Interoperable and Standard e-Health Solution over Bluetooth

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***Abstract*—The new paradigm of e-Health demands open sensors and middleware components that permit transparent integration and end-to-end interoperability of new personal health devices. The use of standards seems to be the internationally adopted way to solve these problems. This paper presents the implementation of an end-to-end standards-based e-Health solution. This includes ISO/IEEE11073 standard for the interoperability of the medical devices in the patient environment and EN13606 standard for the interoperable exchange of the Electronic Healthcare Record. The design strictly fulfills all the technical features of the most recent versions of both standards. The implemented prototype has been tested in a laboratory environment to demonstrate its feasibility for its further transfer as real solution to the healthcare system.**

I. Introduction

Interoperable exchange of information can be understood as huge benefits for health systems and telemedicine programs: patients will enhance information about their health and doctors have the ability to easily monitor vital signs. Thus, the interoperability of Medical Devices (MDs) and Personal Health Devices (PHDs) from different vendors and the integrated exchange between heterogeneous Health Care Information Systems (HCIS) through standardization are basic requirements in the design of new personal health solutions. In this context, ISO/IEEE11073 (X73) [1] for interoperability of MDs and PHDs, and EN13606 [2] for Electronic Healthcare Record (EHR) exchange are the two standards called to solve this interoperability leak and support the implementation proposed in this paper.

X73 [1] was initially designed in 2004 to address Intensive Care Units scenarios covering MD communication at the Point-of-Care of the patient (X73PoC). With the emergence of new transmission technologies and wearable devices, the standard has evolved to the most recent version for PHDs: X73PHD. EN13606 [2] has strongly evolved from lasts two decades until it has been completed in 2010. It allows representing any information included in the EHR, as well as its communication between EHR systems, managing semantic interoperability of the transmitted data. EN13606 is based on a dual model: Reference Model (that supports information and is defined by kinds of top-down structures: *extract, folder, composition, section, entry, cluster, and element*) and Archetype Model (that define "knowledge": an archetype is a pattern that represents the specific characteristic of the clinical data).

One of the main challenges in the standard-based design is to overcome the resistance from the manufacturers to adopt the new standards for its further implementation in solutions transferable to the healthcare system [3], [4]. Several previous contributions have been developed in order to implement a standard-based platform for e-Health [5], [6]. Figure 1 shows the evolution in the last year. The first 1.0-αlpha platform [5] was focused on PoC for fixed scenarios by integrating X73PoC and ENV13606. The second 1.5-βeta platform [6], also for fixed scenarios, evolved to PHD with independent transport layer, episodic sending data for Protocol Data Units (PDUs) and a plug-and-play and optimized Finite State Machine (FSM). The last 2.0-BT platform, presented in this paper, evolves for wireless and personal scenarios over Bluetooth technologies.

Bluetooth is a specification for Wireless Personal Area Networks (WPANs) that enables communication between devices via secure and free radio link (2.4 GHz). Currently, there are many manufacturers that already incorporate Bluetooth technology into the design of MDs and PHDs, but they are still releasing their own proprietary solutions while X73PHD is leading to a consolidated status. Nevertheless, since USB and Bluetooth have been adopted as a transport layer technologies for the X73PHD communication stack by the Continua Health Alliance, in last months, new MDs and PHDs have been developed fulfilling the Continua Certification [7]. Thus, this paper covers the design and implementation of the 2.0-BT platform for personal healthcare through X73PHD and EN13606 standards over Bluetooth. Section II analyses the standard-based design of the proposed solution, detailing its key aspects and technical characteristics. Section III describes the end-to-end implementation and Section IV presents the results obtained with a blood pressure on Bluetooth technology and a wireless manager on HTC-3G SmartPhone. The conclusions and future lines of work overall are discussed in Section V.

