An Integrated Healthcare Information System for End-to-End Standardized Exchange and Homogeneous Management of Digital ECG Formats

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***Abstract*—This paper investigates the application of the enterprise information system (EIS) paradigm to standardized cardiovascular condition monitoring. There are many specifications in cardiology, particularly in the ECG standardization arena. The existence of ECG formats, however, does not guarantee the implementation of homogeneous, standardized solutions for ECG management. In fact, hospital management services need to cope with various ECG formats and, moreover, several different visualization applications. This heterogeneity hampers the normalization of integrated, standardized healthcare information systems, hence the need for finding an appropriate combination of ECG formats and a suitable EIS-based software architecture that enables standardized exchange and homogeneous management of ECG formats. Determining such a combination is one objective of this paper. The second aim is to design and develop the integrated healthcare information system that satisfies the requirements posed by the previous determination. The ECG formats selected include ISO/IEEE11073, Standard Communications Protocol for Computer-Assisted Electrocardiography, and an ECG ontology. The EIS-enabling techniques and technologies selected include web services, simple object access protocol, extensible markup language, or business process execution language. Such a selection ensures the standardized exchange of ECGs within, or across, healthcare information systems while providing modularity and accessibility.**

***Index Terms*—ECG, enterprise systems, healthcare-integrated systems, management, standard.**

I. Introduction

IN THE past decade, enterprise information systems (EIS) have gained increasing attention since they integrate and extend business processes within and across corporations and country borderlines, thereby improving efficiency, competency, and competitiveness [1]. In this context, various EIS-enabling techniques and technologies have been reported. These techniques include enterprise application integration (EAI), service-oriented architecture (SOA), or business process management (BPM), among others [2]. EIS applications often require an appropriate combination of these techniques.

Integrated healthcare information systems (IHIS) can be seen as a type of EIS addressing healthcare stakeholders' requirements. A number of experiences of EIS in the healthcare environment have already been reported in the literature [3]–[5]. Indeed, the exchange of clinical information, in general, is a crucial factor in the provision of high-quality eHealth and telemonitoring services. The application of information and communication technologies (ICT) in this process vastly improves the management and exploitation of traditional telemonitoring services. However, the lack of uniform criteria often implies the arbitrary existence of disjointed silo systems that hamper the seamless communication between fully fledged, interlinked applications and ultimately the effective construction of a cohesive medical record. The application of standards—along with the aforementioned techniques for enabling an EIS approach—is the internationally adopted strategy for overcoming the interoperability gap.

A. ECG Standardization Arena

In this context, cardiovascular condition telemonitoring has undergone a paradigm shift in recent years, due mainly to the increasing need for interoperability and standardization. There are many standards and protocols in this area, specifically in the digital ECG standardization arena. However, the current situation of the standards and norms is rather complex and must be considered within a context of constant growth and change. A comprehensive review on digital ECG formats can be found in [6].

Within the ECG domain, the most widely known efforts are those supported by standard development organizations, including the Standard Communications Protocol for Computer-Assisted Electrocardiography (SCP-ECG) [7], Health Level Seven annotated ECG (HL7 aECG) [8], Medical waveform Format Encoding Rules [9], or the Digital Imaging and Communications in Medicine (DICOM) Supplement 30 [10]. Nevertheless, a plethora of digital ECG formats—both binary or based on

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extensible markup language (XML)—has been also proposed in the literature [6].

Additionally, ongoing developments of specific ontologies covering the ECG domain are also fostering ECG interoperability. Examples of efforts currently under development include the National Center for Biomedical Ontology bioportal [11], and an initiative headed by Gonçalves [12]. In 2009, Gonçalves *et al.* presented an application-independent ontological analysis of the ECG [13]. In 2010, they tested this ECG ontology to achieve semantic integration between digital ECG data formats [14] by mirroring the key fields of several standardization initiatives—SCP-ECG, HL7 aECG, and MIT-BIH—to their ontology. The outcomes to date—a Resource Description Framework (RDF) serialization in XML (i.e. an RDF/XML) of the proposed ECG ontology—can be downloaded from [15].

In this convoluted context, some wider medical standardization initiatives—not only focused on the ECG signal but on specific medical interfaces—also address digital ECG interoperability. These initiatives include standards for medical device (MD) interoperability—e.g., the ISO/IEEE11073 family of standards—or specifications for the interoperable exchange of electronic health records (EHR)—such as ISO/EN13606, openEHR, or HL7. The ISO/IEEE11073 family—usually referred to as X73—has evolved from a previous effort focused on the point of care (PoC) to a new paradigm for personal health devices (PHDs). Regarding the ECG domain, the IEEE has recently approved the ECG specialization (IEEE Standard 11073-10406-2011) [16]. This document establishes a normative definition of the communication between personal monitoring ECG devices (1–3 leads) and concentrator devices (CDs), which would be able to concurrently manage other PHDs in compliance with X73. This device specialization leverages a previous attempt to standardize X73PoC ECG devices (IEEE P11073-10306 [17]). As regards EHR initiatives in the ECG domain, only openEHR has published an archetype for the interoperable exchange of ECGs at the moment of writing [18], although archetypes for ISO/EN13606 or HL7 templates could be built along similar lines.

B. Issues Resulting From the Large Variety of Existing and Emerging Digital ECG Formats

The existence of medical standards for the ECG does not guarantee the implementation of homogeneous, standardized solutions for digital ECG recording, transmission, exchange, storage, and visualization, since the integration of different standards into end-to-end solutions remains an intricate and complex task. Hence, one of the main challenges in digital ECG standard-based research is the subsequent transfer of new findings to the healthcare system.

