Standard-Compliant Real-Time Transmission of ECGs: Harmonization of ISO/IEEE 11073-PHD and SCP-ECG

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Abstract— **Ambient assisted living and integrated care in an aging society is based on the vision of the lifelong Electronic Health Record calling for HealthCare Information Systems and medical device interoperability. For medical devices this aim can be achieved by the consistent implementation of harmonized international interoperability standards. The ISO/IEEE 11073 (x73) family of standards is a reference standard for medical device interoperability. In its Personal Health Device (PHD) version several devices have been included, but an ECG device specialization is not yet available. On the other hand, the SCP-ECG standard for short-term diagnostic ECGs (EN1064) has been recently approved as an international standard ISO/IEEE 11073-91064:2009. In this paper, the relationships between a proposed x73-PHD model for an ECG device and the fields of the SCP-ECG standard are investigated. A proof-of-concept implementation of the proposed x73-PHD ECG model is also presented, identifying open issues to be addressed by standards development for the wider interoperability adoption of x73-PHD standards.**

I. Introduction

INTEROPERABILITY is a prerequisite and an enabler for versatile, integrated, efficient and useful communication between Medical Devices (MDs) and host systems in the context of comprehensive high quality eHealth services [1,2]. During the last years, various proposals have emerged so that the different electronic MDs are able to communicate with an Electronic Health Record (EHR) server, in order to promote the creation of an end-to-end standard-based interoperable eHealth services. The most prominent of these efforts are the family of standards ISO/IEEE 11073 (usually referenced as x73) that enables communication between MDs and external Compute Engine (CE) systems, and EN13606 that allows the interoperable exchange of the EHR. Some other initiatives, as the Continua Health Alliance [3], have emerged to improve the quality of personal healthcare.

In the particular case of digital ECG signals, a wide variety of standards have been proposed, since the ECG is considered part of different use cases ranging from diagnostic examinations, to home care, emergency care, and to clinical trials. In these diverse contexts, a plethora of ECG standards has been proposed or implemented. Some of the more widely known are: SCP-ECG (European standard EN1064), HL7 aECG (American standard, ANSI), MFER (Japanese standard), or Dicom Waveform Sup 30.

The x73 family of standards, initially driven by IEEE and then adopted by the CEN and ISO, arises from the need to propose robust, open and interoperable technical solutions in the field of systems and devices for telemonitoring of patients in home or mobile scenarios. On the other hand, the SCP-ECG standard [4], fostered by the European project OpenECG [5] has the task of promoting standard exchange and storage of short term diagnostic ECGs in a coordinated and interdisciplinary manner. However, there are several issues relevant to the coordinated use of SCP-ECG in an x73 context that have not yet been adequately addressed or where no consensus has been reached.

The standard x73 has evolved from the patient Point-of-Care (x73-PoC) [6] to new Personal Health Devices (x73-PHD) [7]. So far, only a reduced set of PHDs have been defined for x73-PHD (Pulse Oximeter, Blood Pressure, Thermometer or Weighing Scale). Although an ECG profile was defined for x73-PoC [8], an ECG profile for x73-PHD is not yet available [9]. Recently, the latest version of the SCP-ECG standard has become an international standard as ISO/IEEE 11073-91064:2009, part of the x73 family [10]. However, several issues remain open as regards to the harmonization of the x73 standards necessary to implement end-to-end eHealth services.

In this paper, we report the results of a project to investigate x73 compliant real-time transmission of ECG signals. In Section II the end-to-end scheme as a proof of concept is presented. The harmonization of the x73 and SCP-ECG as well as the design of an x73-PHD model taking into account the SCP-ECG fields are analyzed in Section III. Design choices, implementation of the relevant agent-manager interface in a pre-existing x73 framework, and open issues are detailed and discussed in Section IV.

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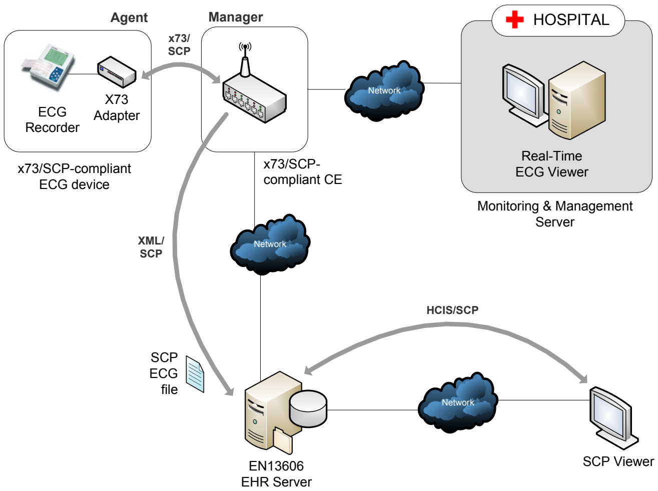

Fig. 1. Overall end-to-end standard-based architecture.