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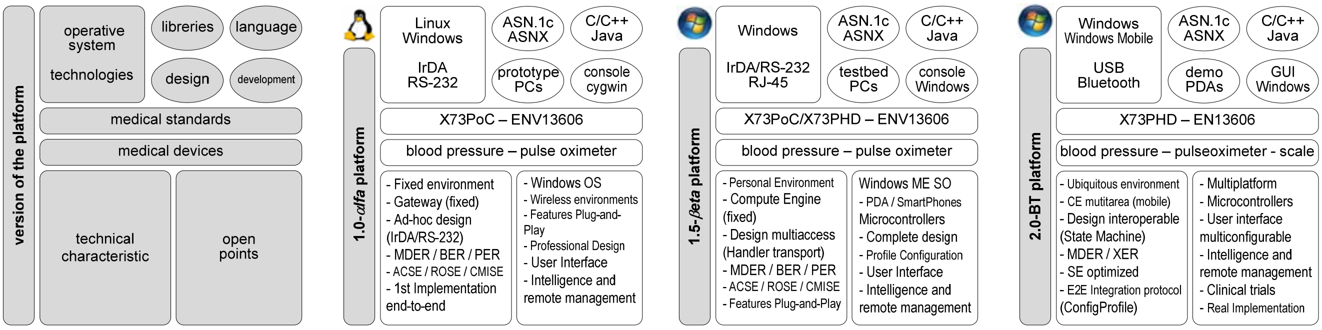


Fig. 1. Evolution scheme of the standard-based platform for e-Health

II. STANDARD-BASED DESIGN FOR 2.0-BT PLATFORM

The design of this last 2.0-BT platform integrates all the evolutions of the X73PHD and EN13606 standards, optimizes the programming code supported by C/C++ and Java over Windows and Windows Mobile, and incorporates features to allow its application to personal health solutions. It consists on the implementation of the X73PHD standard on a system composed of several PHDs and a Compute Engine (CE) that acts as X73 manager. Also it takes into account the monitoring and statistical study of traffic, watching the incorporation of any changes in the definitions of data types, to optimize the exchange of information in terms of time and cost. The reduction of complexity to achieve, with reference to the previous platform is based on drastic X73PoC/X73PHD while optimizing the memory usage. The rate of the transmitted signal is characterized by the structure of the data (single samples or vectors), size, and the required transmission frequency, so they can be managed efficiently as interconnection technologies (association and authentication process, header size and speed of transmission).

Finally, within this platform, the contribution developed in this article attempts to resolve the open points in the latest version, keeping the structure of the stack and the subsystems of the previous platforms, and based on the modification of legacy software that can be applied to personal devices through the transport layer with Bluetooth technology. To achieve this, Windows Mobile was the candidate as the most widespread of the current technology state. Thus, it was necessary to modify the libraries that were available in the previous platform to make the software compatible. Another change has been the separation of the specifications of each PHD. It has developed a different source file for each common library PHD; in this way, when required to integrate a new device, the only requirement is to integrate a new file in the solution for its proper function. Finally, the state machine has been linked independently and coded using object-oriented programming. This code fragment is obtained by means of separating the blocks of the standard with custom programming of the solution, subject to change with future developments of the platform.

The design requirements and implementation specifications of this contribution to the platform are marked by the need to rely on the X73PHD standard to provide interoperability communication between each MD (X73 agent) and CE (X73 manager). The rule described by a finite state machine (FSM, Finite State Machine [1]) included in the Communication Model, describes how to synchronize the operation between the MD and CE. With the following states defined in the X73PHD FSM: DISCONNECTED, CONNECTED, UNASSOCIATED, ASSOCIATED, CONFIGURING and OPERATING, the operation process would be (see Fig. 2):