The existing lack of worldwide consensus within the digital ECG standardization arena encourages further investigations into protocol engineering in order to accomplish fully fledged interoperable cardiology ecosystems. A common practice is to design mapping and harmonization mechanisms between digital ECG formats, in an attempt to partially overcome ECG interoperability issues. Examples of such research processes include mappings between SCP-ECG and DICOM [19], [20], SCP-ECG and HL7 aECG using general data format (GDF) as intermediate structure [21], or SCP-ECG and ISO/IEEE11073 [22], to mention only a few. Similarly, alignments between standards are usual, such as SCP-ECG, which has become an international standard as ISO/IEEE11073-91064:2009, part of the X73 family.

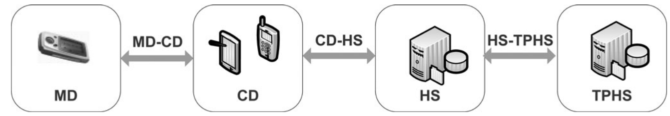

Fig. 1. Typical eHealth end-to-end architecture.

Despite these efforts, the issue of integration of digital ECG standards into daily clinical practice is of paramount importance. Indeed, hospital management services are faced with the challenge of having to cope with several different digital ECG formats and, moreover, several different visualization applications. Therefore, a method to uniformly administer the various formats would enhance the hospital information system and with it, physicians' daily practice. A potential solution for this problem is a framework providing converters for the different ECG formats to a central format so that they can be homogeneously handled at the hospital information system and uniformly visualized thereafter.

C. End-to-End eHealth Information Frameworks Within the EIS Paradigm

The historical context described previously has encouraged the eHealth community to develop integration initiatives, enabling different MDs to communicate with CD that gather and forward medical data to a host system (HS)—usually referred to as EHR—which, in turn, can share medical data with third party HS (TPHS)—i.e., external EHRs (see Fig. 1). The purpose of these initiatives is the promotion of end-to-end standard-based interoperable eHealth services.

Some previous works have considered the design and implementation of standard-based end-to-end e-Health solutions [23]–[25], but these attempts were general eHealth architectures and therefore not focused on the complex situation of the digital ECG standardization process. Furthermore, these attempts were neither designed nor developed from the standpoint of EIS. Some common EIS-enabling techniques and technologies include EAI, SOA, or BPM [2], briefly described as follows.

1) EAI provides a framework for the integration of enterprise data sources and sinks so that intraorganizational and interorganizational systems can be seamlessly built [26], [27]. EAI-enabling technologies range from electronic data interchange to web services (WS) [2].
2) SOA is an emerging paradigm that enables seamless coordination of heterogeneous information systems, providing platform-, language-, and operating systems-independent services [2], [28], [29]. The common way to enable SOA architectures is by means of WS. There are several different architectural options for building WS, namely, XML-remote procedure call (XML-RPC) [30], simple object

access protocol (SOAP) [31], and representational state transfer (REST) [32].

3) BPM aligns all aspects within an organization with the help of ICT, thereby enhancing effectiveness and efficiency, reducing costs, and increasing agility to respond to ever-changing environments [2], [33], [34]. Designing and modeling enterprise workflows is the common method used to track process-related information [35]–[37]. Workflows—together with formalized reference models—play an important role in the management of business domains [38]. Specific tools are used to manage business processes with information technology. These tools include Petri nets applied to workflow management [39], web services business process execution language (WS-BPEL) [40], or business process model and notation [41].

It is clear that current and next generation end-to-end telecardiology frameworks urgently require the seamless integration of interoperability and cardiology standards into adequate frameworks based on the innovative principles of the EIS paradigm. However, an appropriate and consistent application of the existing and emerging standards, techniques, and technologies needs to be carried out before an integrated, standardized ecosystem can be achieved.

D. *Objectives and Structure*

This paper, therefore, aims at designing and developing an IHIS for the standardized exchange and homogeneous management of digital ECG formats. The specific objectives are 1) to discuss and select an appropriate combination of digital ECG formats and an adequate combination of EIS-enabling technologies to be used in the framework, 2) to design and develop such a framework and the software architecture thereof, fulfilling the requirements posed by the previous selection, and 3) to discuss other existing and emerging options in the complex context of digital ECG formats as well as to debate the practical utility of the system resulting from the use of EIS-enabling technologies.

This paper is organized as follows. Objective 1 is outlined in Section II, objective 2 in Section III, and objective 3 in Section IV. Finally, the conclusions are drawn in Section V.

II. Design Premises for Selecting the Appropriate Digital ECG Formats and the EIS-Enabling Technologies

This section is divided into two sections. The first sets out a reasoned argument for selecting the appropriate combination of ECG formats and standards. The second explains the reason for choosing a suitable combination of EIS-enabling technologies for the framework based on general and specific desiderata.

A. *Selection of ECG Formats*

For the selection of the appropriate standard or protocol at the different interfaces or entities of the framework, several considerations must be taken into account. At the MD–CD interface, the X73PHD standard is the only MD interoperability initiative to date that provides off-the-shelf standard-based devices [42]. Several previous contributions have applied X73 on ECG acquisition by implementations of the X73PoC ECG device specialization draft [43]–[46]. However, no previous work has implemented the emerging X73PHD ECG device specialization.

Since X73PHD covers only the MD–CD interface, the harmonization with other protocols is required in order to forward the digital ECG beyond the CD in a standardized way. Different approaches include the mapping of the attributes and classes of the X73PHD ECG device specialization to 1) an ECG ontology or 2) an existing ECG data format. The existing ECG ontologies [11], [13] were discarded because development and dissemination are at an initial—albeit relatively mature—phase. Hence, they are not yet suitable for digital ECG exchange with external applications. Therefore, the possibility of mapping the classes and attributes of the X73PHD ECG device specialization to a standard digital ECG format was considered. Among the broad range of possible solutions [6], the SCP-ECG standard was selected for the CD-HS interface, mainly due to its alignment with X73PHD (ISO 11073-91064:2009) [47] and the wide variety of existing tools for handling it. An extended explanation of the rationale for the harmonization between X73PHD and SCP-ECG—as well as the harmonization itself—can be found in [22]. Nonetheless, no previous work has covered the integration of the X73PHD ECG device specialization with other ECG formats in a standard-based end-to-end telecardiology scenario.

