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continued →
Original Research
Seamless Integration of ISO/IEEE11073 Personal Health Devices and ISO/EN13606 Electronic Health Records into an End-to-End Interoperable Solution

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Abstract
The new paradigm of personal health demands open standards and middleware components that permit transparent integration and end-to-end interoperability from new personal health devices to healthcare information system. The use of standards seems to be the internationally accepted way to face this challenge. In this article, the implementation of an end-to-end standard-based personal health solution is presented. It integrates the ISO/IEEE11073 standard for the interoperability of personal health devices in the patient environment and the ISO/EN13606 standard for the interoperable exchange of electronic healthcare records and proposes a new approach for the end-to-end ISO/IEEE11073–ISO/EN13606 communication. The design strictly fulfills all the technical requirements of the most recent versions of both standards. An entire prototype has been designed, developed, and tested as a proof-of-concept of a personal health solution.

Key words: end-to-end interoperability, ISO/IEEE11073, ISO/EN13606, personal health

Introduction
The remarkable growth of information and communication technologies during recent decades has fostered the development of new and innovative healthcare applications. From traditional and local healthcare environments such as hospitals or intensive care units, several medical services have migrated to remote and ubiquitous scenarios. These include ambient assisted living, elderly and chronic patient care, home teleassistance, imminent disease management, healthy living, training monitoring, and wellness and fitness, among others. This evolution of the application environment to the patient/user context implies the creation of home, personal, and body area networks, extending the concept of telemedicine applications (usually called e-health) to new paradigms of mobile environments (m-health), ubiquitous healthcare systems (u-health), and user-centered personal health solutions (p-health). All these systems and applications make use of medical devices (MD) to acquire biomedical signals and measurements that can be sent to healthcare information systems (HCIS). Subsequently, health information is analyzed by physicians who eventually provide professional supervision and advice. Nowadays, a wide range of solutions is being created in this area with new personal health devices (PHD) for biomedical signal acquisition based on wireless technologies. However, the transparent use by doctors and patients of different network technologies in this context is a necessary condition for a successful implementation of new p-health solutions.

Most previous healthcare solutions and medical systems developed by manufacturers are based on proprietary protocols and specifications. This has resulted in a lack of interoperability, especially in the case of end-users and HCIS managers, which complicates the incorporation of new MDs and PHDs to achieve a global and ubiquitous solution where the patient becomes the center of the healthcare system. In this context of heterogeneous solutions, initiatives such as HealthVault have been developed to achieve large-scale p-health ecosystems. The solution created by the Microsoft Health Solutions Group links PHD data to electronic healthcare record (EHR) and offers application tools for the user to enable to collect biometric data from a considerable list of MDs, regardless of its communication protocol. This framework bypasses the use of a standard for transferring information from MD to a computer engine (CE) and relies on an adaptation layer, which is specific for every MD. Once acquired, data can be uploaded directly to a proprietarily-formatted regional repository serving as an EHR, accessible for both the user and healthcare providers. This approach could be enough to set up a workable telemonitoring system; however, it is not cost efficient, because it requires one adapter for each and every device to be supported. Hence, standardization seems to be the most efficient way to achieve an interoperable ecosystem, as has been remarked in much of relevant bibliography. International organizations have been working for several years on the promotion of standardization to fill this interoperability gap. Originally, the European Committee for Standardization (CEN, with its specific Technical Committee
for Health Informatics CEN/TC251, in which our research group collaborates\(^\text{11}\) promoted the definitions of several norms for medical information interoperability. These norms have been adopted by the ISO (following the ISO/CEN Vienna Agreement) and constitute the two standards that support the proposed implementation: ISO/IEEE11073 (X73)\(^\text{12,13}\) and ISO/EN13606.\(^\text{14}\)

X73 was initially designed in 2004 (by absorbing three previous standards: ENV13734/VITAL, ENV13735/INTERMED, and IEEE1073/MIB) to address intensive care unit scenarios focused on covering MD interoperable communication at the Point-of-Care of the patient (X73PoC).\(^\text{12}\) With the emergence of new transmission technologies (such as universal serial bus [USB], Bluetooth, and ZigBee) and wearable devices with new features and capabilities, the existing protocol was regarded as complex and in need of revision, leading to a more lightweight version. This evolution resulted in the creation of the most recent version for PHDs (X73PHD).\(^\text{13}\)

The ISO/EN13606 norm has been developed to exchange EHRs between HCIS in a semantic interoperable way and is able to represent all information included in EHRs. Its aim is to standardize the way EHR extracts are interchanged to guarantee interoperability. Thus, ISO/EN13606 is not intended to specify the internal architecture of the EHR system or the mechanisms used to store data in HCIS, but how the clinical information must be transmitted. ISO/EN13606 is based on a dual model: the Reference Model (that defines “information” representing the medical data and is structured using a top-down tree model: extract, folder, composition, section, entry, cluster, and element) and the Archetype Model (that defines “knowledge”: an archetype is a template that represents the specific context and semantic characteristics of the medical data by imposing restrictions on the reference model). For example, the patient’s blood pressure measurement is stored using a structure in the reference model, but what exactly this information expresses is defined in the archetype model as a compound value of systolic and diastolic pressure. Eventually, because of new discoveries in medicine, it may become important to include additional measurements (such as the heart rate) with the blood pressure tests. In such a case, only the archetype (knowledge) would change, whereas information remains unalterable. ISO/EN13606 has extensively evolved over the last two decades until its completion in 2010.\(^\text{14}\)

