2009 Fourth International Multi-Conference on Computing in the Global Information Technology

Recent Innovative Advances in Biomedical Engineering: Standard-based Design for Ubiquitous p-Health

J.Escayola, I.Martínez, J.Trigo, J.García
Aragon Institute for Engineering Research (I3A/GTC)
University of Zaragoza (UZ)
c/ María de Luna, 3, 50018 Zaragoza, Spain
{jescayola, imr, jtrigo, jogarmo}@unizar.es

M.Martínez-Espronceda, S.Led, L.Serrano
Electrical Electronics Engineering Dept.
Public Univ. Navarra (UPNA)
Campus de Arrosadía s/n. 31006 Pamplona, Spain
{miguel.martinezdeespronceda,santiago.led,lserrano}@unavarra.es

Abstract— **Continuous technological innovations are bringing new opportunities to healthcare applications. Although these improvements apply to most of its different fields, outstanding results are being achieved in medical devices interoperability, oriented to ubiquitous solutions including wearable devices, focused to the new paradigm of Personal Health (p-Health). These evolutions can improve the quality of the patient's care, increase the user's interaction and, furthermore, lead to new medical use cases based on Ambient Assisted Living, home monitoring of elderly, heart failure, chronic, under palliative care or patients who have undergone surgery, urgencies and emergencies, or even fitness auto-control and health follow-up. Furthermore, in order to assure p-Health applications to be fully compatible with larger global e-Health systems in terms of terminology homogenization or plug-and-play operation, proposed solutions have to be based on interoperability. In this paper, recent innovative advances in biomedical engineering applied to standard-based telemedicine solutions are detailed.**

Keywords—healthcare applications, interoperability, medical devices, standardization, telemedicine solutions.

I. INTRODUCTION

Through the last decade, a great progress has been achieved on healthcare applications, due mainly to the advances in the Information and Communication Technologies (ICTs) resources. The application environment has been extended from hospital-located healthcare services to the patient/user's context. This new approach brings recently elaborated concepts like Personal Area Network (PAN) and Body Area Network (BAN) [1]. Moreover, the user's ability to get around while being followed-up will bring the Ubiquitous Health (u-Health) into scene. All of these scenarios rely on specific Medical Devices (MDs) based on sensors to acquire the user's biosignals (electrocardiographic (ECG) signal, pulse, weight, blood pressure, etc.). Thus, they can be evaluated later either by the same user or the professional healthcare service providers. Personal Health Devices (PHD) attempt to allow the user to manage the measurement process at any point when possible making use of wireless technologies and portable computing devices in order to report signal and events to remote supervision.

Such a freedom in elaborating high quality sensors combined with user's centered features raises the number of MDs introduced by each manufacturer in the market. The interoperability problem emerges because a healthcare application must be applied to every use case based only on the type of measured data along with its proprietary format adopted by every MD. It forces the system designer to use a unique set of devices. Thus, it leaves out others MDs with similar or probably better specifications and misses updates or changes because of system failures. This is the main aim because a standardization effort is necessary [2].

In this context, different institutions, organizations and research groups have been working several years ago. The European Committee for Standardization (CEN, with its Technical Committee CEN/TC251) is the main European organization in this field, within Spanish Standardization Association (AENOR/CTN139 where our research group works), as national CEN mirror [3]. From this joint work, is necessary an analysis of the recent advances in biomedical engineering applied to the standard-based design. The emphasized key points within the proposal of implementation guidelines are the point-of-start for further developments. Following this survey, several contributions [4]-[6] have been developed in Europe and EE.UU. for studying the viability of standard-based implementations.

This paper presents an extended review of the most recent innovative advances in biomedical engineering applied to the standard-based design for ubiquitous and personal healthcare environments. In Section II the lack of interoperability and the need of standard integration are achieved to new PHDs. Section III details the technical characteristics of ISO/IEEE11073, as standard solution for MDs interoperability. The required specifications as implementation guidelines for standard-based designs are described in Section IV. In Section V, a complete analysis of new uses cases and application environments focused on p-Health solutions is presented. Finally, the future trends and open points related to standard harmonization and implementation into microcontroller-based devices are discussed in Section VI.