As stated earlier, the issue of seamless integration of the digital ECG formats reaching the HS is of utmost importance. There are different approaches to this from the point of view of internal ECG storage, namely 1) using an existing ECG format, 2) creating and using a new format or 3) using an ECG ontology. Approach 1 could lead to mapping gaps between the different formats [21]. Approach 2 would imply the study of every new format to be included and, eventually, the modification of the designed central format, thus enabling all the fields or attributes of the new format to be supported. This would not be the case in a (well-founded) ECG ontology (approach 3), since the terms in a controlled vocabulary must correspond to at least one meaning (“nonvagueness”), and no more than one meaning (“nonambiguity”), and these meanings must correspond to no more than one term (“nonredundancy”) [48]. Therefore, since an ECG ontology represents what an ECG is, the use of ECG ontologies for semantic interoperability of ECG data is a feasible, efficient alternative [14]. In addition, ontologies enable semantic data integration within, or across, application, organizational boundaries [49], [50]. In this context, no previous work has covered the design and development of an ontology-driven backend component for the homogeneous management and visualization of digital ECG formats. More specifically, the ECG ontology created by Gonçalves *et al.* [13] has been selected for the task.

Finally, beyond the HS, the existing standardization initiatives for the interoperable exchange of EHR are HL7, ISO/EN13606, and openEHR. At the time of writing, no previous work has developed either an HL7 template or an ISO/EN13606 archetype covering the ECG. OpenEHR, on the other hand, is promoting ongoing work aimed at an ECG archetype [18]. However, the purpose of this archetype is to record the electrocardiographic interpretation of the electrical activity of the heart by an ECG device rather than the ECG samples themselves. Therefore, SCP-ECG has been selected for the external exchange of digital ECG beyond the HS, without disregarding future definitions of standardized ISO/EN13606 archetypes or HL7 templates, or the completion of the OpenEHR archetype.

B. Selection of EIS-Enabling Techniques and Technologies

For the selection of the appropriate techniques and technologies, the following generic and specific desiderata have to be taken into account. The first is the seamless integration of the CD of the platform with other HS based on WS and XML—both previously developed by our group [23]—and, eventually, with other TPHS systems. The flawless communication of the HS of the proposed system with external TPHS is also required. Second, there is the leverage of the previous initial programming efforts of the X73PHD-based MD–CD communication, developed in C++ [22]. In addition, it is intended that the proposed system should not only be platform independent in terms of programming language and operating systems, but also provide format-independent ECG management within the backend component. Furthermore, as SCP-ECG has been selected as the digital format for exchanging ECGs, a technology that enables seamless and straightforward transmission of binary files is desired. Third, a well-designed management of ECG formats that fosters the reuse of software intra- and inter-organizationally is also necessary. In the light of these considerations, the selection of the EIS-enabling techniques and technologies can be described as follows.

1) EAI: WS have been selected as they enable flexible, scalable, and adaptable EAI frameworks, thereby facilitating the integration of heterogeneous applications built with different programming languages and on different platforms [51]. This meets the first desideratum, since seamless inter- and intra-enterprise integration is enabled.
2) SOA: SOAP is a loosely coupled evolution of XML-RPC, and therefore, XML-RPC was discarded. Selecting SOAP or REST is still a matter of discussion for SOA developers. In the proposed system, binary SCP-ECG files are to be transmitted. As SOAP provides straightforward methods for sending binary files, this protocol has been selected. As a result, XML will be used since SOAP relies on this language format. As regards methods for attaching files with SOAP, there are various possibilities available including direct internet message encapsulation, SOAP with attachments, or message transmission optimization mechanism (MTOM). MTOM [52] has been selected, as it is the only World Wide Web Consortium (W3C) recommendation for such a purpose. Moreover, the SOA paradigm allows the recursive aggregation of services as well as the reuse of existing componentized sets of software functionalities [53]. By using these technologies, the second desideratum would be satisfied. The use of SOAP and XML would enable seamless integration of the CD—leveraged from previous efforts and already programmed in C++—and the HS—coded in Java (to be introduced in the next section). Besides, the use of software as a service will enable the reuse of the visualization software and the recursive aggregation of compatible ECG formats and standards (by adding the appropriate converter). Finally, binary SCP-ECG files can be easily transmitted using MTOM.
3) BPM: WS-BPEL has been selected since it is a standard created by the Organization for the Advancement of Structured Information Standards for specifying business process behavior based on WS. WS-BPEL uses a number of XML-based specifications, such as web services description language (WSDL) [54], a language that is used for describing the functionality offered by a WS. These technologies would satisfy the third desideratum, since they enhance process management inside and beyond the boundaries of the healthcare organization.

Regarding programming concerns, the web service oxygen tank (WSO2) solution has been selected [55]. Its open-source policy and the wide variety of EIS-enabling configurable modules available were the main reasons for this selection.

III. Proposed IHIS

The design of the telecardiology architecture is presented in Fig. 2. This solution comprises three elements, namely, MD, CD, and HS.

1) *MD:* This element provides the original medical data making use of protocols that follow a proprietary format. Although the X73PHD ECG device specialization has already been released [16], an X73PHD-compliant ECG device is not yet available. Thus, adaptation to X73PHD is needed. This adapter creates the inherent domain information model (DIM), which sets the information structure required to establish the finite state machine (FSM) and allows every PHD to act as agent of the X73PHD communication (see upper area in Fig. 2).
2) *CD:* This is designed as an X73PHD manager that collects the digital ECGs recorded with the X73PHD-compliant MD (or adapter). Subsequently, an SCP-ECG file is generated according to the X73PHD–SCP-ECG mapping (provided in [22]) and other specific configuration information (Config. Profile). Thereafter, the SCP-ECG file is sent by means of WS to the HS (see middle area in Fig. 2) or, eventually, to external SCP-ECG-compliant service providers.
3) *HS:* This is an ontology-driven backend component for the integration and homogeneous management of different ECG formats. The HS comprises four different parts: a servlet (engine), an applet (viewer), a database (storage), and a web page (interface). The ECG files coming from the CD (in compliance with SCP-ECG) or from external applications (in compliance with different ECG formats) are converted to an ontology-based central ECG format to ensure homogeneous management of the ECGs. The ECGs can also be exported to external applications in compliance with SCP-ECG (see lower area in Fig. 2).