However, the existence of medical standards does not guarantee the implementation of a homogeneous p-health solution, given that the integration of different standards into end-to-end solutions remains an intricate and complex task. In this context, some open initiatives such as Integrating the Healthcare Enterprise (IHE)\(^\text{15}\) and Continua Health Alliance\(^\text{16}\) have emerged and are willing to collaborate with the aforementioned organizations to encourage standardization. IHE is an organization composed of manufacturers from all around the world, whose main objective is to adopt the most suitable available standards for every telemedicine service.

Continua Health Alliance is an open nonprofit alliance of industry-leading technology and health companies intending to establish an ecosystem of interoperable p-health systems that empower people and organizations to better manage their health and wellness. Recently, in 2009, its work resulted in an X73PHD certification program with a consumer-recognizable logo for the devices. With this Continua Certification, a device can be used in any healthcare standard-based application regardless of other systems, as long as they all implement standards. In this direction, new MDs and PHDs have been recently released in 2010 fulfilling the Continua Certification Guidelines and thus supporting the transport layer technologies adopted by Continua (USB, Bluetooth, and ZigBee), specifically the new profiles for health applications: USB PHD Class, Bluetooth PHD, and ZigBee HealthCare Profile. All the joint works of these groups have been completed by a specific working group focused on new PHDs,\(^\text{17}\) which has adopted X73 as the standard for device interoperability.

One of the main challenges in standard-based research is its subsequent implementation in the form of solutions transferable to the healthcare system. Several previous contributions have applied X73 in sanitary environments by implementations designed for patient monitoring in the PoC,\(^\text{18}\) analyzed the new approaches for X73PHD as proof-of-concept to test the standard evolution,\(^\text{19–22}\) and detailed implementations of ISO/EN13606 in HCIS.\(^\text{23}\) Nevertheless, these contributions were not sufficiently comprehensive given that they only considered isolated elements of the whole end-to-end architecture. In this context, both IHE and Continua have proposed some initiatives to fill this interoperability gap. These proposals do not usually imply new ad-hoc standards. Instead, they leverage some ideas and profiles from other standards, essentially the Health Level 7 (HL7).\(^\text{24}\) A first HL7-based implementation approach has been already presented in the literature,\(^\text{24}\) but, in any case, it does not fulfill the specific requirements of ISO/EN13606 and X73PHD that are necessary for the implementation proposed in this article.

In the next section, the whole system architecture and standard-based design is described in terms of its technical features. In the X73PHD Implementation and ISO/EN13606 Implementation sections, the implementation of the most recent evolutions of X73PHD and ISO/EN13606 are analyzed by distinguishing, respectively, their specific requirements. In the X73PHD-ISO/EN13606 Communication section, a proposal for an interoperable end-to-end communication based on X73PHD and ISO/EN13606 is presented. The entire prototype that has been designed, developed, and tested as a proof-of-concept of a personal health solution is described in the End-to-End Personal Health Solution section. Finally, the strong and weak points are discussed within the overall conclusions in the last section.

**System Architecture and Standard-Based Design**

The proposed system architecture for the design of a p-health solution based on the X73PHD and ISO/EN13606 standards is presented in Figure 1. This solution includes several PHDs that acquire medical information from the patient environment and a CE that gathers it through an X73PHD communication. The HCIS includes an EHR server that allows the interoperable exchange of EHRs through an ISO/EN13606 communication. The X73PHD-ISO/EN13606 communication between CE and HCIS follows a harmonized procedure that permits the EHR update and the management of different CEs gathering all the data from every patient environment. The standard-based design comprises the following main components:
• PHD: This provides the original medical data by making use of protocols that follow a proprietary format. Although a few Continua-certified PHDs have been recently released in 2010, they are not commercially available. Thus, an adaptation to X73PHD is needed. These adapters create device specializations, indexed in X73PHD as 11073-104xx (Table 1). From these 11073-104xx specializations, the inherent domain information model (DIM) is generated, which sets the required information structure to establish the finite state machine (FSM) allowing every PHD to act as an agent of the X73PHD communication (see upper area of Fig. 1).

• CE: This is designed as an X73PHD manager that gathers medical data from every PHD through its FSM. Subsequently, a file is generated containing these X73 data together with other specific configuration information (Config Profile). This file becomes the data input to the frame creation process for further X73PHD-ISO/EN13606 communication. Thus, the CE acts as a client of the X73PHD-ISO/EN13606 communication with the EHR server (see middle area of Fig. 1). It allows harmonized communication including supervision and remote control, platform updating and management, database access and user info monitoring, etc.

