ECG Data: How Many Standards Do We Need?

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Abstract

The increasing efforts to establish an electronic health record and new requirements of the FDA for provision of original ECG data with clinical studies has re-vitalized the interest and work on communication of ECG raw data and of processing results. Despite the fact that many companies from the United States and from Europe had developed and agreed on the ECG Standard Communications Protocol SCP it was not widely used.

In new Projects, like the German IMEX, the European OpenECG and within an IEEE1073/HL7 working group the whole communication path, available and future standards, considering new requirements from telemedicine, have been discussed. This paper gives an overview on the present state and on some necessary final developments.

1. Introduction

During the past 2-3 decades development work on computerized ECG machines – or more general - on Medical Devices focused on improving their functionality (device functionality, signal analysis, pattern recognition and classification). Communication of ECGs between an ECG Cart and a Data Base Management System (DBMS) has been a long time subject to proprietary solutions. At present the dominant user requirement is information communication and integration. Interconnectivity and interoperability of devices are now key features to be provided.

In 2001 the FDA has revitalized the discussion on open ECG data interchange by requiring for clinical studies besides the measurements, easy to view original waveform data and their annotations. Also the DICOM community needs to integrate ECG signals, e.g., for gated image processing. For distribution of ECGs and their analysis results inside and between Hospitals, the SCP-ECG standard is available but increasingly HL7/XML messaging comes into use. Another upcoming application domain for electrocardiography is home care with wireless telemetric transmission.

2. Communication of biosignals

2.1. ECG System configurations

The most simple and widely used computer assisted ECG system configuration is depicted in figure 1.

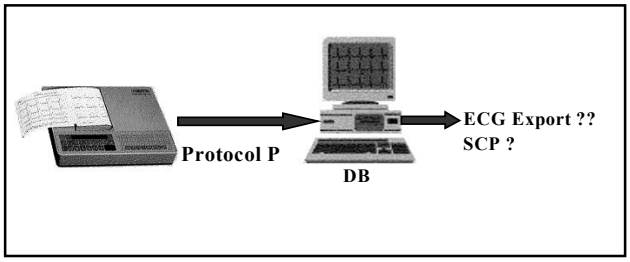

Figure 1. Standard computer electrocardiograph with PC.

The ECG is acquired and processed within an ECG cart which may be capable of transmitting ECG raw data and processing results to an ECG data base system (DB) on a PC. Most frequently a proprietary protocol "P" is used for communication. For the export of raw data and of processing results - if possible at all - mainly proprietary protocols are used, respectively.

Now increasingly standalone ECG amplifiers with integrated digitisation have been developed. They are connected to a PC where analysis and storage of ECGs takes place (Integrated ECG data base management system).

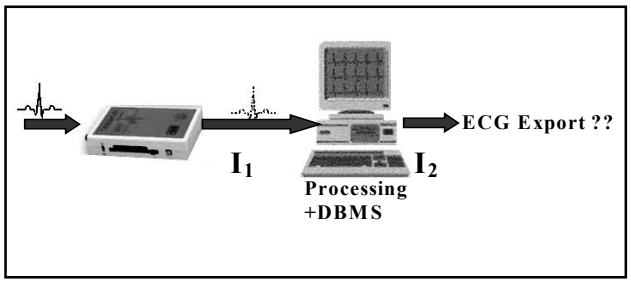

Figure 2. PC ECG system with "stand alone" amplifier.

2.2. A conceptual reference model for biosignal acquisition and communication

Development of micro sensors and microprocessors particularly for home care systems progresses continuously. Acquisition of multiple biosignals, e.g., blood pressure (BP), ECGs, respiration, urine flow and other biosignals, is performed by means of patient worn devices. Collection and communication of data takes place via body area networks (BAN). One example is the German IMEX ("Implantierbare und extrakorporale modulare Mikrosystemplattform") project [1].