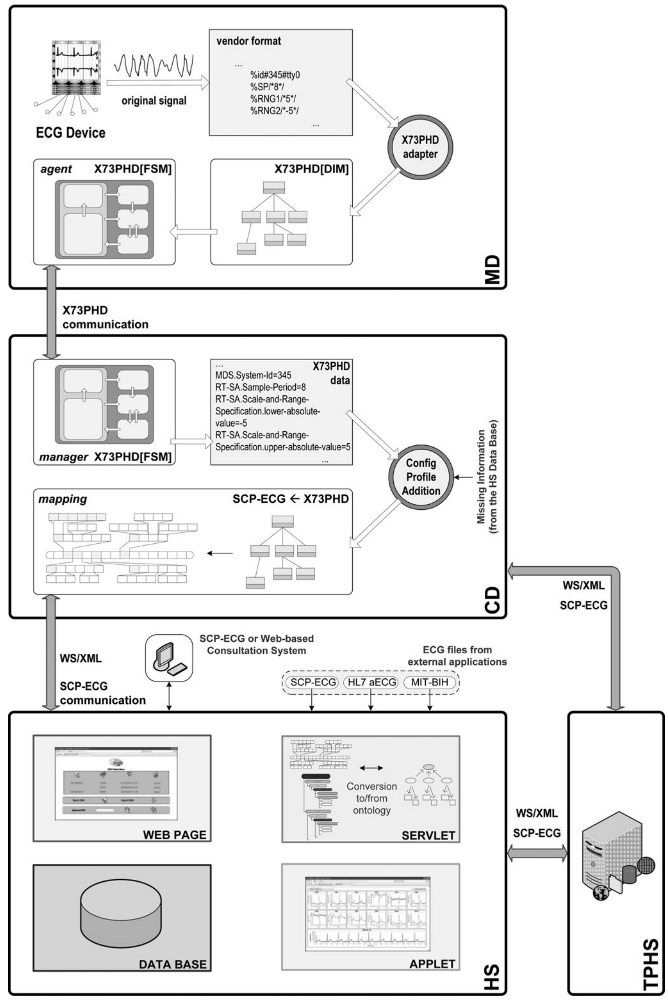

Fig. 2. Proposed system architecture for end-to-end standard-based design of telecardiology solutions.

All the external interactions with the HS are performed through a WS interface and executed with a predefined BPEL workflow.

A. Implementation of IEEE Standard 11073-10406-2011

This section details the first part of the architecture presented in Fig. 2, i.e., the X73PHD communication between the MD and the CD, stressing the X73PHD ECG device specialization.

A simulated X73PHD ECG device specialization based on ISO/IEEE11073 has been implemented in a pre-existing X73PHD platform [23]. Both the MD and the CD were programmed in C++. The X73PHD ECG device specialization (IEEE Standard 11073-10406-2011) was added to this platform within the framework of this research. The DIM of this document was implemented to include the mandatory attributes of the following metrics: a Real-Time Sample Array class to represent the ECG waveform, a Numeric class to represent the heart rate, and an Enumeration class to represent the device status (see [16]). The periodic/aperiodic sessions of the persistent metric (PM) concept (PM store/PM segments) were added to the application to handle previous metric data stored in the MD.

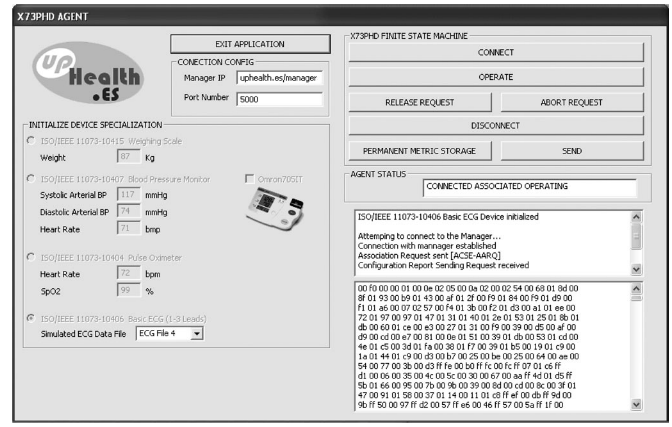

Fig. 3. X73PHD MD application with a basic ECG device specialization initiated and sending simulated Real-Time data.

The pre-existing X73PHD platform was thereafter used to connect, associate, configure, and operate a simulated ECG device. Two major scenarios in telemedicine applications were considered, namely Store-and-Forward and Real-Time to analyze the specific case of the ECG.

Fig. 3 shows the X73PHD MD application that can play the role of X73PHD adapter for non- X73PHD-compliant devices (note the Omron 705IT blood pressure monitor checkbox that allows the connection of this specific MD) as well as that of emulator of any X73PHD specialization for testing purposes. The MD application allows the selection of four different PHD specializations (weighing scale, blood pressure monitor, pulse oximeter, or Basic ECG), as is shown in the upper area in Fig. 3. This selection involves a choice of the specific objects, and the DIM of every device specialization. The X73PHD MD–CD communication model can be tested with the application controls, see middle area of Fig. 3, by selecting the relevant procedure defined in X73PHD FSM: CONNECT, OPERATE, RELEASE REQUEST, ABORT REQUEST, or DISCONNECT. Two different modes for recording and sending measurements—Store-and-Forward and Real-Time—are allowed (see lower area of the X73PHD FSM area in Fig. 3). The PERSISTENT METRIC STORAGE simulates the recording and storage of a measurement to be retrieved subsequently by the CD using the PM-store mechanisms for the request and retrieval of information. The X73PHD SEND button simulates the sending of the data acquired concurrently (i.e. Real-Time mode operation). Different previously recorded ECG files can be used as input. The specific X73PHD FSM status is shown below the X73PHD FSM buttons in Fig. 3 and all the details of the communication process are shown immediately below. This allows further analysis not only of the X73PHD FSM operating flow and testing of all the possible data transmission modes, but also of the details of the hexadecimal code for the X73PHD APDUs for verification purposes.