II. Architecture

The general scheme of an end-to-end standard-based eHealth system serving as a proof of concept can be seen in Fig. 1. In it, an x73/SCP-compliant ECG device (called Agent) records the ECG signal and sends it to the x73/SCP-compliant CE (called Manager). Then, the signal can be forwarded to the Monitoring & Management Server, where a cardiologist can check the ECG signal in a real-time mode. The protocol to be used in this interface is out of the scope of x73 and it is not covered in this paper.

On the other hand, an SCP-ECG file can be generated at the Manager and then forwarded through eXtensible Markup Language (XML) to an EHR server for later EN13606-compliant consultations (although the transmitting protocol in this interface is out of the scope of x73 and it is also not covered in this paper). Finally, the SCP-ECG file can be further observed with all its specific fields by using a HealthCare Information Systems (HCIS).

The main focus of this paper is the interface between Agent and Manager (wherein x73 applies), although some other aspects of the whole scheme are discussed.

III. SCP-ECG and the x73-PHD Model

A. The SCP-ECG standard- implementation choices

The minimum fields required to create an SCP-ECG file are shown in Table I along with the relationship of these fields and tags with the x73 standard. In this study, only the (M)andatory or the (R)ecommended fields of SCP-SCG are covered, and the following assumptions are made: no compression is used, all leads are recorded simultaneously (real-time), the ECG device has no analyzing capabilities, the SCP-ECG compliance category chosen is Type I (as defined in the SCP-ECG amendment) and, finally, an x73 class for Real Time-Sample Array (RT-SA) is used to encapsulate the ECG signal.

TABLE I
Fields Required in SCP-ECG

Section	Tag (SCP qualifier)	Description	Relation to x73
-	-	CRC & Size	*Generated in CE*
0	-	Pointers to Sections	*Generated in CE*
1	2 (M)	Patient ID	*Not defined in x73 (see III.B.4)*
	14 (M)	Acquiring Device ID	***See Table II***
	25 (M)	Date of Acquisition	*Metric:Absolute-Time-Stamp*
	26 (M)	Time of Acquisition	*Metric:Absolute-Time-Stamp*
	0 (R)	Patient Last Name	*Not defined in x73 (see III.B,4)*
	1 (R)	Patient First Name	*Not defined in x73 (see III.B,4)*
	5 (R)	Patient Date of Birth	*Not defined in x73 (see III.B,4)*
	8 (R)	Patient Sex	*Not defined in x73 (see III.B,4)*
	15 (R)	Analyzing Device ID	*Not defined (see Assumptions)*
	34 (R)	Date Time Zone	*Somehow defined (see III.B,2)*
3	-	Number of Leads	*Number of RT-SA instances*
	-	Start & End Sample	*Generated in CE*
	-	Lead ID	*Fully Compatible*
6	-	AVM	*Somehow defined (see Table III)*
	-	Sample Time Interval	*Somehow defined (see Table III)*
	-	Sample Size	*Somehow defined (see Table III)*
	-	Length	*Somehow defined (see Table III)*
	-	Data	*Somehow defined in RT-SA*

TABLE II
Acquiring Device ID Tag

Byte	Description	Relation to x73	Proposed Qualifier
1-2	Institution Number	*not mapped*	O
3-4	Department Number	*not mapped*	O
5-6	Device ID	*see III.B,1*	-
7	Device Type	*not mapped*	NR
8	Manufacturer Code	*not mapped*	NR
9-14	Text Model Description	*not mapped*	O
15	SCP Version	*not mapped*	C
16	SCP Conformance Level	*not mapped*	C
17	Language Support Code	*not mapped*	O
18	Capabilities ECG Device	*not mapped*	O
19	AC Mains Frequency	*not mapped*	M
20-35	FUTURE USE	-	-
36	Length of Analysis Program Number	*not mapped*	NR
*37-**	Analysis Program Number	*not mapped*	NR
-	Serial Number	MDS::SystemModel ModelNumber	M
-	System Software ID	*not mapped*	O
-	SCP Implementation Software ID	*not mapped*	O
-	Manufacturer	MDS::SystemModel Manufacturer	M

The Acquiring Device ID tag is a mandatory tag in SCP-ECG. This tag is further divided into several subsections. These subsections and their relation with x73 classes and attributes can be seen in Table II. The qualifiers (O/M/C/NR) in this table show whether the SCP-ECG attributes should or should not be included (and how) in an x73-PHD ECG device specialization, and their meanings are: (O)ptional, (M)andatory, (C)onditional and (N)ot (R)ecommended.