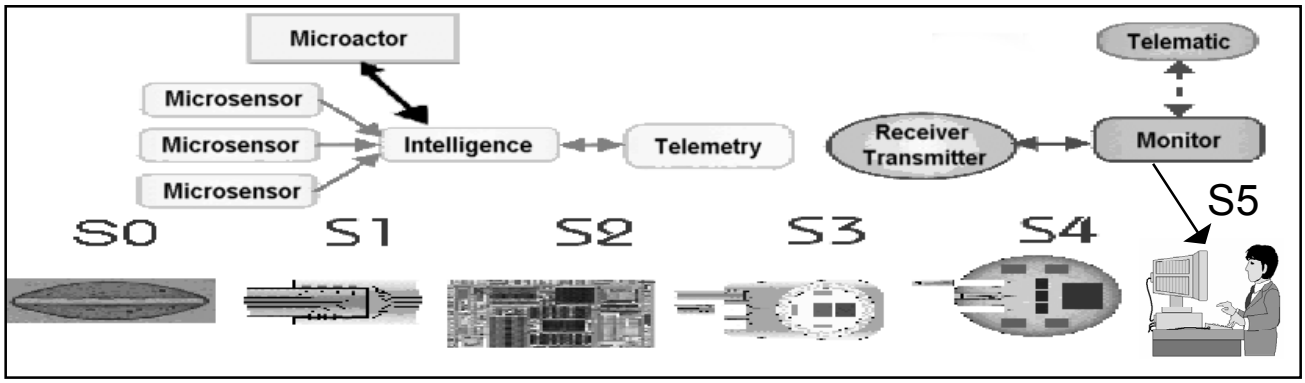

Figure 3. Conceptual reference model for multiple signal acquisition and communication.

Establishing a BAN and it's communication with external device systems and healthcare institutions resulted in an even more detailed analysis of all possible interfaces and their communication requirements (see figure 3). Discussion of this model will help to identify where today standards for ECG data communication are available, or to be extended or added.

S0 refers to the standard between origin of the signal, electrode and sensor input. For electrocardiography this would refer to the lead system and could include the electrode. Except for specific mapping systems the electrode positions for routine electrocardiography are specified [2] and it is widely accepted that silver-chloride electrodes are the "sensors" of choice.

The interfaces $\mathbf{I_1}$ and $\mathbf{I_2}$ (**S1** and **S2** respectively) at the input and output of the "intelligence" depend for electrocardiography on the system configuration.

S1 is specified, e.g., within the IEC Standard 60601-2-CDV51 [2] for ECG carts. For PC ECG systems with stand alone amplifiers the interface at *amplifier-output-PC-input* is **S1** and it is not standardized but a standard is desirable from a consumer and system designer's point of view.

For **S2**/**S3** either at the output of an ECG cart or of a PC-ECG system the applicable standard is clear: since 1993 the **SCP-ECG** European pre-standard ENV 1064 [3] and since 2001 the revised version (1.3) of this standard is as AAMI standard (EC71-D 2001) in place. It is clear that interfacing the "Intelligence", i.e., the processing module with the "Telemetry" module **S2** and **S3** must use the same data interchange format specification. **S2** and **S3** must be fully SCP compatible from the physical layer up to the presentation layer.

A problem with the SCP-ECG standard is that at it's development particularly the manufacturers recommended various options for content and format of the output data (ECG raw data as well as of processing results) with the consequence of a too broad variety of communicated data. True interoperability of device systems from different manufacturers could hard be achieved in this way.

Moreover, for transmission of data a rather basic communications protocol - enhanced X-Modem - was specified, which was appropriate in 1993 but has been passed meanwhile by other, more advanced technical solutions.

In 2001, the FDA initiated a new discussion on ECG data interchange by requiring full disclosure provision of analysis results including "original" ECG wave forms. In 2002, the European OpenECG project [4] was launched to support ECG interoperability and the broad application of the SCP standard. While the FDA requirements brought into focus mainly the necessity of platform and program language independent ECG viewing capabilities, the OpenECG project puts emphasis on getting manufacturers using the interoperability standards like SCP. Within this work barriers for implementation are searched for and as a result from the first OpenECG workshop [5] it was agreed to simplify the SCP Standard by restricting the number of implementation options. While content and format of the SCP-ECG record was not principally questioned there was a strong desire to reduce and to simplify the number of "compliance levels".