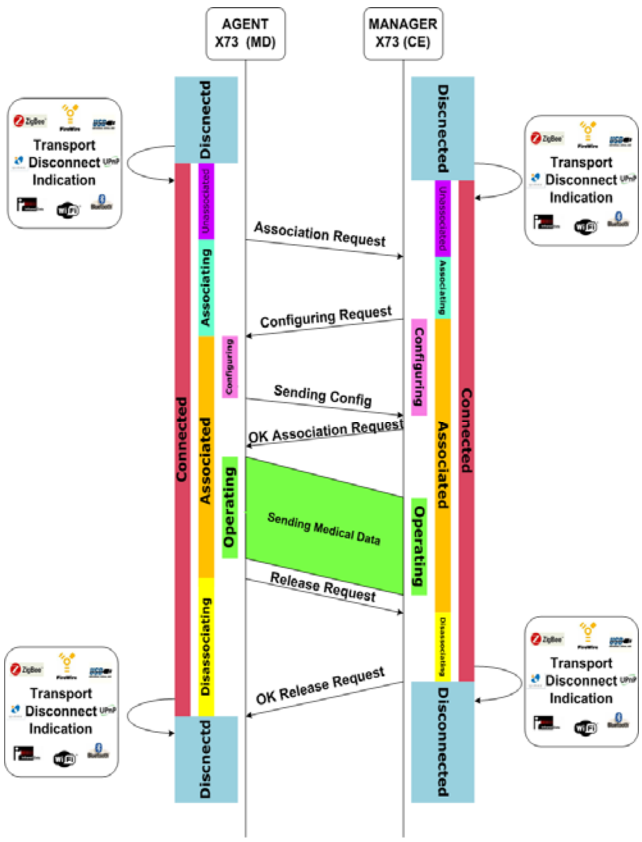


Fig. 2. Agent – manager communication model according to X73 FSM

III. X73PHD/EN13606 IMPLEMENTATION

From these standard-based design guidelines, the implementation has been divided into two parts following both X73PHD and EN13606 standards and supporting the interoperable communication between PHDs over Bluetooth.

Firstly, the X73PHD implementation has been focused on the development of the new Bluetooth module. It includes two main sources with the following technical features:

- *Bluetooth Connection*, for the communication via Bluetooth sockets with several specific functions (see Fig. 3): to search devices (*Discover Devices*), get the number of devices found (*Get Number Device*), get information on the Bluetooth device (*Get Device Information*), find the device names (*Get Local Device Name*) and open the Bluetooth connection (*Open Server Connection*). Fig. 3 shows the operation diagram that has been developed between agent and manager to carry out the interoperable exchange of X73PHD medical data over Bluetooth.
- *X73PHD standard*, for the X73 framework that implements the entire protocol for interoperable communication between PHDs and CE to comply with the standard. They are also defined classes and structures so that through the definition of an object in the *Bluetooth Connection* calls can be made to the functions defined in *X73PHD standard* with just one call through the object library. This source includes a new element in the proposed solution containing PHD specializations for blood pressure device [11073-10407], pulse oximeter [11073-10404], and weighing scale [11073-10415] to allow new devices be introduced in this evolution of the platform. This improves scalability and modularity, since the implementation is structured so that the inclusion of a new emerging PHD over Bluetooth would be easily integrated by only including the new specialization source and its specific object library.

Secondly, the EN13606 implementation is based on Web Services (WS) architecture supported over C# environment, developed on .Net platform and including an Internet Information Server (IIS) to manage ASP.Net dynamic web pages. Figure 4 shows the global scheme for guarantying the EN13606-based design (especially Part 5 that defines the communication model for data exchange). The proposed implementation includes several technologies that provide web interoperability by supporting services and exchanging data in order to develop these procedures and calls: Simple Object Access Protocol (SOAP, based on XML, which provides a standard method for message exchange) and WS Description Language (WSDL, which specifies the syntax and the exchange procedures of these messages). Furthermore, this implementation includes a new application for exchange of EN13606 archetypes, specifically developed to integrate medical data remotely provided for personal health solutions through X73PHD standard.

These archetypes have been implemented following the standard terminology defined by SNOMED-CT [8]. From these premises, the implementation is divided in two levels (see Fig. 4): logic for data access that contains the communication methods with database, and EN13606 framework that generates the EHR extract following iterative techniques from selected parameters in previous level. Thus, from an EN13606 request of the EHR client, the EHR server obtains the *Compositions Identifiers* that fulfil this request and search the required EHR data in database for generate the required *compositions* (*Generate Composition* function). This WS implementation is supported by a public method that includes all the EN13606 restrictions (see upper right area of Fig. 4) distinguishing in mandatory (*subject_of_care_id* as patient's identification) and optional: *time_period* , *meanings*, *sensitivity*, *rc_ids*, *all_versions*, and *multimedia_included*. When all these parameters are obtained and selected and after the EHR header is ready (*GenerateHeaderEHR* function), aforementioned *compositions* (*GenerateComposition* function) are added in order to generate the EHR extract (*GenerateExtract* function) that be sent to the EHR client.