B. The x73-PHD Model

In this paper, a novel ECG device x73-PHD specialization based on SCP-ECG is investigated. The SCP-ECG fields needed to create an SCP-ECG file (described in the previous section) have been taken into account while preparing this definition. This ECG specialization can be seen through the x73 Domain Information Model (DIM). The DIM characterizes information from an Agent as a set of objects with one or more attributes. Attributes describe measurement data that are communicated to a Manager as well as elements that control behavior and report on the status of the Agent. The proposed DIM model diagram can be seen in Fig. 2. Inside the boxes, the minimum SCP fields needed are included (also the section where they appear in the SCP-ECG). As it was explained in Tables I and II, some of these attributes are already somehow mapped in x73, some are not.

TABLE III.
ECG LEAD

SCP	x73
length	$\sum_{i=o}^{\#Arrays} \textit{RT-SA::SaSpec.SampleType.ArraySize}_i \cdot \frac{1}{8}\, \textit{RT-SA::SaSpec.SampleType.SampleSize}$
STI	*RT-SA::SamplePeriod* (scale factor)
AVM	$\left(\frac{1}{2^{\textit{RT-SA::SaSpec.SampleType.SampleSize}}}\right) \cdot (\textit{RT-SA::ScaleRangeSpecXX.UpperAbsoluteValue} - \textit{RT-SA::ScaleRangeSpecXX.LowerAbsoluteValue})$

In this subsection, the proposed DIM for the ECG device is depicted by describing the relationship between the already existing x73 attributes and the SCP-ECG fields to be included and by defining new classes and attributes.

1) Medical Device System (MDS): At a top level, the MDS object represents the properties and services of the device itself, independent of its health data capabilities. Since it represents properties of the device, the ID of the Acquiring Device (Section 1, Tag 14) it has been included in the MDS class. Note that not all bytes of this tag are considered Mandatory (See Table II). Only the Serial Number (MDS::SystemModel.ModelNumber) and Manufacturer (MDS::SystemModel.Manufacturer) are accurately mapped. In SCP-ECG, bytes 5 and 6 of the ID of Acquiring Device (Tag 14 Section 1) define the Device ID. In x73, on the other hand, the System ID attribute of the MDS Class consists of a 24-bit unique Organizationally Unique Identifier (OUI) followed by a 40-bit manufacturer defined identifier. The OUI shall be assigned by the IEEE Registration Authority a value and shall be used in accordance with IEEE Std. 802-2001. As it can be observed, there is a clear lack of consensus around this attribute.

2) Metric: The Metric class is the base class for all objects representing measurements, status, and context data. The date (tag 25) and the time of acquisition (tag 26) are mandatory tags in SCP-ECG. They are directly related to the Absolute-Time-Stamp attribute in the Metric class. The date time zone (tag 34) is a highly recommended tag in SCP-ECG. This tag is not directly related to any attribute in x73 but, as pointed out in 11073-20601, it is possible to report a time that is universally coordinated such as Universal Time Coordinated (UTC). Hence, tag 34 can be covered this way.

3) ECG Lead: The ECG Lead is a real-time sample array object (RT-SA) representing the measure of heart electrical activity over time. This class includes a nomenclature for the ECG leads as addressed in [5]. Note that these nomenclature codes are compatible with the SCP-ECG standard. This class also includes some SCP-ECG attributes already mapped in x73-PHD. These attributes are: length of the array, Sample Time Interval (STI) and Amplitude Value Multiplier (AVM). Their relationship with the x73 RT-SA class is shown in Table III. Managers should be careful when generating the SCP-ECG file since the Sample-Period attribute in x73 is given in 1/8 of millisecond (8000 = 1 second) while STI attribute in SCP-ECG is given in microseconds.

On the other hand, the Sample-Period attribute in x73 is defined as a Relative Time (INTU-32). This could lead to wrongly rounded numbers if 8000 is not a multiple of the sampling rate. For example, if a device has a sampling rate of 1024 samples per second, then its sample period would be 8000/1024=7,8125 and this number cannot be expressed with an INTU-32 type. This can be avoided by defining Sample-Period as a FLOAT. Something similar may happen in SCP-ECG. This type of definitions could somehow limit manufacturer's freedom.

4) Patient: As shown before, there are several fields in SCP-ECG related to patient information that are mandatory or highly recommended. There were two ways to proceed:

- *Including a Patient Class in the DIM*, following the proposed DIM model diagram that can be seen in Fig. 2 (note that Patient class is marked in grey color). This option has some advantages since it allows users not to previously configure the Manager (increasing its potential when the patient has to travel with his MD). However, this idea might be against the x73-PHD philosophy, given that none of the devices defined so far include patient data. Moreover, it can be difficult to apply in MDs that lack of external input for including patient data.
- *Previously configure the Manager* so that it can assign patient data to the received ECG. The Person ID attribute defined in the x73 standard can be used for this purpose. This idea leads us to a useful way to organize and remotely configure MDs. A Configuration Profile (see Fig. 3) can be generated from the Monitoring & Management Server and sent to the CE. This file would gather all the information required and not stored in the MD, for example: the aforementioned patient data, the IP address of the telemonitoring server, or some parameters to configure alarms or manage MDs. Therefore, the ECG exchange between MD and CE is x73/SCP-compliant while the CE-EHR server communication allows the creation of the SCP-ECG file with all the required fields.