Meanwhile, a proposal to reduce the originally four compliance levels to two has been developed within the IEC SC62D working group1. The first one (I) specifies a SCP record containing patient- and record identification and ECG raw-data with or without loss-less compression. Such a record comprises with reference to the SCP Interchange Format the CRC checksum, Record size in

Bytes and the sections 1, 2, 3, and 6. Optionally, section 7, 8 with "global" measurements (intervals) and the textual diagnosis from an interpretive device may be transmitted.

The second specified compliance level comprises additionally section 4 and 5 (pointers to QRS locations and Reference (Average) beat data). A third compliance level has not yet been specified but reserved as place-holder for mobile (telemetric) applications.

For better understanding table 1 below shows structure and content of the whole SCP interchange format.

Table 1 Structure of a full SCP Record

Status	Section IDs	Content
Mandatory	-	Checksum-CRC-CCITT
Mandatory	-	Size of the entire record
Mandatory	0	Pointer to data areas
Mandatory	1	Header Information-Patient data/ECG data
Optional	2	Huffman Tables
Optional	3	ECG Lead Definitions
Optional	4	QRS Locations
Optional	5	Encoded Reference Beat
Optional	6	"Residual Signal" after Reference beat subtraction if reference beats are stored, otherwise encoded rhythm data
Optional	7	Global Measurements
Optional	8	Textual Diagnosis
Optional	9	Manufacturer Specific Diagnostic
Optional	10	Lead Measurements
Optional	11	Universal Statement Codes
Reserved	12-127	Reserved for future use
Optional	128-1023	Manufacturer specific sections
Reserved	1024-65535	Reserved for future use

A significant problem for integrating ECG data into an electronic health record is still a uniform patient and record identification. These data are to be transported through section 1 of the SCP record. Section one is structured in up to 35 tags containing demographic patient data, medical data of the patient including drug and referral information, data about the device, it's settings, the recording location, ECG leads acquired, time stamping and many further details on the ECG record which may be necessary for later comparison with other ECG recordings of this patient.

The next table gives a consolidated overview on this section.

Table 2 Consolidated overview on the content of SCP section one.

Content	Status	Tag IDs
Patient ID	mandatory/ recommended	0, 1, 2, 5
Patient Medical Information	optional	11, 12, 13, 32
Drugs	optional	10, 35
Acquiring Device ID	mandatory	14
Analyzing Device ID	recommended	15
Time stamp	mandatory/ recommended	25, 26, 34
Device Settings	optional	27, 28, 29
ECG Sequence ID	optional	31
Lead System ID	optional	33
Location ID	optional	16-19, 23
Overreading info	optional	21

Within the IMEX project a deep analysis is performed to optimize format and structure of the section 1 data for handling them with micro technology within a BAN as well as for communication with external applications.

3. Interoperability between a device system and a human application

So far, we have discussed from the reference model fig. (3) the interfaces **S1-S3**. Dependent on the system configuration at the application site **S4** could still be an SCP interface like **S3** as long as the ECG data are to be transported electronically, e.g., for telematic applications. If, however, at the transmitter output human interaction with the system takes place, the electronic data need to be visualized and converted for human perception. An additional interface **S5** with an associated standard is necessary for the machine – human communication.

A methodology for communicating medical data (starting from health care scenarios in and around an Intensive Care Unit (ICU)) has been developed and is described in the European Vital Signs Information Representation Standard ENV 13734 [6], published in 2001. A major task after definition of an adequate Domain Information Model (DIM) with all of it's object and attribute definitions was to structure all the information gathered by the large variety of instruments at many points in time from numberless organs or locations on the patient. Only if for each single measurement (object instantiation) an unequivocal term could be found a unique code could be assigned to each measurement and only then an unambiguous information transfer would be possible. We call such a system of terms a *nomenclature.* It's entities form the Medical Data Information Base (MDIB), also called the "Data Dictionary".