978-0-7695-3751-1/09 $26.00 © 2009 IEEE
DOI 10.1109/ICCGI.2009.24

IEEE computer society

II. STANDARD INTEGRATION AND ADVANCES IN MEDICAL DEVICES INTEROPERBILITY

There are several norms and standards for medical information interoperability that are being developed: DICOM [7] for medical images, SCP-ECG [8] for ECG signals intercommunication, HL7 [9] for medical messages exchange, EN13606 [10] for interoperable Electronic Healthcare Record (EHR) exchange, and ISO/IEEE11073 [11] for MD interoperability. The integration in the use of so much standards and their huge scale implantation is complex [6]. Thus, the role of integration associations is even more important than standardization organizations. In this integration effort two initiatives stand out: Integrating the Healthcare Enterprise (IHE) [12] that it is an organization composed by manufacturers all around the world and with the main objective to adopt the most suitable available standards for each specific telemedicine service, and Continua Health Alliance [13] that is an open nonprofit alliance of 22 industry-leading technology and health companies to establish an ecosystem of interoperable personal health systems that empower people and organizations to better manage their health and wellness. From this aim to develop end-to-end solutions based on the patient's network, all the middle stages among MDs communication, EHR integration, and related protocols, should be mutually adapted so there are no further exchange problems among them.

In this direction, several protocols have been proposed to solve the aforementioned interoperability gap in MDs. Nevertheless the standard that reached the highest development level as well as consensus and acknowledgment has been ISO/IEEE11073 (X73) [11]. Their previous versions were originally focused on covering MD interoperable communication at the Point of Care (X73PoC) of the patient. With the emerging of new transmission technologies (like USB, Bluetooth, WiFi, or ZigBee) and wearable devices with limited capabilities, it was seen as a complex protocol that needed a revision leading to a more lightweight version. This evolution raised the creation of the most recent version for Personal Health Devices (X73PHD) oriented to p-Health.

From this evolution, all the X73PHD development has been carried out by the PHD Working Group (PHDWG), within a group of numerous companies and institutions that have collaborated in the development process, bringing different perspectives to the PHDWG. Recently, its work has been adopted by Continua Health Alliance as standard *de factum* for MDs interoperability, and an objective of the alliance is to establish a certification program with a consumer recognizable logo for the devices. With this certification, a device can be used in any X73-compliant healthcare applications regardless the rest of the systems, as long as they all implement X73PHD. So far, a pulse-oximeter with X73PHD over Bluetooth as transmission protocol has been yet developed [14] and successive X73PHD devices are expected to be developed soon.

At this moment, a release of X73PHD exists along with the associated MD specifications (indexed in X73PHD as 11073-104XX): pulse-oximeter (-10404), heart rate monitor (-10406), blood pressure monitor (-10407), thermometer (-10408), weighing scale (-10415), glucose meter (-10417), cardiovascular fitness and activity monitor (-10441), strength fitness equipment (-10442), independent living activity hub (-10471) and medication monitor (-10472). Meanwhile, new ones are currently under development (Figure 1 shows the PHDWG voting results for most desirable MDs): breathing rate, spirometer, basic ECG (3-leads), peak flow meter, INR-blood coagulation, physical activities of daily living monitor, CO_2 meter, insulin pump, fetal monitor, body composition analyzer, or simple EEG (1-lead), among others .

The standard follows constantly under development and new features are expected to be added to future versions, like more transmission efficiency to arise MD operational limitations, remote control for externally configuration or changing possibility of MD operational parameters on demand, multi-patient enhanced compatibility, etc. Furthermore, in our current work, we are working towards two of the priority tasks: making X73PHD interoperable with other protocols (like SCP-ECG or HL7, as previously mentioned), and solving the end-to-end implementation [5] since the medical data has been acquired from MDs (automatically or with minimal user's interaction), managed by a Compute Engine (CE) through X73PHD, externally transmitted through a new protocol for End-to-End Standard Harmonization (E2E-SHP), and stored into a EHR server for their standard exchange through EN13606 (see Figure 2).