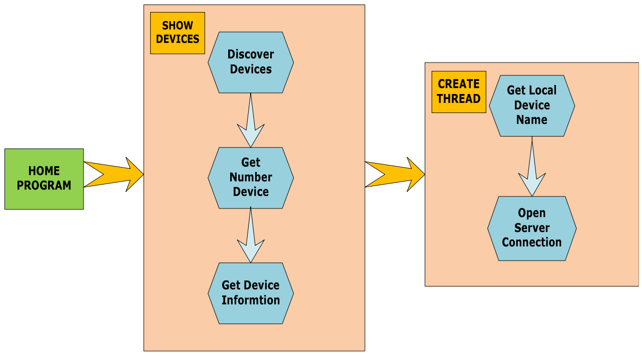


Fig. 3. X73PHD implementation over Bluetooth module

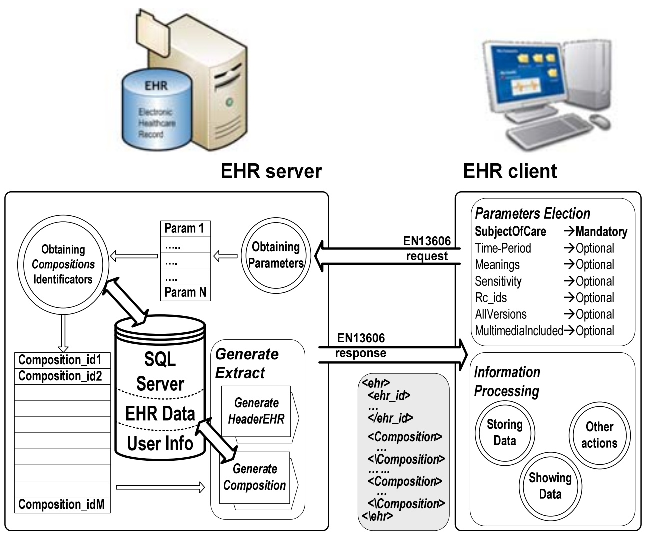


Fig. 4. EN13606 implementation for interoperable exchange of EHR

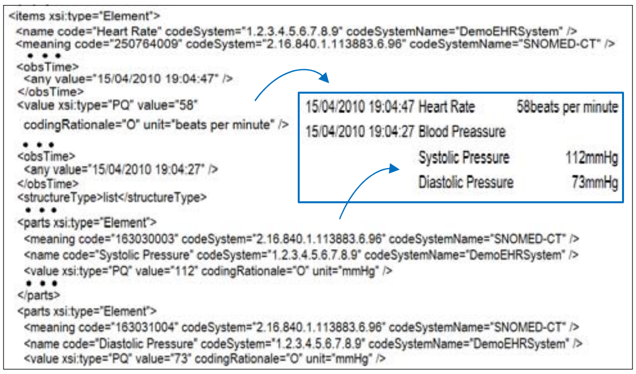
IV. RESULTS

As a result of the abovementioned standard-based design and implementation, an entire test bed has been evaluated. It is focused on patient telemonitoring and includes several PHDs: the *A&D Medical UC321* Bluetooth weighing scale, the *Datex-Ohmeda 3900* RS-232 pulse oximeter, the OMROM 7051T USB blood pressure device and the *A&D Medical UA-767PBT* Bluetooth blood pressure device. This implementation was developed at the beginning of 2010 and there were no X73-compliant PHD, so their X73PHD FSMs have been simulated through several mobile adapters with Bluetooth interface, acting as X73PHD agent/manager, and implemented over a *HTC* 3G SmartPhone device.