In addition to the configuration problem, there is also a harmonization issue regarding the patient data. In SCP-ECG, the Patient ID (Tag 2, Section 1) is a string text tag used as primary key in the management database. In x73, the Person ID attribute is a 2-byte field used to discriminate different users of the same MD. Therefore, they should not be considered equivalent, although they are somehow related.

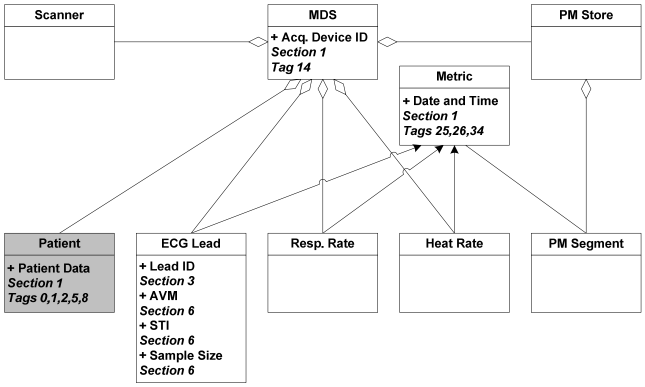

Fig. 2. Proposal of DIM model for x73/SCP-ECG specialization

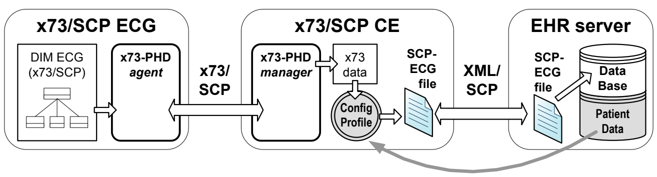

Fig. 3. Proposal of Configuration Profile for integrating patient data in x73/SCP-compliant CE

IV. Implementation

To the best of our knowledge, there is no previous work in this context. An x73-PHD platform had been implemented by our group [11]. That application was developed in a PC environment using C++ and it included all the classes, attributes and x73-PHD protocols defined in the x73-PHD document that were needed to simulate Agents and Manager. The MDs specialization implemented were Pulse Oximeter, Blood Pressure and Weighing Scale.

Within the project described in this paper, a custom-defined x73-PHD ECG specialization (following the previous section premises) has been added to this platform. In order to do that, the DIM of the ECG device specialization has been implemented. As a proof of concept, the patient class was included. Then, the pre-existing x73 platform was used to connect, associate, configure, and operate (following the Finite State Machines (FSM)) a simulated ECG device in compliance with the SCP-ECG standard. The parameters defined in the previous section are sent during the state Connected-Associated-Configuring of the state machine. The ECG data are sent in the Connected-Associated-Operating state using the PeriCfgScanner class. In order to reduce message overhead, the Buf-Scan-Report-Grouped Event Report has been used. Agent and Manager must previously agree the Reporting Interval. This value is dependent on the SamplePeriod and the ArraySize. Thus, the x73-PHD standard is followed by an Agent to configure a simulated ECG device and then send a real-time ECG to the Manager. This signal could be forwarded to the monitoring server and real-time checked by a specialist. Finally, the Manager generates a SCP-ECG file that can be sent to an EHR Server and included in the patient history. The SCP files generated with our application have been successfully tested using the certification service provided by the OpenECG portal. This tool includes a content checker as well as a format checker.

V. Conclusions And Future Directions

The harmonization of two closely related standards has been analyzed and investigated. The relationships between the fields and attributes of both standards have been described. This process has sometimes led us to unclear and ambiguous situations that need to be taken into account when defining the ECG device specialization. On the other hand, a simulated and custom-defined ECG MD specialization has been successfully implemented as a proof-of-concept.

From these results, the further research trends are: investigation and inclusion of the rest of the SCP fields; implementation of the Store&Forward (S&F) feature, making use of the PM-Store Class; integration with SCP-ECG messages, by analyzing and investigating the utility of the messaging part within the framework of x73 (this only applies to S&F); implement the CP approach; inclusion of the real-time remote monitor, investigating the protocol to be used; and, finally, parameter configuration since there are a lot of parameters of an ECG device that are susceptible to be set up by remote monitoring services (resolution, sample interval, amplitude…). Regarding the latter trend, two potential alternatives in which we are currently working are: make use of presumably forthcoming x73 documents for remote control or consider the SNMP protocol to include Managers and Agents in the management process.

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