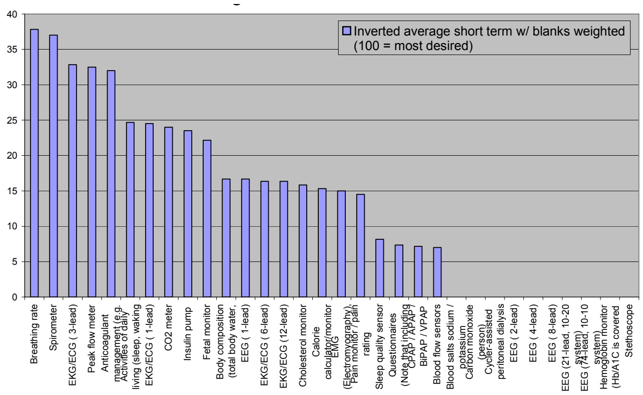


Figure 1. New MDs approved by PHDWG for inclusion in X73PHD (*extracted from PHDWG*)

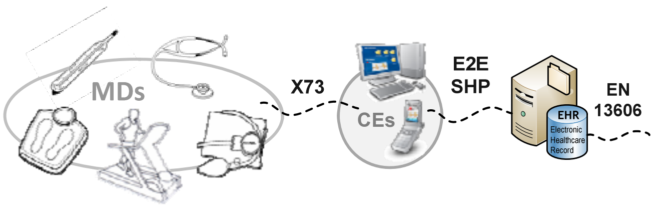


Figure 2. Guidelines for standard-based end-to-end implementations

III. BRIEF TECHNICAL REVIEW OF ISO/IEEE11073 AS STANDARD SOLUTION FOR MDS INTEROPERABILITY

The detailed description of the X73PHD standard can be found in [11]. Thus, in this section a basic description of its structure and the most interesting issues that make possible the communication between *agents*/MDs and *managers*/CEs is presented. X73PHD has thoroughly simplified the architecture of the protocol into three models (see Figure 3):

- Domain Information Model (DIM) typifies the information inside the agent as a set of objects. Each object has one or more attributes which describe measurement data that are sent to the manager and elements that control the behavior of the agent.
- Service Model provides methods to access data that are sent between both systems (agent and manager) to establish the interchange of DIM's data.
- Communication Model describes the network architecture in which one or more agents communicate with a single manager via point-to-point connections. For each link, the Finite State Machine (FSM) controls the system behavior.

X73PHD evolves from X73PoC with a new protocol stack that is divided into three levels (see Figure 4):

- Device Specializations. A set of model descriptions which collects the total of objects and attributes related to the device components, like an overall system's configuration (Medical Device System, MDS), Persistent Metric (PM-Store and Segments) or Metric Specifications. New agents are continuously being added, by developing their MDSs.
- Optimized Exchange Protocol. The main part of the standard consists of a medical and technical terminology framework (DIM) which will be encapsulated inside the Protocol Data Unit (PDU). A Service Model defines a set of messages and instructions to retrieve data from the agents based on the DIM.
- Transport Layer. Data transmission will be held over a transport technology due to X73PHD identifies assumptions that require direct support by this layer, allowing various transports to be implemented (X73PoC established higher dependency between transport and upper and lower layers). Thus, transport specifications are out of the scope of X73PHD, while other Special Interest Groups (SIG) are working towards profiles definition for Bluetooth, USB, ZigBee, etc.

Finally, the main characteristics that X73PHD enhances the previous X73PoC are the following:

- Since the manager knows the standard specifications, the agent does not have to send its configuration unless it uses a different one. In that case, the manager will ask for that configuration in order to be able to work with that agent and to store this configuration for following reconnections. This avoids the configuration procedure which can be a high time-consuming task in the case of multi-specialized MDs (such as multi-parametric monitor with blood pressure, pulsioximeter and glucometer).
- It defines different transport profiles, taking into account conditions of communication channel (application level).
- It is independent of the transport layer. This significantly reduces the implementation problems. The protocol assumes functionalities that the selected technology should fulfill. If that would not be possible, it admits the definition of functionalities through a shim layer.
- It reduces the complexity of the objects tree of the DIM, removing redundant classes and adding new ones such as PM that allows storing measurements that can be sent when the manager requires them.
- A much more complete FSM is thoroughly described and tested to prevent any potential error during the operation of the protocol. The design of X73PHD FSM is more versatile than that used in X73PoC since it has added new functionalities such as to have the agent configuration at manager's disposal.