• EHR server: This comprises two modules: the first acts as a server of the X73PHD-ISO/EN13606 communication with the CE, given that it is responsible for receiving X73 data from CEs, decoding specific frames, and extracting the appropriate medical data (distinguishing the associated user information) for storage in the database of the EHR server. The second acts as an ISO/EN13606 client/server with a double function: the processing of ISO/EN13606 queries coming from EN/ISO13606 clients (mapping their queries to the server databases), and the retransmission of ISO/EN13606 extracts following the ISO/EN13606 archetype model to third-party ISO/EN13606 servers (see lower area of Fig. 1).

From this system architecture and standard-based design, the implementation has to guarantee several technical specifications regarding the specific requirements of both X73PHD and ISO/EN13606 standards, as is explained in the following two sections.

**X73PHD Implementation**

A detailed description of X73PHD can be found in Ref.\textsuperscript{13} The implementation proposed in this article strictly follows the standard, fulfilling all the technical requirements for guaranteeing the X73PHD-based design. A complete implementation scheme is shown in Figure 2, including the FSM (see upper left area), the protocol stack (see lower left area), the graphical user interface (GUI; see upper right area), the application protocol data units (APDUs; see upper right area), and the frame creation process (see lower right area).

The X73PHD communication follows an agent–manager configuration that is based on a well-defined object-oriented paradigm. The solution has been implemented using C++ programming language for several reasons: it is supported by most of the embedded system development tools (in its embedded C++ version), it can be integrated into Windows applications either for desktop computers or
Windows Mobile by including the Microsoft Foundation Class libraries for GUI design, it provides low-level access methods to control buffers and communication drivers, and the use of pointers allows management of object trees and efficient use of the memory and data frames. Although Java language was also considered prior to the development, the need for accessing low-level hardware components and the existence of an already designed platform implementing a previous version of the X73PHD standard led to the selection of C++. Therefore, using Microsoft Visual Studio C++ and Microsoft embedded Visual C++ allowed the targeting of two different platforms while keeping the codes (specially the X73PHD communication library) as close as possible. Despite obvious graphical differences, interfaces can be created to desktop as well as mobile environments with these libraries.

The X73PHD DIM and FSM have been completely developed with this programming framework, including the set of messages defined in the X73PHD Service Model and using Abstract Syntax Notation One (ASN.1) code scheme. In addition, the implementation provides data conversion from the ASN.1 notation to transfer syntax, using optimized Encoding Rules for MDs (MDER). Further, this implementation leverages some aspects of previous contributions based on X73PoC, such as the Service Element division from Association Control, Common Management Information, and Remote Operation (optimized for MDER) (see lower right area of Fig. 2). All the data type classes are defined in X73PHD using ASN.1 (see upper middle area of Fig. 2). The result is an abstract declaration of the data (name and type) to be used later in the protocol. Then, these complex data have to be mapped into a byte-frame to be manipulated by a computer and subsequently sent over a transport protocol. This byte-representation is achieved using MDER, a more efficient version of the classic Binary, Packet, and eXchange Mark-up Language (XML) Encoding Rules (BER, PER, and XER) also supported by the standard definition. Although BER, PER, and XER have available C++ compilers for conversion, MDER requires additional modifications and code arrangements in the compiler to obtain C++ encoding functions. This approach increases the complexity of the implementation, as well as its memory requirements. For this reason, a direct byte-encoding technique has been used in this solution to provide transparency to the frame creation process to compose APDUs as well as reduce memory requirements. Several representative APDUs of X73PHD communication, such as Data Request Action, Association Request, Release Request, or Abort, are shown in the upper right area of Figure 2. Special precautions have to be taken while defining the frame creation within the code to avoid critical protocol errors. Thus, the frame processing has been strongly atomized by taking advantage of MDER features.

#### Table 1. IEEE11073-104xx Specializations for Personal Health Devices

<table>
<thead>
<tr>
<th>IEEE Std.</th>
<th>Pulse oximeter</th>
<th>Basic ECG (3-leads)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11073-10404-2008</td>
<td>P11073-10406</td>
<td>Respiration rate</td>
</tr>
<tr>
<td>11073-10407-2008</td>
<td>P11073-10413</td>
<td>InR-blood coagulation</td>
</tr>
<tr>
<td>11073-10408-2008</td>
<td>P11073-10418</td>
<td></td>
</tr>
<tr>
<td>11073-10415-2008</td>
<td>P11073-10419</td>
<td></td>
</tr>
<tr>
<td>11073-10417-2008</td>
<td>P11073-10420</td>
<td></td>
</tr>
<tr>
<td>11073-10441-2008</td>
<td>P11073-10421</td>
<td></td>
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<tr>
<td>11073-10442-2008</td>
<td>P11073-10443</td>
<td></td>
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<tr>
<td>11073-10471-2008</td>
<td>P11073-10443</td>
<td></td>
</tr>
<tr>
<td>11073-10472-2010</td>
<td>P11073-10443</td>
<td></td>
</tr>
</tbody>
</table>

![Fig. 2. X73PHD implementation scheme including the complete design of the FSM, the protocol stack, the graphical user interface (GUI), the application protocol data units (APDU), and the frame creation process. X73PHD, ISO/IEEE11073 Personal Health Devices; FSM, finite state machine.](image-url)
and the fact that several information fields are always located in the same position of the frame structure, such as protocol-definition headers, length/segment indicators, and measurement containers.