A prerequisite to develop a nomenclature is the establishment of "systematic" names. For this we have used the methodology described in the European pre-standard prENV 12264 (1995): Categorial Structures of Systems of Concepts – Model for Representation of Semantics (MOSE) [7]. Figure 4 depicts the basic structure of the systematic names used to characterize uniquely each ECG measurement, Beat annotation or any diagnostic interpretation [6,7].

specified in [2]. No standard (**S1**) exists for the communication between an ECG stand alone amplifier and a processing device. For the Interfaces **S2-S4** the SCP interchange format is very suitable and should be used. To achieve full interoperability with external human users (**S5, - "**applications") representation of data needs to follow the specifications of the Vital Signs Standard. Only then, the full interoperability between applications can be reached - not limited to electrocardiography.

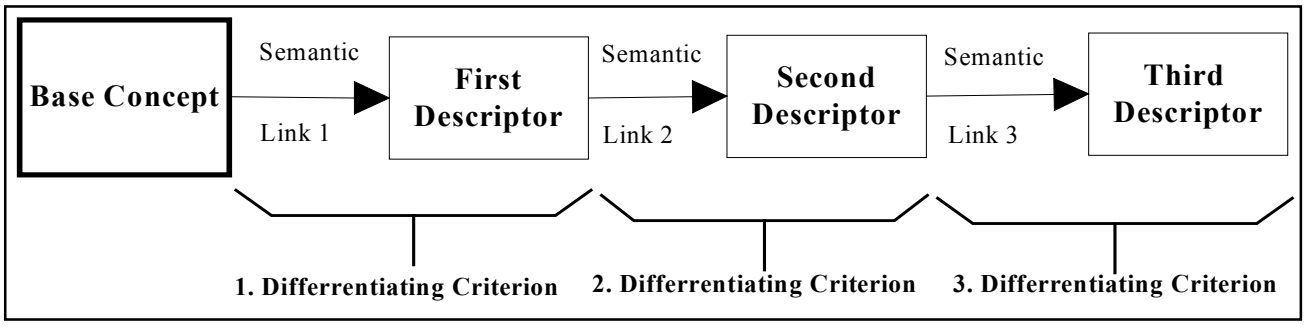

Figure 4. Structure of systematic names used to establish the domain nomenclature

For the **base concepts** in Electrocardiography terms like *Electric Potential, Magnitude, Duration, Angle, Slope or Pattern* turned out to be useful. For **semantic links** terms like *has origin, has method, is computed as, concerns* or *has context* were found. **Descriptors** following the semantic links could be ECG<lead>, Vector, Maximum P(-wave), Arrhythmia, CVS (Cardio-Vascular-System). The following examples illustrate the systematic names for description of an ECG measurement and a specific pattern and the assigned codes:

(a) QRS Duration in lead V6:

Duration|ECG<v6>,QRS|Heart|CVS ↔ code 7936

(b) ECG with Arrhythmia

Pattern|Arrhythmia|ECG,Heart|CVS ↔ code 17424

Meanwhile, two code blocks of 16 bit size have been specified for ECG measurements; the first one by the CEN project team that has essentially worked out the Vital standard [6] and the second one by members of the IEEE 1073/HL7 [8] working group focussing on beat-, wave component, rhythm and noise annotations to support the FDA-HL7 project.

4. Summary and conclusion

Interoperability of medical devices in general and of ECG computer systems specifically is at present the first priority development demand. The inventory of the IMEX project has revealed that at least four information transfer interfaces (**S0 – S4**) are to be passed by a biosignal, respectively by an ECG, from the signal source to the "End" device. This could be a monitor or a telematic system with consulting and/or archival services. For the first interface at the electrode site in electrocardiography a standard is set by the lead systems and

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