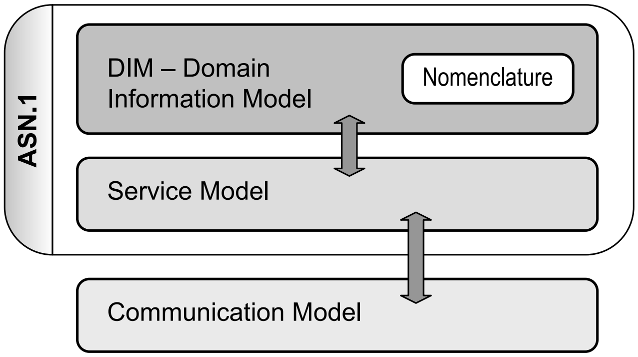


Figure 3. Three levels-distributed X73PHD architecture

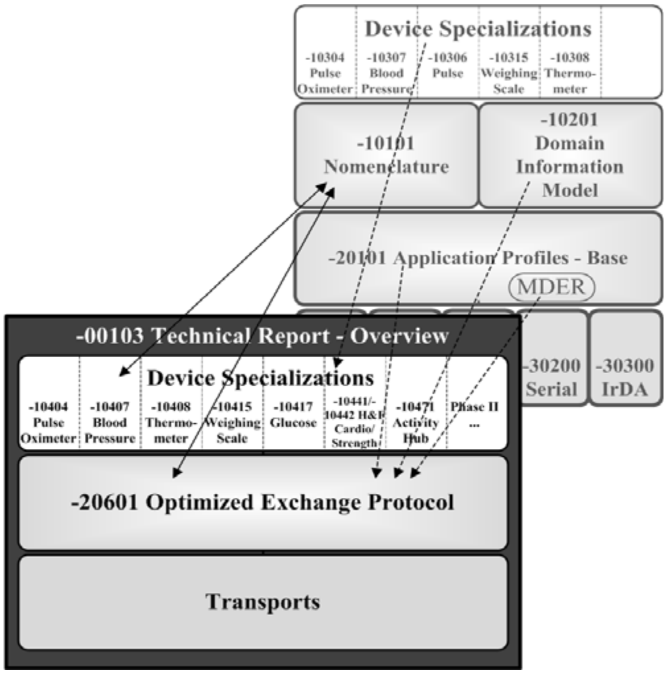


Figure 4. Evolution of protocol stack from X73PoC to X73PHD (*extracted from PHDWG*)

IV. Key points in the standard-based designs. ISO/IEEE11073-compliant implementation guidelines

In order to success when developing standard-based p-Health solutions, in this case applying X73PHD over a system defined by several MDs and a CE, the following key points should be followed:

- Allow the system to incorporate much more devices than previous designs and integrate with new MDs, by making use of several transport technologies. At this point, X73PHD defines a set of quality parameters and protocol payload that must be met, regardless of the type of transport technology both wired (USB and Ethernet) and wireless (Bluetooth and ZigBee).
- While working on mobile environments, CE will be running on a mobile platform (Smartphone, PDA). All kind of hardware/software solutions should be evaluated prior to any development. Some of the facts to consider are: battery autonomy, complexity of usage, stability, user's interface design, as well as programming issues, etc.
- The protocol's traffic efficiency should be analyzed so that new optimizations can be added to the protocol. For instance, although a specific MD Encoding Rule (MDER) was designed for X73PoC, X73PHD and the new specifications could require a revised version of MDER, or the data type defined in ASN.1.
- A *Test Mode* Graphical User Interface (GUI) should be implemented in both MD and CE to evaluate the protocol layers independently. As X73PHD is a new standard and drafts have been available for a short time, new devices could still have protocol frame errors that would lead the system to a critical failure. Also, it can be used as a verifying tool for new implementations with X73PHD.
- As noted before, PHD devices usually have limited hardware/software specifications and resources. It is necessary then to optimize as much as possible the code, having microcontroller platforms as a reference. This requirement being satisfied, upgrading to a higher platform with more resources should be feasible.
- Transport technology has to be selected considering different issues. The type of signal should make some technologies more favorable against others, as data size, frequency, robustness against transmission errors, delivery priority, to name a few, may differ. At the same time, wireless transmission cannot be used, for instance in hospital environments without a proper EM-isolation, and wired technologies will significantly reduce the mobility of the equipment and patients/users.
- At a protocol software development stage, X73PHD has gathered a clear description through several revisions and the collaborative work from the members of the team. Designing the protocol behavior, although complex in certain aspects can be achieved with standard programming skills. On the other hand, Continua Alliance has designed a C++ library stable enough to be applied and reduce developing time.

V. New uses cases and application environments for standard-based p-Health solutions

When developing the standard features and specifications, it has been necessary to define a set of closed conditions of use of the protocol. These are called Use Cases (UCs), and pretend to collect both standard's potential application and end-user's requirements. In general, the system adopts a star topology in which CE is located in the center and MDs are distributed composing the user's BAN or PAN.