Finally, to reduce the complexity of the implementation, the protocol stack and data structure models from X73PHD have been analyzed and optimized. Although previous works incorporated a whole seven-layer model and processed the APDU layer-by-layer, this approach is able to process all the APDU at once by reading its header. This means that during the analysis of an APDU, a field content chart will be followed to simplify the FSM operation. As the frame structure is known previously, it is possible to read and match certain blocks within an APDU without the need to process the whole packet. From this point, a solution design based on frame pattern methodology has been developed. Designated byte-patterns have been previously stored in the memory and completed with the necessary parameters prior to being sent. This simplifies the processing required as there is no need to process every frame. In the case of agents, some of the reply-frame fields can be automatically completed from the state-tables and the received frame, by adding the required information to a predefined pattern. Thus, this implementation includes all states and procedures defined in X73PHD FSM: disconnected, connected, unassociated, associating, associated, configuring, operating, and disassociating (see upper left area of Fig. 2).

The entire X73PHD communication process between agent and manager is schematized in Figure 3 and detailed in the following steps:

- From the disconnected state, when both agent and manager are turned on, the local initialization procedure is executed. After this initialization, a connection procedure is established through the transport layer by means of a specific X73PHD indication (Transport Connect Indication).
- This procedure has been implemented by means of a generic transport layer (X73PHD technology handler), independent of the transport level of the X73PHD framework and open to the inclusion of new communication technologies. In the proposed solution, this transport handler includes Transmission Control Protocol/Internet Protocol (TCP/IP) support for communication with the EHR server and USB/Bluetooth support for connection with PHDs. Thus, the communication with the physical layer is carried out through an application programming interface in the lower stack levels (L3-L1), and the communication with the application layer (via sockets for both PHD and CE) through a system of buffers in the upper stack levels (L4), as is shown in the right-hand area of Figure 3.
- If the connection has been successfully driven, then both devices enter into the connected state but unassociated. Thus, to become associated, the agent sends an Association Request (AARQ) to the manager.
- If the manager already knows the agent configuration, either because it is standard or it has the configuration stored from previous operations, agent and manager enter into the associated state and will be ready to operate. Otherwise, the manager will ask previously for the agent configuration (Configuring Request) by exchanging a configuration event report with the contents of the DIM (Sending Config), which is essentially the PHD configuration. The capability of storing the DIM provided by the X73PHD speeds up the Plug-and-Play (PnP) procedure in the manager in further associations. After this, the manager confirms the status (OK Operating Request) and enters the operating state.
- In the operating state, the medical data transmission begins. Following the X73PHD definition, either the agent sends a spontaneous measurement to the manager without it first being requested by the manager (agent-initiated), or the manager

Fig. 3. Agent (PHD)--manager (CE) communication model according to X73PHD FSM, including the implemented X73PHD technology handler. CE, Compute Engine.
requests the agent for measurements on demand (manager-initiated). In the latter case, three modes can be used: single response (data-req-mode-single-rsp), time period (data-req-mode-time-period), or no time limit (data-req-mode-time-no-limit).

- At any time, both agent and manager may become disassociated because of error situations, end of measurements, or other circumstances. In such a case, there is either a disassociation request (Release Request [RLRQ]) followed by a confirmation on the other side (OK Release Request [RLQE]) or a direct Abort Request (ABRT), ending in the disconnected state. In this transition, the implemented X73PHD technology handler goes into operation to release the transport connection.

**ISO/EN13606 Implementation**

A detailed description of ISO/EN13606 can be found in Ref. 14 and a proof-of-concept design in Ref. 23. The proposed implementation strictly follows the latest version of the ISO/EN13606 to fulfill all the technical requirements included in the five parts of the standard (Part 5 specifically defines the communication model for data exchange). Figure 4 shows the overall scheme for guaranteeing the ISO/EN13606-based design. This implementation is based on a Web services (WS) architecture, which includes a set of technologies that provide Web interoperability by supporting services and exchanging data. Providers offer WS as remote procedures and users requiring WS call these procedures through Internet connections. Thus, this implementation includes several technologies to develop these procedures and calls: Simple Object Access Protocol (based on XML), which provides a standard method for message exchange and WS Description Language (which specifies the syntax and the exchange procedures of these messages).

