SCP-ECG in an ISO/IEEE 11073-PHD world: Store-and-Forward Transmission and Messaging Part.

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Abstract—**The storage and retrieval of digital ECGs in a standard-compliant way has been a key issue during the last decades. The SCP-ECG standard, one of the top efforts in this area, has been recently approved as part of the ISO/IEEE 11073 (x73) family of standards, a reference standard for medical device interoperability. For the Personal Health Device (PHD) version of the x73 standard several devices have been defined, but an ECG device specialization is not yet available. In this paper, the relationships between the SCP-ECG fields and messages and the particular way of the x73-PHD standard to deal with stored data are investigated and discussed. A proof-of-concept implementation of the x73-PHD storage and retrieval method applied to ECGs is also presented, identifying open issues and potential modifications to be considered for the wider interoperability adoption of x73-PHD standards.**

I. Introduction

A wide range of the existing Telehealth applications do not usually require an immediate response, such as, for example, a consultation for dermatology or radiology. The Store-and-Forward (S&F) technique, due to its characteristics, is the best suited technology to be applied in those situations, and also the future of Telehealth points to significant growth of such applications in many areas of health care service delivery [1].

The electrocardiographic (ECG) signal, especially in non-emergency situations, is particularly suitable for S&F telemedicine from a technical point of view [2]. In this context, a large variety of protocols and standards have been proposed. Some of the more widely known are: SCP-ECG (European standard EN1064), HL7 aECG (American standard, ANSI), or DICOM Waveform Sup 30. In the near future, the rising ISO/IEEE 11073-PHD (x73-PHD) standard will also be able to cover the S&F transmission of ECG data.

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In the literature, several projects covering the relationship between two or more of these standards can be found (Fig.1). Examples of those relationships are: SCP-ECG with DICOM [3,4]; SCP-ECG and HL7 aECG with DICOM [5]; SCP-ECG with HL7 aECG [6]; or SCP-ECG with x73-PHD [7].

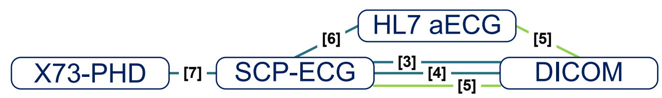

Fig. 1. Relationship between the different formats.

SCP-ECG [8] and x73-PHD [9] are two close-related standards. As a matter of fact, the latest version of the SCP-ECG standard has recently become an international standard as ISO/IEEE 11073-91064:2009, part of the x73 family [10], although an ECG profile for x73-PHD is not yet available [11]. Nonetheless, in the particular case of S&F transmission, there are still several issues in the coordinated use of SCP-ECG in an x73-PHD world that have not been adequately investigated and analyzed yet.

II. Architecture

The general scheme of an end-to-end standard-based Telehealth system serving as a proof-of-concept can be seen in Fig. 2. In it, an x73/SCP-compliant ECG device (called Agent) records and stores the ECG signal. Later, this Agent connects with an x73/SCP-compliant entity (called Manager) and informs that there are stored data in the Agent not sent yet. The Manager can forward this message to a Management Server which answers, deciding whether to retrieve this information or not. Then, the Manager will proceed and execute the decision, making use of the x73 procedure to deal with stored data. If the selected choice is to retrieve the data, the Manager will retrieve them and generate an SCP-ECG file. After that, the file can be forwarded through eXtensible Markup Language (XML) to an Electronic Healthcare Record (EHR) server for later consultations in compliance with EN13606 standard. Finally, the SCP-ECG file can be observed with all its specific fields by using a HealthCare Information Systems (HCIS).

The transmitting protocols in the interfaces beyond the Manager are out of the scope of x73-PHD and they are not covered in this paper. This paper focuses on the Agent/Manager interface (wherein x73-PHD applies), but some other aspects of the whole scheme are discussed.

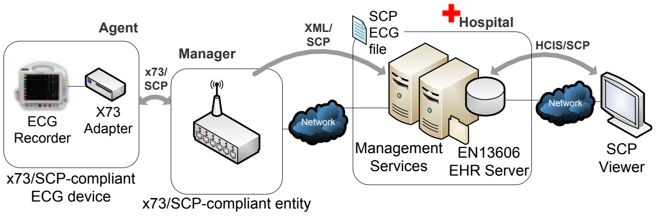

Fig. 2. Overall end-to-end standard-based architecture.