The "classic" UCs (X73PoC-based) have been initially focused on Intensive Care Units (ICU) applications or bedside, mainly concerned about monitoring, pre- and post-surgery and bedside disease management. In short, MDs used are most of them fixed, wall powered, not designed to be wearable or at least portable.

Advances in both biomedical engineering and telemedicine potential users like fitness and personal care forced the need of a new standard, as mentioned earlier, and therefore new UCs were developed. When the initial set of devices intended to work with X73PHD was to be made, a survey was used to obtain data from the companies. In this survey, it was pointed out, for each device, the need to apply X73PHD to its communications. Final classification was made based on the interest of experts in developing the standard or providing help for that during the process and the availability of a working group. Thus, the most relevant UCs for p-Health are: healthy living / wellness & fitness, imminent disease management, assisted ambient living, elderly patient care, diabetes and home monitoring of single cardiac patient. Furthermore, these UCs have been arranged in three groups, as it is shown in Figure 5, which also includes the associated MDs to be standardized to X73PHD.

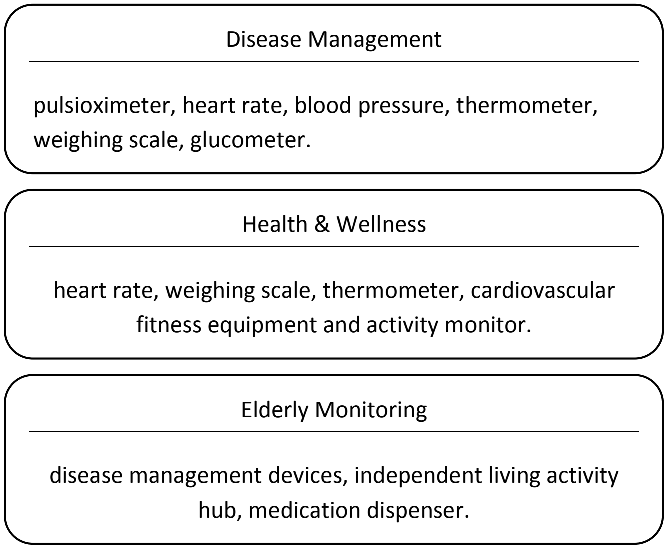

Disease Management
pulsioximeter, heart rate, blood pressure, thermometer, weighing scale, glucometer.
Health & Wellness
heart rate, weighing scale, thermometer, cardiovascular fitness equipment and activity monitor.
Elderly Monitoring
disease management devices, independent living activity hub, medication dispenser.

Figure 5. Use cases classification for standardization to X73PHD

After a considerable period of time understanding and developing solutions based on the standard (first making use of the classic X73PoC and later with the new X73PHD), we raised the possibility of applying the standard to new MDs and UCs, as it is detailed in this section.

While new MDs could be brought into the standard's scene, and even X73PHD could be merged (or at least be adapted to) with other standards, the personal feature of these MDs will probably require additional modifications within the agent itself. A PHD could be used by a patient not only at home but at an ICU from a Health Centre, as previously mentioned, where an unknown CE is installed. In this case, patient's biosignals repository location and user's credentials could be allocated inside the device.

Following this idea, as the e-Health application is desired to be focused in a p-Health environment, UC focused on patient monitoring was considered. While home or even mobile monitoring have been widely analyzed, the process of hospital admission is a challenge for p-Health with the new available technologies, portable and integrated devices. Moreover, is a representative implementation example due to the fact that it is mandatory in the healthcare protocols.

Other implementation example is oriented to Blood Donor Centre where can be found out that blood collection monitors are being used, and they are provided with a Bluetooth module that reports the donation's log after the operation has finished. Such MD is meant to be used only at very specialized applications, far from personal use. Nevertheless, we foresee a p-Health system with different application being merged in a unique platform, for which purpose normalizing the communication protocols will ease and simplify the configuration/operation of these systems. At the same time, human error while manipulating devices or annotating the results gathered can be greatly lowered.

Finally, because one of the main advantages of X73PHD is its object oriented data information model. As X73PHD combines basic classes defined and extending/adding attributes when needed, new MDs can be brought into the protocol's specialization list. With this in mind, our group developed a wearable INteligent HOLTer (HOLTIN) device to be used as a proof of concept of the new 1-3 ECG lead specialization. By that time, no ECG drafting was yet initiated, but after several surveys run by the X73PDHWG, it was a matter of time when a model for ECG related devices would be created. Therefore, our ECG was provided with an additional feature, in parallel with another project under development: SCP-ECG. The ECG model for X73PHD is completed with new attributes, so the data gathered from the device can be converted into a SCP-ECG version at the CE side.