The implementation of this WS architecture has been supported over two development environments: C# and Java. The C# environment has been implemented over the .Net platform including an Internet Information Server to manage ASP.Net dynamic Web pages. The Java environment has been implemented over the Axis2 platform including an Apache Tomcat as servlets container. The only difference between these two environments is the data type accepted for WS as input. C# inputs only require to be defined as data classes, whereas Java inputs have to fulfill the Java Application Programming Interface specification for XML (JAX-RPC-1). Because the complexity and variability of the input parameters are very high, and to integrate this implementation with the previous X73PHD implementation, the C# environment has been selected by default. However, the solution integrates the Java environment to provide a homogenous tool that accepts structured data input, which is very useful for decoding all data types into a harmonized solution. Further, a new application for exchange of ISO/EN13606 archetypes has been included, specifically developed to integrate medical data provided remotely for p-health solutions through the X73PHD standard. These archetypes have been implemented using the Archetype Data Language defined by ISO/EN13606 and bound to the standard terminology defined by SNOMED-CT. 26

From these premises, the implementation is divided into two levels (see left area of Fig. 4): the logic for data access that contains the communication methods with the database, and the framework that generates the EHR extract following iterative techniques considering selected parameters in the previous level. Thus, from an ISO/EN13606 request from the EHR client, the EHR server obtains the Compositions Identifiers that fulfill this request and searches the required EHR data in the database to generate the ISO/EN13606 compositions (Generate Composition function).

This WS implementation is supported by a public method that includes all the ISO/EN13606 restrictions (see upper right area of Fig. 4) distinguishing mandatory (subject_of_care_id as the identification of the patient) and optional (time_period selected time interval), meanings (set of coded values of the meaning of each standard term following a specific clinical terminology), sensitivity (integer that allows levels and categories to be established), rc_ids (register identifiers to be included in the EHR extract), all_versions (Boolean that selects if all the versions of the EHR extract are included or not), and multimedia_included (Boolean that indicates if the EHR extract includes encapsulated data in multimedia format). When all these parameters are obtained and selected, and after the EHR header is ready (GenerateEHRheader function), the aforementioned ISO/EN13606
compositions (GenerateComposition function) are added to generate the EHR extract (GenerateExtract function) that is to be sent to the EHR client. This entire process consists of several specific functions that develop these main tasks:

- Processing of data input to limit the maximum number of required compositions in an ISO/EN13606 request (Fig. 4).
- Generation of Instance Identifiers (II) as generic data type for the exchange of clinical information following the ISO/DIS 21090 specification27 as recommended by ISO/EN13606.
- Creation of every ISO/EN13606 composition, section, entry, cluster, and element (distinguishing elements whose value property contains Physical Quantity [PQ] or Encapsulated Data [ED]).
- Obtaining of Coded Value (CV) that supports several situations: association of the generic terms with standard clinical terminology through SNOMED-CT, determination of the data type that contains every ED, identification of which compression method is used to store medical data, and selection of the algorithm used to generate the signature that every ED requires to guarantee the integrity of transmission.

Figure 5 shows an example of a complete EHR extract, containing additional fields such as archetype_id (to identify the pattern data that are transmitted afterward), which has been generated and validated following ISO/EN13606.

**X73PHD-ISO/EN13606 Communication**

As stated before, X73PHD covers the PHD-CE interface, whereas ISO/EN13606 covers the interoperable exchange of EHRs. A Wide Area Network interface typically connects the CE and the EHR server. So far, no specific standard has been defined to cover this interface. However, some initiatives (driven by IHE and Continua) have been proposed to bridge this interoperability gap. The IHE-Patient Care Device (IHE-PCD) Technical Committee has proposed the Device to Enterprise Communication (DEC, called PCD-0128). This profile leverages messages from HL7 v2.6 to connect the CE to the EHR server. The "Subscribe to Patient Data" (called PCD-0229) is an extension of that profile that splits this interface to filter the data generated in the p-health environment. Within the Continua guidelines, the CE-EHR server interface has been further subdivided into two subinterfaces, by including a new element addressed for back-end services. The first subinterface is out of the scope of Continua Design Guidelines v1. For the second subinterface, Continua has chosen the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile and, on top of that, the HL7 Personal Health Monitoring (PHM) Report document.

These IHE and Continua proposals do not imply the definition of new ad-hoc standards. On the contrary, they leverage some profiles and procedures from other standards, essentially HL7 (IHE-DEC leverages HL7 v2.6 messages and Continua makes use of the HL7-PHM profile). As the proposed implementation is based on ISO/EN13606 and X73PHD, these HL7-based approaches are not the most suitable options for fulfilling their specific requirements. Moreover, the inherent verbosity and complexity of HL7 has led us to design a