III. Store&Forward In x73-PHD And SCP-ECG

A. The x73-PHD's persistent metric concept

The Persistent Metric (PM) concept in x73-PHD provides a method for representing, accessing, and transferring large amounts of metric data hierarchically stored in the Agent. A PM store consists of the following four key parts [9]:

1) PM-Store: This is the top most object and it contains attributes about the storage object as well as zero or more PM-Segments. Agents typically use multiple PM-Stores if they stores data with different characteristics.

2) PM-Segment: This object contains attributes that describe the segment as well as zero or more entries. Agents typically use multiple PM-Segments if they need to structure the stored data in a more hierarchical form.

3) Entry: Each entry holds an optional header and one or more elements. An entry typically contains a measurement (Numeric, Real Time Sample Array (RT-SA), etc.).

4) Element: Each element holds data from one or more metric measurements.

The PM-Store concept of x73-PHD only suggests a hierarchical approach to arrange metric data. The final organization (as well as the internal physical storage) is device-dependent, so it is covered later in Section V.

B. The SCP-ECG groups of information data

The minimum fields required to create an SCP-ECG file can be subdivided into six different groups, according to the information they are related to: patient, device, temporal, lead, waveform, and the data themselves (see Table I).

In this study, only the mandatory and the recommended fields of SCP-ECG are covered. The following assumptions are made: no compression, all leads are simultaneously recorded, the SCP-ECG device has no analyzing capabilities and it stores patient information, the SCP-ECG compliance category chosen is Type I (as defined in [8]) and, finally, a RT-SA is used to encapsulate the ECG within the PM-Store.

C. x73-PHD PM-Store and SCP-ECG format relationship

These are two suitable ways to arrange ECG data. The main difference is that, while SCP-ECG is a standard specially designed for electrocardiography, x73-PHD is a wider standard, so the PM-Store is a broader idea in order to handle the large variety of existing metric data. This makes x73-PHD more versatile. In an SCP-ECG file, all six groups of information must be stored but, not all these groups are needed to be stored from an x73-PHD PM-Store perspective.

TABLE I
Types of Fields in SCP-ECG and their Relationship with x73-PHD PM-Store

Group	Section	Tag	Description	Relationship with x73-PHD PM-Store
Patient	*1*	0 1 2 5 8	Patient Last Name Patient First Name Patient ID Patient Date of Birth Patient Sex	*PM-Segment::PM-Seg-Person-Id*
Device	*1*	14	Acquiring Device ID	*Not included*
Temporal	*1*	25 26 34	Date of Acquisition Time of Acquisition Date Time Zone	*PM-Segment::PmSegmentEntryMap. SegmEntryHeader (Time Stamp)*
Lead	*3*	-	Lead ID	*PM-Segment::PmSegmentEntryMap. SegmEntryElem.metric-type.code*
Waveform	*6*	- - - -	Amplitude Value Multiplier Sample Time Interval Sample Size Length	*Related to RT-SA (typically one PM-Segment Entry)*
Data	*6*	-	Data	*Related to RT-SA (typically one PM-Segment Entry)*

Table I also shows the relation of these SCP-ECG fields with the x73-PHD PM-Store concept:

1) Patient: These SCP-ECG fields can be covered using the PM-Seg-Person-Id attribute. The Manager will be able to gather the patient data to generate an SCP-ECG file.

2) Device: This information is related to the ECG device. This kind of information is sent during the configuring process. Thus, storing this information is not required.

3) Temporal: Entries optionally include a time reference.

4) Lead: The SCP-ECG Lead ID can be included when defining the PMSegmentEntryMap attribute.

5) Waveform and Data: These SCP-ECG fields fit perfectly in a RT-SA class. As said before, an entry typically contains a measurement (in this case, a RT-SA).

Some other considerations, such as, a different patient approach or the relation of the SCP-ECG fields to the x73-PHD RT-SA, were covered in a previous work [7].

IV. Messaging Part

A. The x73-PHD method to manage stored data

When an Agent implements one or more PM-Store objects, the Agent reports about the existence of the PM-Store object during the configuration phase (attributes: Handle and PM-Store-Capab). The Manager uses this information to query the PM-Store object(s) of the Agent by using the following methods or services:

1) Retrieve PM-Store attributes: The Manager may query each PM-Store to request all or some attributes be returned.

2) Retrieve PM-Segment information: The Manager can retrieve information on the segments and request to return information from: a) all-segments, b) a particular list of segments, or c) any segments within a given time range.

3) Transfer PM-Segment content: The Manager is able to retrieve specific PM-Segments. The Agent shall decide if the request can be honored and shall return a successful response code or an appropriate error code. The Agent shall send reports until all entries are sent or the transfer is aborted.