As an example of the end-to-end standard-based communication, Fig. 5 shows the entire process from the medical data acquisition to the EHR extract of the patient. This example shows how this solution is available for updating or adding new PHDs and being integrate in HCIS. Figure 5(a) shows the snapshot from the non-standard PHDs following the proprietary format. The original medical data corresponds to a measurement of the arterial pressure with the Bluetooth blood pressure device: 112 mmHg of systolic pressure, 73 mmHg of diastolic pressure, and 58 bpm of pulse. Figure 5(b) shows the messages appearing on the screen of the *HTC* 3G SmartPhone device, acting as X73 manager (CE) of the X73PHD communication with the X73 adapter. It details the connection procedure (*Search*, by founding the Bluetooth address (*idX73PHDagent*) associated with the X73-adapter for the blood pressure PHD), the transmission procedure (*Start* by sending X73 frames that determine the X73PHD FSM) and the sending procedure that shows the aforementioned acquired data: "*X73 Medical Data: SYS 112 DIA 73 PULSE 58*". After receiving the required measurements the communication has to be disconnected (*Exit*, according X73PHD by sending *release request* frames) in order to be ready for a further connection. Finally, Figure 5(c) shows the fragment of a capture of an EHR extract where these medical data are exchanged according to EN13606. This fragment details only the three selected EN13606 elements following SNOMED-CT: "*Heart Rate*" (value="58", unit="beats per minute"), "*Systolic pressure* (value="112", units="mmHg") and "*Diastolic pressure* (value="73", units="mmHg").

(a) Original medical data

(b) X73PHD data over SmartPhone



(c) EHR extract according EN13606 standard

Fig. 5. X73PHD/EN13606-based end-to-end communication process

V. CONCLUSION

This article has proposed a solution that features interoperability and ubiquity by using existing open standards and new wireless technologies to create a end-to-end working system. With this approach, patient can interact with the system remotely without having to go to a medical center, using small and wearable devices for guarantying interoperability regardless of manufacturer. This is the first step for its further implantation in a real healthcare service solving restrictions from the hospital administration board and technical limitations as radio-frequency interferences or security problems related to Bluetooth technologies.

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REFERENCES

[1] ISO/IEEE11073 Health informatics. Point-of-Care Medical Device Communication standard (X73-PoC). [1st Ed.: 2006. Last Ed.: 2009]. Personal Health Devices standard (X73-PHD). [1st Ed.: 2009. Last Ed.: 2010]. *IEEE Standards Association http://standards.ieee.org/. http://www.ieee1073.org*. Last visit: 06/10.

[2] EN13606 - CEN/TC251. Electronic Healthcare Record (EHR) Communication Standard. Parts 1-5. http://www.medicaltech.org. 1st Ed.: 2004. Last Ed.: 2010. Last visit: 06/10.

[3] M. Clarke *et al.*, "Developing a standard for Personal Health Devices based on 11073", *Int Conf IEEE Eng Med Bio Soc (EMBS)*, pp.6175-6177, 2007.

[4] M. Clarke, "Remote care of patients: PHD standard ISO/IEEE11073-20601", *J Healthcare IT Management*, 4(1):33-35, 2009.

[5] I. Martínez *et al.*, "Optimization Proposal of a Standard-based Patient Monitoring Platform for Ubiquitous Environments", *Int Conf IEEE Eng Med Bio Soc (EMBS)*, pp. 1813-1816, 2008.

[6] I. Martínez *et al.*, "Integration Proposal through Standard-Based Design of an End-to-End Platform for p-Health Environments", *Int Conf IEEE Eng Med Bio Soc (EMBS)*, pp. 4639-4642, 2009.

[7] Continua Health Alliance. *www.continuaalliance.org*. Certified products: *Nonin* pulse oximeter, *Roche* glucose device reader, *A&D Medical* blood pressure monitor and weigh scale, *Omron* blood pressure monitor, body composition monitor, pedometer. Last visit: 06/10.

[8] Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT). International Health Terminology Standards Development Organization (IHTSDO). *www.ihtsdo.org/snomed-ct/*. 1st Ed.: 2008. Last visit: 06/10.