Fig. 4 shows the X73PHD CD application that collects data from the different X73PHD MDs. The details of the communication process for the MDs that connect to the CD are shown in the upper area in Fig. 4. The exchanged X73PHD messages for the first MDs developed (weighing scale, blood pressure device,

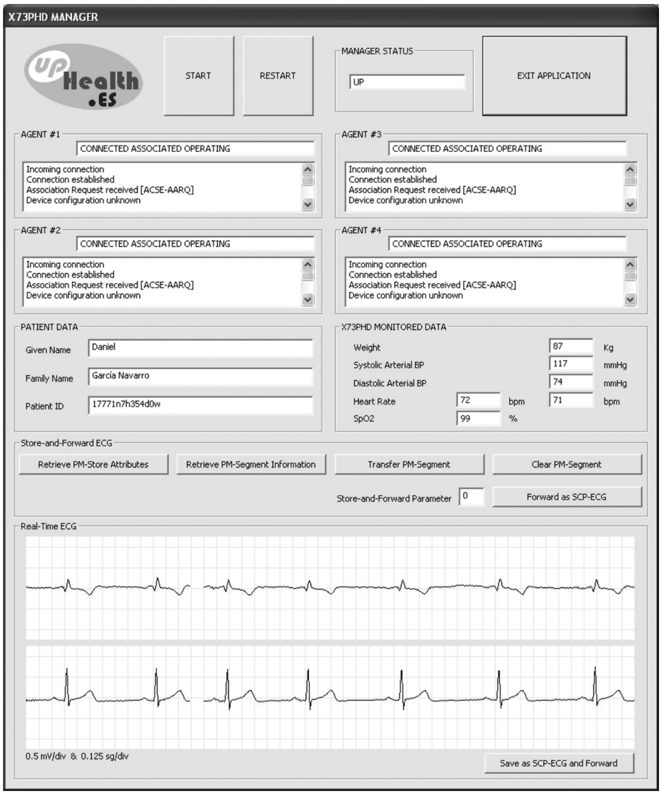

Fig. 4. X73PHD CD application for handling different X73PHD device specializations (the basic ECG device specialization both for Store-and-Forward and Real-Time scenarios is shown in the lower area of the figure).

and pulse oximeter) as well as for the newly implemented ECG device are also shown in the upper area in Fig. 4. The patient data and the monitored data for the first MDs developed are shown in the middle area in Fig. 4. The communication flow for the ECG is shown in the lower area in Fig. 4 (first, the Store-and-Forward scenario and, second, the Real-Time scenario). Regarding the Store-and-Forward scenario, the buttons that correspond to the X73PHD PM-store methods have been added (retrieve PM-store attributes, retrieve PM-segment information, transfer PM-segment content, and clear PM-segment). A text box is used to introduce the Store-and-Forward configuration parameter (e.g., to identify a specific ECG to be retrieved). The transferred ECGs are automatically mapped to SCP-ECG and stored in the CD in order to be eventually forwarded to the HS or, eventually, to external SCP-ECG-compliant service providers. Finally, the Real-Time area shows the ECG data as they are received by the CD. The visualized data can also be mapped to SCP-ECG and forwarded to the HS or, eventually, to further processing entities. The communication to HS or TPHS is carried out by means of the appropriate WS. In the example in Fig. 4, the four MDs developed are connected simultaneously to the CD. The simulated ECG device is sending two leads in a Real-Time mode. Thus, the CD shows a two-lead ECG in the lower area in Fig. 4.

The intended use for these two applications is in an advanced development environment. Simpler frontends can be designed for enhanced user experience.

B. *Communication From an X73PHD-Compliant CD to the HS*

Once the ECG data reach the CD, the X73PHD-compliant ECG data are mapped to SCP-ECG (see middle area in Fig. 2). For this to happen, harmonization between the different fields of X73PHD and SCP-ECG is required. This harmonization is explained in detail in [22]. As shown in [22], some mandatory data in SCP-ECG (such as patient data) are not present in X73PHD. All missing data are added by the X73PHD CD without the need for the X73PHD standard to make specific requirements. Therefore, they are retrieved from an XML-based Config. Profile sent from the HS to the CD. The SCP-ECG files generated by the developed application have been successfully tested using the certification service provided by the OpenECG portal [56]. This service includes an SCP-ECG content checker and a format checker.

Thereafter, the generated SCP-ECG file can be sent to any other external SCP-ECG-compliant backend component for further analysis, or to the HS of the standard-based end-to-end solution. In any case, the SCP-ECG file is wrapped in an XML-based envelope to accomplish an appropriate EIS approach. More specifically, WS and XML-based transmission—i.e., two EAI-enabling technologies—have been used to communicate the CD and the HS. Furthermore, SOAP—i.e., a SOA-enabling technology—has been added to the architecture. The attached SCP-ECG binary files are sent using MTOM. As stated earlier, WSO2 has been selected for programming the EIS approach. WSO2 provides binary and source code for building WS that provides complete enterprise SOA middleware stacks available for a number of programming languages, including C++ and Java. This enables seamless communication between the CD—coded in C++—and the HS—coded in Java. As regards BPM, the integration of the BPEL workflow as well as the WS offered by the HS is explained within the next section.

C. *Integration of Digital ECG Formats into the HS*

The SCP-ECG files mapped from X73PHD as well as other ECG files (in compliance with different ECG formats) are stored and managed in the HS (see lower area in Fig. 2). As several different digital ECG formats are managed, seamless integration and management is required. In order to homogeneously handle the different ECG formats, an ontology-driven HS comprising four main components has been designed.