**EHR_EXTRACT**

```xml
ehr_system.extension = HCIS
ehr_system.assigningAuthorityName = Aragon Healthcare Service/AHS
ehrr_system.valid_time = 1/1/1990 – 1/1/3000
ehr_id.extension = EHRExtract.120025022008
ehr_id.assigningAuthorityName = AHS
ehr_id.valid_time = 1/1/1990 – 1/1/3000
subject_of_care.extension = 441003686941
subject_of_care.assigningAuthorityName = AHS
subject_of_care.valid_time = 1/1/1990 – 1/1/3000
time.created = 20100415190405
rm_id = ISO/EN13606-1.0
COMPOSITION
rc_id.extension = 0003
rc_id.assigningAuthorityName = HCIS / AHS
rc_id.valid_time = 1/1/1990 – 1/1/3000
name = Telemedicine Data List
sensitivity = 3
commitual.ehr_system.extension = HCIS
commitual.ehr_system.assigningAuthorityName = AHS
commitual.ehr_system.valid_time = 1/1/1990 – 1/1/3000
commitual.committer.extension = Perez MD
commitual.committer.assigningAuthorityName = AHS
commitual.committer.valid_time = 1/1/1990 – 1/1/3000
commitual.committer_time_committed = 20100415190405
ENTRY
rc_id.extension = 0004
rc_id.assigningAuthorityName = HCIS / AHS
rc_id.valid_time = 1/1/1990 – 1/1/3000
archetype_id.extension = CENArch.Entry.TMWeightMeasure.v1
archetype_id.assigningAuthorityName = HCIS
archetype_id.valid_time = 1/1/1990 – 1/1/3000
name = Weight measurement
codingScheme = 2.16.840.1.113883.6.96
meaning.codingSchemeName = SNOMED
meaning.codingSchemeVersion = 7
meaning.codeValue = 301333006
meaning.displayName = Body weight measurement
synthesized = FALSE
sensitivity = 3
ELEMENT
rc_id.extension = 0005
rc_id.assigningAuthorityName = HCIS / AHS
rc_id.valid_time = 1/1/1990 – 1/1/3000
name = Weight measurement
codingScheme = 2.16.840.1.113883.6.96
meaning.codingSchemeName = SNOMED-CT
meaning.codingSchemeVersion = 7
meaning.codeValue = 301333006
meaning.displayName = Body weight measurement
sensitivity = Clinical
synthesized = FALSE
value.PQ.value = 77
value.PQ.units = kg
value.PQ.property = Weight
```

WS architecture supported by a simplified but efficient XML-based approach for the proposed implementation. This XML interchange document satisfies the particular requirements of the previously detailed X73PHD and ISO/EN13606 implementations with strict constraints for providing interoperability, security, reliability, and privacy requirements as well as simplicity of use. An example of this XML approach is shown in Figure 6.

![Fig. 5. Example scheme of an ISO/EN13606-compliant EHR extract of the patient.](image-url)
From the point-of-view of the CE, the designed XML takes into account the available data that are relevant for their inclusion in EHR from several PHD specializations, retaining a homogeneous nomenclature. From the point-of-view of the EHR server, it includes the information needed to locate and integrate data into the ISO/EN13606 architecture. The content and structure of this XML document depends on a specific configuration file (Config Profile; see Fig. 1) retrieved from the EHR server. This Config Profile is configured in collaboration with medical specialists and from previous analysis of health use cases. Thus, it states specific medical information about the patients (idCollecter), their associated PHDs (deviceInfo), the requested measurement procedure (timeStamp), and some other technical information from the PHD setup, such as device type (MDC_ATTR_ID_TYPE), model (MDC_ATTR_ID_MODEL), battery thresholds (MDC_ATTR_VAL_BATT_CHARGE), etc.

With these premises for the X73PHD-ISO/EN13606 communication, the functional design of the end-to-end architecture is shown in Figure 7. It consists of four procedures (CE communication, PHD connection, System control, and Medical data acquisition) that govern the whole performance of the p-health solution. The sequence of steps determining these four processes is as follows:

- **CE communication.** An executable application is launched in the CE (step 1). The remote communication process between the CE and the EHR server is initiated by testing the CE connectivity (step 2). First, it is necessary to check if there is previously acquired X73PHD data waiting to be sent to the EHR server (step 3). If this is the case, the medical data are sent (step 4). Second, it is necessary to check that the Config Profile has not been modified (step 5). Otherwise, the Config Profile is updated in the EHR server and sent to the CE (step 6).

- **PHD connection.** This procedure follows strictly the agent–manager communication model defined by X73PHD FSM. Thus, from the disconnected status, the CE searches for PHDs available in the patient network (step 7). The PHDs located send their X73PHD Identification Codes to the CE (step 8). Among the PHDs found, the CE selects for connection those assigned to each patient according to each Config Profile (step 9); this allows several patients (for example different members of the family) to use the same CE. If the connection with these selected PHDs has been successfully driven, these PHDs and the CE enter into the connected status (step 10). From this, both devices change to the associated (step 11) by exchanging the DIM or directly with a PnP configuration. From this status, every PHD and the CE are ready to operate following the X73PHD standard (step 12).

- **System control.** Once the PHDs and the CE are connected and associated, the system remains in stand-by status (step 13). Optionally, in this status, the Config Profile could be updated (step 14) or the PHD connections could be changed (step 15), returning to steps 6 and 10, respectively. The CE remains in this status until its date/time matches with the date/time of the measurements prescribed in Config Profile (step 16). Then the user/patient must log into the system (step 17), and as the same CE may be shared by several users/patients, the customized GUI is set up for every user/patient (step 18).