4) Clear PM-Segment: The Manager may clear a PM-Segment at any time, typically straight after the entire segment was transferred to the Manager. The segment selection criteria are the same as in IV.A.2).

TABLE II
SCP-ECG Messages and their Relationship with x73-PHD PM-Store Methods and Services

Type	Description	Sub-Type	Description	Sub-Code	Description	Relationship with x73-PHD
I	Identification	-	Uniquely identify the requesting device	-	-	*Covered by x73-PHD configuring procedure*
R	Request	*E*	Send ECG List for Specified Patient	-	-	*Retrieve PM-Segment information (Response)*
		I	Send Patient List for Specified Name	-	-	*Does not make any sense in x73*
		L	Receive ECG List for Specified Patient	-	-	*Retrieve PM-Segment information (Invoke)*
		P	Receive Patient List for Specified Name	-	-	*Does not make any sense in x73*
		R	Receive ECGs	*0*	No request mask needed: send all ECGs	*Can be covered by using Transfer PM-Segment (Invoke)*
				1	Requested ECG, will have Date and Time	
				2	Latest ECG	
				4	1st Previous ECG	
				8	2nd Previous ECG	
				16	Baseline ECG if present, otherwise oldest ECG	
				32	All Since, will have Date and Time	
		S	Send ECGs	-	-	*Transfer PM-Segment (Response)*
		X	Escape to Vendor Specific Request	*Vendor Code*	Vendor Specific Code	*Not standard*
S	Status	*G*	Ok	-	-	*Covered by the x73-PHD FSM*
		E	Error	*Number*	Some error codes are provided	*See IV.C)*
A	Advisory	-	Provides additional information	-	-	*Not mapped. See IV.C)*
D	Done	-	Completion of a command	-	-	*Covered by the x73-PHD FSM*

B. The SCP-ECG messaging part

The messaging part of SCP-ECG (informative, but not normative) describes the type of information that can be requested and transmitted between a cart and a host in order to manage stored ECGs that are yet to be forwarded. It also describes the format of these messages and its usage. The different data messages (Identification, Request, Status, Advisory and Done) and its usage are shown in Table II. The relationship with x73-PHD is covered in Subsection IV.C).

C. x73-PHD and SCP-ECG messages relationship

The detailed analysis of the x73-PHD and SCP-ECG messages relationship (see Table II) is explained below:

1) Identification, Status-Ok and Done. These SCP-ECG messages are covered by the x73-PHD Finite State Machine (FSM) itself.

2) Status-Error. This SCP-ECG message provides a little collection of fixed error codes (*EC*). Some of them are mapped by x73-PHD frames such as, for example, badly-structured-apdu (*EC*=5). Some other error codes do not make any sense as, for example, patient name invalid (e.g. *EC*=11), since no patient information is stored in the ECG device. However, these types of error codes can be useful in the Manager/Management Server interface.

3) Request. This SCP-ECG message is further subdivided in the following sub-types:

- *Sub-Types P and I* do not make sense in x73-PHD (since there is no patient information in the ECG device) but may be useful in the Manager/Management Server interface.
- *Sub-Types E and L*. These messages request to receive and send an ECG list for a specified patient. They can be covered by the Retrieve PM-Segment information method, although the procedure is different: while these messages specify a patient by sending a list of her/his identification parameters (ID, Name, Sex and/or Date of Birth), the x73-PHD method only uses the Person-Id. Once the x73-PHD method has retrieved the PM-Segment information, the Manager is able to create a list of ECGs for a specific patient. Besides, in x73-PHD, the rest of the parameters (not only the ones related to the person) are susceptible to be the base of a request list.
- *Sub-Type R*. After retrieving the PM-Segment information, the Manager can choose any segments to be transferred using only the segment handle by means of the Transfer PM-Segment method (Invoke). In SCP-ECG, there are only a few bit-mapped possible choices.
- *Sub-Type S.* Taking into account the differences between these two protocols, this message is directly related to the x73-PHD Transfer PM-Segment (Response).

4) Advisory. In order to avoid the rising of a time-out, this message provides additional information in case that a large amount of time is needed to elaborate the response. There is no such a concept in x73-PHD. Nevertheless, some time-outs can be set (Clear, Confirm, Transfer).

Furthermore, some other technical issues have been considered in order to complete this study. The Clear PM-Segment idea is not present in SCP-ECG, so the manager is not able to remove ECG data stored in the device. This is done by the ECG devices, which can be usually configured so that the ECG is deleted after a successful transmission.