1) *Java-Servlet:* The servlet performs the parsing and subsequent conversion of ECG files into the ontology-based data format. Thus, it incorporates all the previously developed parser modules. In the proposed framework, SCP-ECG, HL7 aECG, and MIT-BIH have been considered. In a similar fashion, the servlet performs the conversion to SCP-ECG of the ECGs stored in the database that are to be exported.
2) *Java-Applet:* The applet is basically the viewer itself. It displays the ECG signals as well as patient and manufacturer data. It also allows measurements to be taken on the ECG signal. An applet vastly simplifies accessibility, since only a standard web browser is required to use the system.

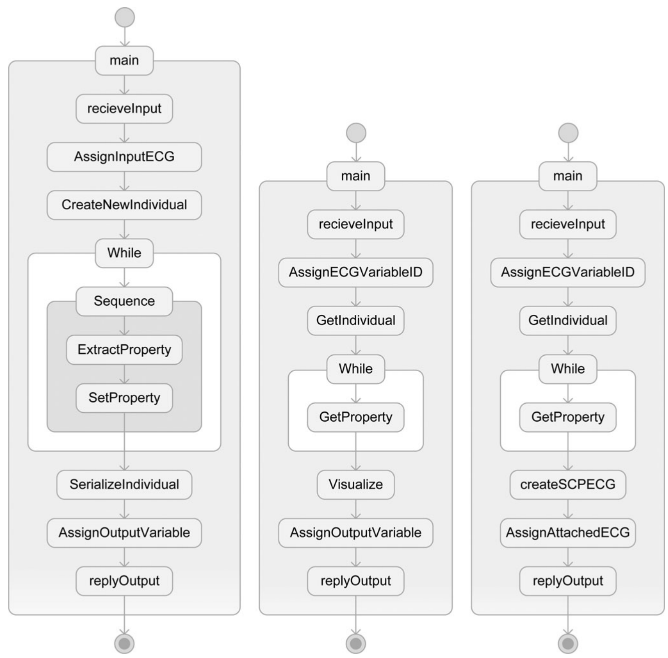

Fig. 5. HS WSs: (a) upload, (b) open, and (c) export.

3) *Database:* Within the database, the ECG files are stored. The database may be accessed through the web page (to list the stored ECG) and the servlet (to extract an ECG recording session or to store a new one). The ECGs are stored following an ontology-based format.
4) *Web page:* Finally, the web page is used to emulate a Hospital Information System. It interacts with the database, the servlet, and the applet. Three main user actions can be triggered from the web page: open (to visualize an ECG using the applet), export (to create and download an SCP-ECG file), and upload (to add a new ECG in compliance with the central ontology-based format by parsing the attributes of the different incoming digital ECG formats).

The three WSs explained previously—upload, open, and export—have been defined in WS-BPEL (see Fig. 5) following a top-down design methodology and using the WSO2 Carbon Studio, which offers an open-source graphical tool for this purpose. For the sake of clarity, and with the intention of illustrating the ontology approach, opaque activities have been included in the BPEL diagram although these are not necessary for describing the WS. The WS-BPEL graphs are automatically transcoded into WSDL, which is an XML-based file defining the WS.

The central ECG format is ontology-based. The existing ECG ontology created by Gonçalves *et al.* [13] was selected. As explained earlier, the ECG attributes of the different formats can be mirrored to the ECG ontology [14]. This ontology-driven framework was programmed in Java using the web ontology language application program interface [57].

First, the ontology must be loaded. An OWL-RDF parser takes the RDF/XML file provided by Gonçalves *et al.* and attempts to construct an OWL ontology that corresponds to the subject–predicate–object triples represented in the RDF [58]. Once loaded, three main actions (i.e., the WS) can be performed through the web page: upload, open, and export (see Fig. 5). Under the ontology-based approach, the upload WS implies the creation of a new individual (a new ECG) within the ECG ontology. An individual is made an instance of a class by adding an assertion to the ontology (*createNewIndividual*). The mandatory attributes of the incoming ECG file are subsequently extracted by means of specific SCP-ECG/HL7 aECG/MIT-BIH parsers (*excractProperty*). These attributes are converted into properties of the new individual—i.e., setting new values to the objects of the existing RDF triples (*setProperty*). Thereafter, the new individual is serialized into RDF/XML and added to the database (*serializeIndividual*). Both the “open” and “export” WS access the database and obtain an existing RDF/XML ECG file and load the existing individual selected by the user (*getIndividual*). Both functions, then, extract the properties of the selected individual (*getProperty*). If “open” is being performed, the individual is sent to the applet to visualize the ECG (visualize), and if “export” is being performed, an SCP-ECG file is built for exportation to external applications (*createSCPECG*).

These actions can also be seen in an entity-relationship diagram of the system as shown in Fig. 6. The core classes and methods implemented are shown together with the main actions: open, upload, and export.

The proof-of-concept design of the HS application is shown in Fig. 7, where the ECGs of the database are listed. The actions (i.e., WS) allowed include opening an existing ECG, exporting an ECG in SCP-ECG format, and uploading a new ECG through the web page in different formats (SCP-ECG, HL7 aECG, or MIT-BIH).

Fig. 8 presents the ECG viewer. This viewer shows the different leads contained in the ECG file. Further details can be displayed by clicking the top-right checkbox. Different configurations have been preconfigured for the visualization of the ECG leads, such as 2 rows $\times$ 6 columns, 3×4, 12×1, 2×1, or 1×1. The viewer also offers the possibility of zooming, printing, and measuring the amplitude and time intervals.

Although the ECG backend component has been designed for web access, it is worth mentioning that an offline application has also been developed. This offline application has been created from the applet code by means of Java Web Start and Java Network Launching Protocol.