Within our work, the healthcare environments and UCs that have been evaluated for a X73PHD potential implementation are following described.

A. *Intensive Care Units*

UCI represents the clear example of local patient monitoring with a later data report to a central computer. For each patient, full monitoring equipment is set, and the data coming from all the patients are observed from the central computer. Within every patient's box, several MDs can be found, like multi-parameter monitor, infusion pump, ECG, pulse-oximeter, heart rate monitor and capnography among others. Alert and signal management for every box is carried out by using dedicated monitors. In fact, MDs' output has to be converted into the proprietary *Flexport* protocol (see Figure 6) and sent to the central system, which collects all the signals and alerts and show the overall status. Because of this transformation step, not all devices can be used in the ICU monitoring system, even when they meet the ICU requirements. If data needs to be retrieved from the patients EHR, HL7 is the protocol used for this purpose.

A system's improvement is designed together with incorporating X73 to the communications. As noted before, MDs are chosen according to the overall monitoring application compatibility. The optimal solution should be allowed to incorporate any kind of MD, independently of any compatibility restriction. With this degree of freedom, in a device failure situation, it could be replaced with another device that, even it has more complexity or rest of specifications are unnecessary, it will meet the minimum requirements for monitoring. At the same time, parameter reporting could be achieved wirelessly (under certain security restrictions) and system status can be received not only on the supervision system but also on PHDs (see Figure 7). With this solution, ICU personnel can attend other issues while receiving updates real-time.

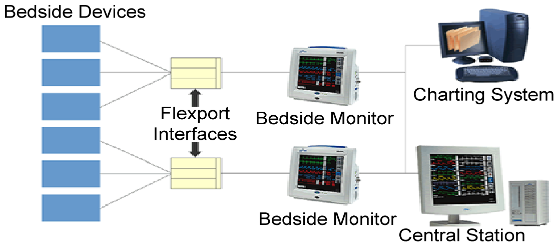


Figure 6. ICU local monitoring through *Flexport* protocol

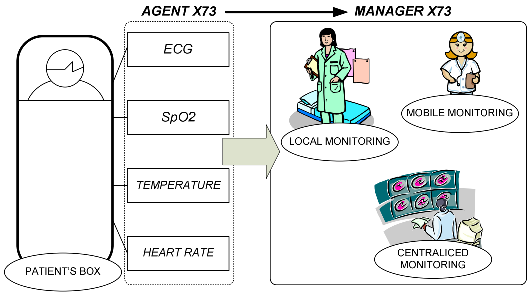


Figure 7. ICU distributed monitoring through X73PHD standard

B. *Hospital Admission*

Within the same hospital, another potential application for X73 was found at the hospital admission process. Patient's biosignals are retrieved so an initial status is stored, along with the patient identification number (related to the EHR).Temperature, SpO_2, blood pressure and heart rate are measured, using a single multi-parameter monitor (see Figure 8). Once the values are stabilized, they are transferred to the patient's EHR. The hospital is using a device that even it allows to send the signal to the computer, due to protocol incompatibilities is not used. Simply, the nurse checks the data and incorporates it manually into the patient's form. At present, a solution is being developed that allows automating the process by adding an adaptation software layer at the computer. Although this is one feasible solution, inside the computer already coexists different application with different data format. Even if compatibility issues are solved, replacing MD for another (in case of malfunction, for instance) will make the system useless.

Adding X73 to the process has many advantages against the previous solution. Firstly, the X73 protocol library is designed to provide universal communications, does not need to be revised for every MD. Secondly, even if the admission application that runs in the computer requires some data conversion or needs to access the MD in a specific manner (sockets, COM port, etc.), the X73 library can provide all of them, as it is being designed to support several transport technologies. Finally, it allows the possibility of adding wireless transport to the process (see Figure 9).