- **Medical data acquisition.** The PHD initiates the process of medical data transmission to the CE according to the X73PHD standard (step 19). The CE temporarily stores them for their further transmission to the EHR server (step 20). Optionally, the CE could filter and preprocess these data, involving warnings or alarms to the EHR server because of incorrect measurements, data out of range, etc. (step 21). The connectivity with the EHR is tested again (step 22). If the result is successful, the acquired measurements and optional alarms are sent (step 23) and an acknowledgement confirmation must be sent from the EHR server to the CE to complete the procedure (step 24). Otherwise,

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Fig. 6. eXchange Mark-up Language format for the X73PHD-EN/ISO13606 communication.

From the point-of-view of the CE, the designed XML takes into account the available data that are relevant for their inclusion in EHR from several PHD specializations, retaining a homogeneous nomenclature. From the point-of-view of the EHR server, it includes the information needed to locate and integrate data into the ISO/EN13606 architecture. The content and structure of this XML document depends on a specific configuration file (Config Profile; see Fig. 1) retrieved from the EHR server. This Config Profile is configured in collaboration with medical specialists and from previous analysis of health use cases. Thus, it states specific medical information about the patients (idCollecter), their associated PHDs (deviceInfo), the requested measurement procedure (timeStamp), and some other technical information from the PHD setup, such as device type (MDC_ATTR_ID_TYPE), model (MDC_ATTR_ID_MODEL), battery thresholds (MDC_ATTR_VAL_BATT_CHARGE), etc.

With these premises for the X73PHD-ISO/EN13606 communication, the functional design of the end-to-end architecture is shown in Figure 7. It consists of four procedures (CE communication, PHD connection, System control, and Medical data acquisition) that govern the whole performance of the p-health solution. The sequence of steps determining these four processes is as follows:

- **CE communication.** An executable application is launched in the CE (step 1). The remote communication process between the CE and the EHR server is initiated by testing the CE connectivity (step 2). First, it is necessary to check if there is previously acquired X73PHD data waiting to be sent to the EHR server (step 3). If this is the case, the medical data are sent (step 4). Second, it is necessary to check that the Config Profile has not been modified (step 5). Otherwise, the Config Profile is updated in the EHR server and sent to the CE (step 6).

- **PHD connection.** This procedure follows strictly the agent–manager communication model defined by X73PHD FSM. Thus, from the disconnected status, the CE searches for PHDs available in the patient network (step 7). The PHDs located send their X73PHD Identification Codes to the CE (step 8). Among the PHDs found, the CE selects for connection those assigned to each patient according to each Config Profile (step 9); this allows several patients (for example different members of the family) to use the same CE. If the connection with these selected PHDs has been successfully driven, these PHDs and the CE enter into the connected status (step 10). From this, both devices change to the associated (step 11) by exchanging the DIM or directly with a PnP configuration. From this status, every PHD and the CE are ready to operate following the X73PHD standard (step 12).

- **System control.** Once the PHDs and the CE are connected and associated, the system remains in stand-by status (step 13). Optionally, in this status, the Config Profile could be updated (step 14) or the PHD connections could be changed (step 15), returning to steps 6 and 10, respectively. The CE remains in this status until its date/time matches with the date/time of the measurements prescribed in Config Profile (step 16). Then the user/patient must log into the system (step 17), and as the same CE may be shared by several users/patients, the customized GUI is set up for every user/patient (step 18).

- **Medical data acquisition.** The PHD initiates the process of medical data transmission to the CE according to the X73PHD standard (step 19). The CE temporarily stores them for their further transmission to the EHR server (step 20). Optionally, the CE could filter and preprocess these data, involving warnings or alarms to the EHR server because of incorrect measurements, data out of range, etc. (step 21). The connectivity with the EHR is tested again (step 22). If the result is successful, the acquired measurements and optional alarms are sent (step 23) and an acknowledgement confirmation must be sent from the EHR server to the CE to complete the procedure (step 24). Otherwise,
the CE stores the data until the connection is available again (step 25). Once the X73PHD data are confirmed and stored in the EHR server, the system is ready for further interoperable exchange of EHRs following the ISO/EN13606 standard (step 26). Finally, the CE checks for more required measurements by returning to step 19 (in the case of the same user/patient) or 17 (if the user/patient is different). Otherwise, the system returns to the stand-by status (step 13).