IV. Discussion

The discussion section is divided into two sections. The first deals with the final selection of ECG formats and standards compared to other possible approaches. The second describes the practical usefulness of the proposed system in terms of interoperability and management.

A. Discussion on the ECG Formats Selected

A proof-of-concept design for an end-to-end standard-based ontology-driven cardiology solution has been successfully developed and implemented. The rationale behind the selection of the different standards and norms used in the proposed solution is explained in the introduction. However, other approaches could have been selected and they are discussed in the following.

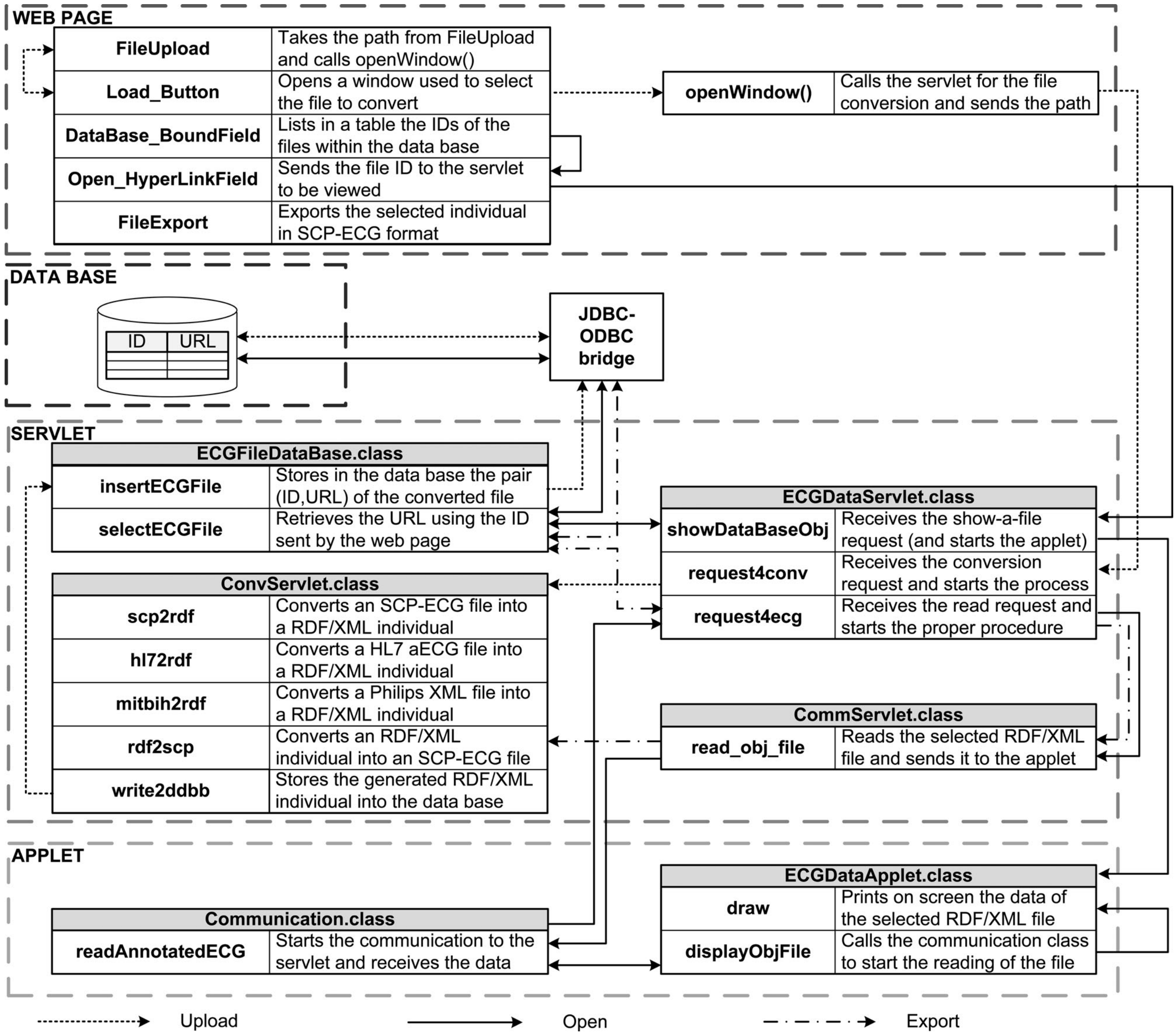

Fig. 6. Entity-relationship diagram including the core classes and methods implemented, together with the main actions—open, upload, and export—that can be performed.

SCP-ECG has been selected as the exchange format. Possibly the emerging ECG ontologies may be considered more appropriate for such a purpose. However, the existing ECG ontology that can be used has only recently been defined and its usage is not widespread. Therefore, ECG ontologies have not yet reached a point at which they can be regarded as suitable for exchanging digital ECG recording sessions with external applications. An existing ECG standard (such as SCP-ECG) currently provides higher cross-entity interoperability. In any case, the foreseeable spread of ontology-based CDs and HSs will make them appropriate in the near future. Indeed, the use of ontologies to exchange telemonitoring data between the CD and the HS is a current line of research in our group [59], [60]. These papers propose a Home Telemonitoring Patient Profile Ontology to facilitate the semantic exchange and integration of medical data. The imminent completion of this ontology will lead to the integration of ECG recording sessions in an RDF/XML format and the replacement of the current plain XML-based format, as our group recently proposed in a solution that also achieved the seamless integration of ISO/IEEE11073 and ISO/EN13606 [23].

The use of an ECG ontology as a central format is suitable and beneficial for a HS, since an ontology-driven HS prevents potential mapping gaps between the fields or attributes of the different ECG standards, while also providing a homogeneous framework. At the same time, this approach draws on the enhanced features of the semantic web by facilitating eventual automatic processing and integration of information related to the ECG recording sessions available on the HS.