Figure 8. Multi-parameter monitor for hospital admission

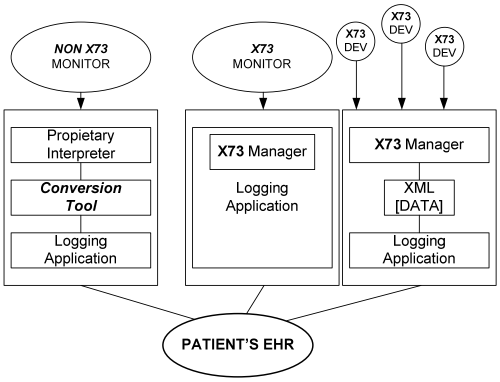


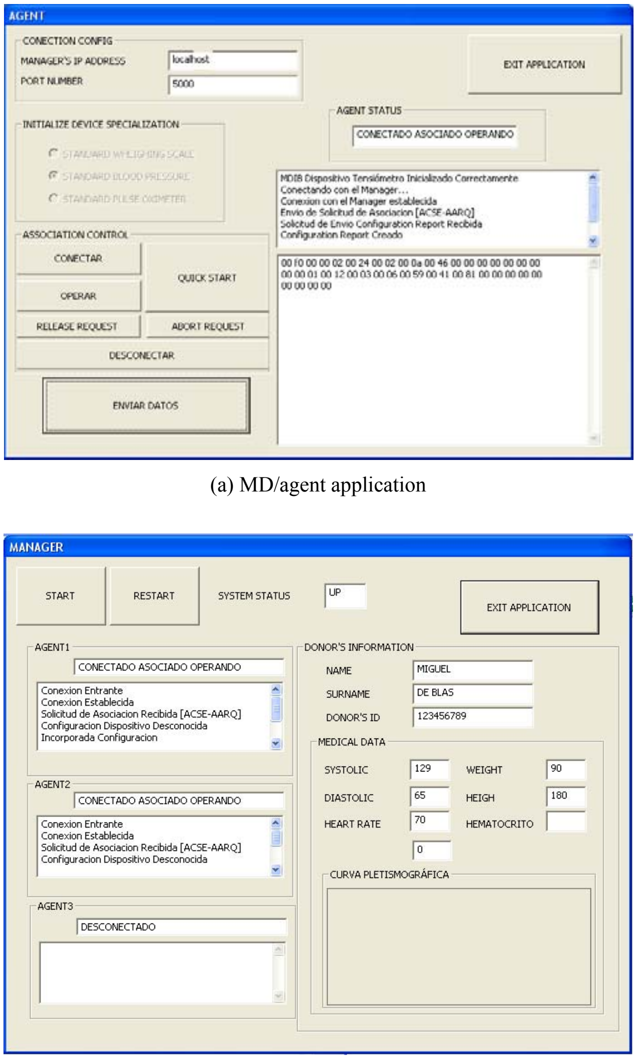
Figure 9. X73 design of a multi-parameter monitor

C. *Blood Donor Centre*

At first, donors have to be checked prior to the donation process. This includes incorporating the personal information, besides the blood pressure and heart rate, hemoglobin level, weight and height (the last two are usually provided by the donor itself). At present, all the values are manually introduced into the donor's form, although the devices used for the measurement process allow a signal transmission. Once the check has been completed, the donor will access to the next room in where the blood extraction will begin. The used blood collection monitors are *Biomixer-330* with a Bluetooth module that reports the donation log (blood flow, time duration) once is finished. Such information will be attached to the donor's EHR. In this case, the overall logging process is based on proprietary measuring devices, software and hardware (Bluetooth dongle for the PC). Although the application is highly convenient, it only works if the devices are from the same manufacturer. If for any reason, some of the devices stop working and there is no possibility to have them repaired or obtain new ones, the trolleys attached to these devices will not be used, or the whole system needs to be changed to another provider. This shows the need for incorporating standardized devices. With this achieved, even new features can be added to the system, like donor monitoring, wireless monitoring converting the medical device into a more complete acquisition device.

As a proof-of-concept, we developed a X73PHD-demo testbed (see Figure 10) that simulates the checking process for the intercommunication between a CE/manager and the corresponding MDs (weighting scale, blood pressure device, and pulse-oximeter) in order to obtain required vital signs for blood donor centre: blood pressure and heart rate, hemoglobin level, weight and height. The solution graph that implements the X73PHD communication module is shown in Figure 11. It includes the X73PHD FSM, data type definition (coded in ASN.1 and C++ classes), MDER-coded frame management, and all the protocol features and layer's function description (coded in C++). The use of frame templates generated previously (knowing the position of bytes in the transferred message) reduces frame creation process, and its X73PHD-compliant design of the transport module, allows incorporating TCP/IP connections (for Ethernet, USB, etc.) and new technologies as Bluetooth.