The SCP-ECG request messages Sub-Types *P* and *L* (that list files or patients) are blind, to a certain extent, since the Manager does not know what the cart actually stores. Instead, in x73-PHD, the Manager first asks for the parameters he wants to know about and then creates a specifically designed list for retrieving the metric data. However, in SCP-ECG the device is able to initiate the sending of stored ECGs, while in x73-PHD the device just informs of the existence of stored data. Then, the Manager (or further decision entities) resolves either to retrieve this information or not.

In SCP-ECG the maximum message size is 256Bytes. This sometimes leads to forced truncations to comply with this restriction, but these shortenings are usually not critical. In x73-PHD, the frames shall be no larger than 63KBytes (from Agent to Manager) and 8KBytes (from Manager to Agent).

Finally, in x73-PHD, it is encouraged to pack as many entries as possible into the Event structure to optimize the transmissions. In the particular case of ECGs, probably more than one Event will be needed, so the Manager has to take care of this control with SegmDataEventDescr. In contrast, the control of the SCP-ECG file length is accomplished by lower protocol layers.

V. IMPLEMENTATION

An end-to-end standard-based platform was implemented by our group [12]. It was developed using C++ and included all the required classes, attributes and specifications defined in x73-PHD. The first device specializations implemented were: pulse-oximeter, blood pressure and weighing scale. Later, a custom-defined x73-PHD/SCP-ECG specialization was added [7]. Within the project described in this paper, the simulated ECG device was used to record, store and later transmit an ECG by means of the PM-Store concept. In our application, it has been organized as follows:

- *PM-Store:* It contains all the ECGs stored in the device. The attribute Number-Of-Segments specifies the number of stored ECGs.
- *PM-Segment:* An ECG. The PM-Seg-Person-Id attribute identifies the patient/user.
- *Entry:* It encapsulates one lead (per Entry) in a RT-SA structure. Therefore, it contains the data itself but also the information related to this lead, such as Sample Size or Scale and Range specifications.
- *Element:* One single ECG sample. The first elements in the entry correspond to the information related to this lead.

The x73-PHD standard establishes that only complete entries shall be included in a SegmentDataEvent. Depending on different parameters (sample rate, simple size or time recorded) the total length of one lead could exceed the limit of 63KBytes. Two approaches can be considered:

- *Split up the leads into several entries/segments.* This might obscure the hierarchical organization. Besides, some minor modifications should be done in the x73-PHD standard in order to keep track of the fragmented ECG.
- *Entries can be fragmented.* The idea is to modify the x73-PHD, so that one Entry can be divided into sequential SegmentDataEvents. In our implementation, this approach has been followed. When holding a fragmented Entry, the field segm-evt-entry-count is set to zero. Besides, two new fields have been added to the SegmDataEventDescr struct in order to keep count of the Entry fragment being transmitted: segm-evt-entry-fragmnt-index (index of the fragment) and segm-evt-entry-fragmnt-total (total number of fragments that compound one Entry).

Regarding the internal physical storage, in our application the data are stored in a file exactly in the order that the Manager would ask for them, so that it is quicker to create response messages or SegmentDataEvents.

Thus, the x73-PHD standard is followed by an Agent to configure a simulated ECG device, record and store an ECG signal and finally send it to the Manager using the PM-Store concept, classes and procedure (including a modification to deal with large ECGs). After that, the Manager generates a SCP-ECG file that can be sent to an EHR Server and included in the patient history. The SCP-ECG files generated with our application have been successfully tested using the certification service provided by the OpenECG portal [13]. This tool includes a content checker and a format checker.

VI. CONCLUSIONS AND FUTURE DIRECTIONS

The S&F feature by means of the PM-Store class has been implemented in a pre-existing x73-PHD platform that included a simulated and custom-defined ECG device. An enhancement to cover the transmission of large ECGs has been proposed and discussed. The ability of the SCP-ECG messaging part within the framework of x73-PHD has been investigated. The relationships between the different fields and messages of both standards have been described.

This process has proved that the x73-PHD PM-Store concept is a well-defined idea to manage metric stored data, including ECGs. The open approach used in x73-PHD to define the messages and fields covers practically the whole SCP-ECG messaging part. Some SCP-ECG ideas, that lose their sense in an x73-PHD interface, can be profitably transferred to the Manager/Management Server interface.

The main further research trend is the implementation of the Management Server. It could cover not only the medical management (medication reminder alarms or modification of parameters, such as resolution, sample interval, amplitude…) but also the technical management of the device, including this way Managers and Agents in the management network.

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