Finally, the standardized exchange of EHR requires that the interoperable exchange of EHR be promoted. ISO/EN13606 is well positioned in this respect due first to its dual model approach, second, to the fact that it is already the European standard, and third, that it is supported by the ISO. The drafting of ISO/EN13606 has completed recently (the last part was

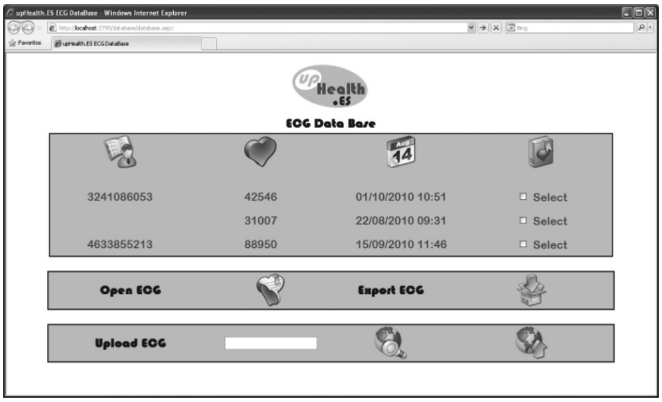

Fig. 7. Proof-of-concept web application for homogeneous ECG management.

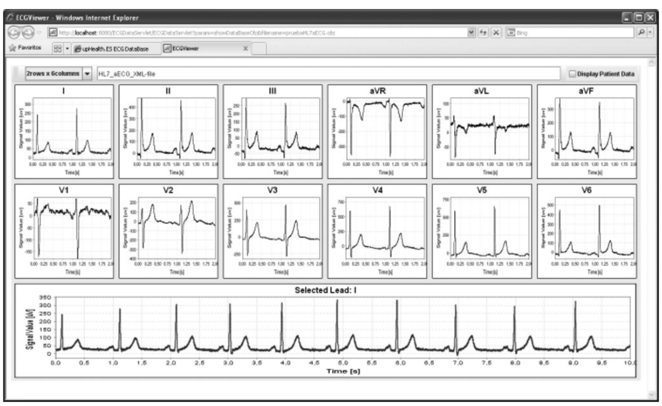

Fig. 8. Web-based Java application for the homogeneous visualization of digital ECG.

approved in February 2010), but it is still a long way off generalization. In this process, establishing reference archetypes will be crucial in defining the information model into which existing and prospective systems must map. Regarding the ECG, only openEHR has currently started the process of creating a consistent, nonoverlapping, interlinked ECG archetype. To date however, it only goes so far as to address the interpretation of ECG. The presented end-to-end cardiology framework has been designed and developed without overlooking foreseeable extensions to dual-based standardization efforts for the interoperable exchange of EHR, such as ISO/EN13606 or OpenEHR. Once completed and released, these specifications will be considered for replacing SCP-ECG as the exchange format in the proposed platform. To simplify this future task, there is a close relation between the language that has been selected to handle the ECGs at the HS of the proposed solution (OWL) and the traditional language used for archetype description, i.e., archetype definition language (ADL). In this respect, mappings between ADL and OWL have already been presented [61], and some authors have recently suggested that OWL be used instead of ADL for the ISO/EN13606 EHR architecture to provide direct support for exploiting reasoning on clinical knowledge [62], [63].

B. Discussion on Practical Usefulness

The practical usefulness of the system is discussed in this section, principally in terms of interoperability and management.

As regards interoperability, it is true that the use of SOA and XML—instead of simple SCP-ECG files—entails an increase in the overhead and, therefore, a decrease in efficiency. On the other hand, as argued previously, the use of WS and SOA enables seamless integration with intra- [23] and inter-organizational businesses (e.g., external TPHS). Furthermore, it enables entities programmed in different coding languages to communicate seamlessly. Moreover, the use of EAI-enabling technologies (i.e. WS) to communicate the CD and the HS would help administrators in managing the concurrent gathering of measurements by generating a single XML file with different signals, e.g. pulse, weight, ECG, etc. This could be useful since although the proposed system deals with the standardized exchange and homogeneous management of ECG formats, it has been built, to all intents and purposes, as a potential telemonitoring solution for cardiovascular conditions. Indeed, by selecting the X73PHD standard, different biomedical measurements for following up cardiovascular diseases can be concurrently integrated.

Regarding management issues, it could be said that given that only three WS are offered (moreover, these are synchronous and independent), this is a small proof-of-concept HS and the potential benefits of the BPEL workflow design are not fully exploited. However, this methodology significantly improves the management and organization, and enhances the probability of success if the proposed system were to be integrated into a larger, scalable healthcare information system. Besides, the use of ontologies entails an increase in the complexity of the system, forced to process RDF/XML management procedures that would not be required otherwise. However, this selection vastly improves the usefulness of the system, as the ECG ontology enables the reuse of software and the straightforward aggregation of new compatible ECG formats. Furthermore, it enables potential reasoning in relation to biomedical measurements.

V. Conclusion

The need for standardization and seamless interoperability in ECG environments has led to the discussion, proposal, and implementation of an IHIS for end-to-end standardized exchange and homogeneous management of digital ECG formats. The system has been built following the EIS paradigm by using EAI-SOA- and BPM-enabling techniques and technologies—such as WS, SOAP, XML, or BPEL, which enhances homogeneous management, increases interoperability between intra- and inter-organizational boundaries, and facilitates the reuse and recursive aggregation of software. Besides, this framework guarantees the specific requirements established by X73PHD and SCP-ECG, thereby facilitating the standardized exchange of digital ECG formats within, or across, healthcare information systems. Furthermore, an ontology-driven backend component for the integration and homogeneous management of electrocardiography formats capable of reaching a central hospital server has been designed and developed, thereby solving the problem of coexisting ECG formats and avoiding the use of multiple ECG viewers. The designed ECG backend component provides modularity (supporting a new ECG format is as easy as mirroring its attributes or fields to the central ontology) and accessibility (a single web page is required to use the system). In addition, the homogeneous management of ECGs would ease comparisons between ECGs, thereby reducing the possibilities of diagnostic misinterpretation.

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