End-to-End Personal Health Solution

With the aforementioned standard-based implementation and the new proposal of X73PHD-ISO/EN13606 communication, an entire prototype has been designed, developed, and tested as a proof-of-concept of a p-health solution. Figure 8 shows the X73PHD-ISO/EN13606 prototype including several PHDs, managed from an ASUS AOpen MoDT Flex i945GTt-VFA computer (acting as X73PHD CE), and another Flex i945 computer (acting as EHR server) connected with the CE through the Internet over a TCP/IP network. Although a few Continua-certified PHDs have been recently released, they are not commercially available. Hence, in this implementation (developed at the beginning of 2010), the X73PHD FSMs of each PHD has been simulated through several adapters acting as X73PHD agents: the A&D Medical UC321 Bluetooth weighing scale, the Datex-Ohmeda 3900 RS-232 pulse oximeter, the OMRON 7051T USB blood pressure device, and the A&D Medical UA-767PBT Bluetooth blood pressure device. As an example of the end-to-end standard-based communication, Figure 9 shows the entire process from the medical data acquisition to the EHR extract of the patient for the Bluetooth blood pressure device.

Figure 9a shows the measurement acquisition process of arterial pressure and heart rate with the Bluetooth blood pressure device. The original medical data corresponds to a measurement for an arterial pressure of 109 mmHg systolic pressure and 62 mmHg diastolic pressure and for a heart rate of 58 beats per minute.

Figure 9b shows the X73PHD agent application that can play the role of the X73PHD adapter for non-X73PHD-compliant devices as well as emulator of any X73PHD specialization for testing purposes. It allows the selection of the PHD specialization (weighing scale, blood pressure device, or pulse oximeter) to be initialized, as is shown in the upper left area of Figure 9b. This selection involves a choice of the specific objects, services, and communication model of every device specialization. The X73PHD agent–manager communication model can be tested with the application controls (see lower left area of Figure 9b) by selecting every procedure defined in X73PHD FSM: disconnect, connect, operate, etc. The specific agent status is shown in the upper right area of Figure 9b and all the details of the communication process are shown just below. This allows further analysis of the X73PHD FSM operating flow and the testing of all the possible data transmission modes that X73PHD defines for agent and manager, as well as the details of the hexadecimal code for the X73PHD APDUs.
Figure 9c shows the X73PHD manager application that collects different X73PHD agents. The details of the communication process (similar to the agent application) for the three aforementioned agents (weighing scale, blood pressure device, or pulse oximeter) are shown in the left area of Figure 9c. The received X73PHD measurements are shown in the right area of Figure 9c, detailing their contents (in this example: “Medical Data: Systolic 109, Diastolic 62, Heart rate 58”). Finally, the manager checks if more measurements are to be made. Alternatively, a menu is used to disassociate the PHD and CE or disconnect them as indicated by the FSM.

Finally, Figure 9d shows a fragment of a capture of an EHR extract where these medical data are exchanged according to ISO/EN13606. This fragment details only the three selected EN13606 elements following SNOMED-CT: “Heart Rate” (value = “58,” unit = “beats/minute”), “Systolic Pressure” (value = “109,” unit = “mmHg”), and “Diastolic Pressure” (value = “62,” unit = “mmHg”).

This example shows how all intermediate communication procedures are transparent for final users (patients and doctors). Only the proprietary PHDs are nonstandard but, using X73-adapters, the entire p-health solution is directly available for the addition of new PHDs, the update of the PHD profiles, or the integration into different HCIS.

Conclusions

The need for standardization and seamless interoperability in healthcare environments has motivated the proposal and implementation of an interoperable end-to-end personal health solution. This solution guarantees the specific requirements established by the most recent versions of the X73PHD and ISO/EN13606 standards and proposes a new approach for the end-to-end X73PHD–ISO/EN13606 communication. This prototype implements new transport technologies such as USB and Bluetooth and includes new functionalities not yet supported in previous implementations, such as Plug-and-Play capabilities, integration of PHDs, and remote configuration through the end-to-end communication. Following the challenges currently under discussion in the CEN, future research work will be focused on alarm management, multiple PHD connections with one or multiple CEs, harmonized and wireless managers, and new ZigBee technology. The clinical validation of the prototype with these new contributions could allow its subsequent transfer to the healthcare system.

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The authors have published several previous contributions to this work about (a) the application of the first version of the ISO/IEEE11073 standard in sanitary environments by its implementation, to monitor patients in the Point of Care\(^\text{18}\); (b) the analysis of the new approaches of the ISO/IEEE11073 standard for personal health devices as proof-of-concept to the standard evolution\(^\text{22,32}\); (c) the isolated implementations of the first version of ISO/EN13606 (2004) in healthcare information systems\(^\text{23}\); and (d) the proposal of implementation of the ISO/IEEE11073 standard in ECG devices for heart failure patients' follow-up\(^\text{4,25}\).

REFERENCES

6. HealthVault (Microsoft Health Solutions Group). Regional repository for PHD with over 60 certified medical devices [available in the US and Canada (via Telus Health Space) and soon in the UK and Germany (via Siemens)]. Available at www.healthvault.com/personal/index.aspx (last accessed July 2010).
9. Warren S, et al. Lessons learned from applying interoperability and information exchange standards to a wearable point-of-care...


31. HL7–PHM Reports. Available at www.hl7.org/Special/committees/healthcaredevices/index.cfm (last accessed July 2010).


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