Finally, a GUI has been designed, taking advance of the Microsoft Foundation Class (MFC) libraries. Several MDs (as long as the specification is included into the libraries) can be selected on the agent application for protocol and application testing, see Figure 10(a). And on the manager application, see Figure 10(b), a CE can be initialized to receive agent connections and process the data exchange. Both GUIs offer the necessary controls and message window to run depuration test, visualize the transmission/ reception buffers, byte coding as well as force the system to run into different states (*abort, data request*, etc).



MANAGER'S IP ADDRESS: localhost
PORT NUMBER: 5000
AGENT STATUS: CONECTADO ASOCIADO OPERANDO

```
MDIB Dispositivo Tensiómetro Inicializado Correctamente
Conectando con el Manager…
Conexion con el Manager establecida
Envio de Solicitud de Asociacion [ACSE-AARQ]
Solicitud de Envio Configuration Report Recibida
Configuration Report Creado
```

```
00 f0 00 00 02 00 24 00 02 00 0a 00 46 00 00 00 00 00 00 00
00 00 01 00 12 00 03 00 06 00 59 00 41 00 81 00 00 00 00 00
00 00 00 00
```

(a) MD/agent application

SYSTEM STATUS: UP

AGENT1: CONECTADO ASOCIADO OPERANDO

```
Conexion Entrante
Conexion Establecida
Solicitud de Asociacion Recibida [ACSE-AARQ]
Configuracion Dispositivo Desconocida
Incorporada Configuracion
```

AGENT2: CONECTADO ASOCIADO OPERANDO

```
Conexion Entrante
Conexion Establecida
Solicitud de Asociacion Recibida [ACSE-AARQ]
Configuracion Dispositivo Desconocida
```

AGENT3: DESCONECTADO

DONOR'S INFORMATION
NAME: MIGUEL
SURNAME: DE BLAS
DONOR'S ID: 123456789

MEDICAL DATA

SYSTOLIC	129	WEIGHT	90
DIASTOLIC	65	HEIGH	180
HEART RATE	70	HEMATOCRITO	
	0		

(b) CE/manager application

Figure 10. X73PHD-demo testbed for Blood Donor Centre

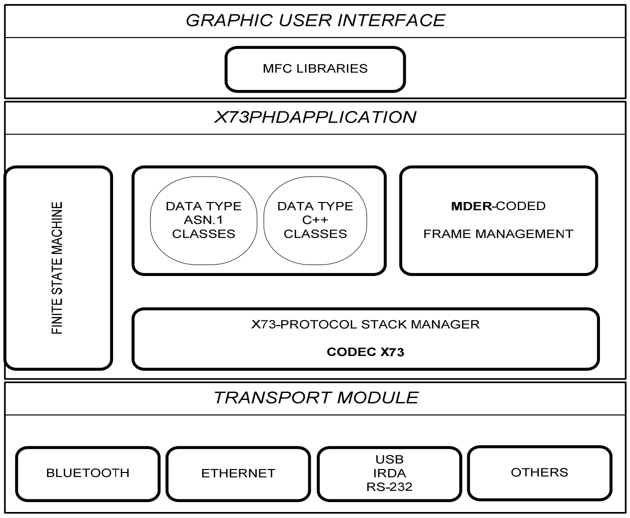


Figure 11. Design scheme for X73PHD communication module

D. *Assisted Living. Heart failure patients' follow-up*

Nowadays, Ambient Assisted Living (AAL) related processes are of special interest. However, it is noticeable that a great number of hospitals and healthcare centers do not provide services for patient's monitoring at home, or at least to allow the patient to check their status (like blood pressure, SpO_2, etc.) and report them to hospital. Generally, as it has been found in many other hospitals, there exists a health self-control program in which the user measures several vital signs following a protocol provided by the specialist and then sends the values using the computer, mobile, or just by phone.

In this context, our group has developed X73-compliant solutions for heart failure patient's follow up called INteligent HOLTer (HOLTIN). This system is a suitable platform in order to implement a X73PHD-compliant heart failure patient's follow up solution, based on wearable MDs with ultra low power consumption. The system provides specialists with a wireless monitoring service to control ECG signal during long periods (several days or even weeks) in patients that suffer non-risk cardiac pathologies whose symptoms are syncopes and paroxistic arrhythmias.

Some features of the HOLTIN system are: non invasive, low cost, reduced complexity and high autonomy. HOLTIN system is made up of several devices in a BAN/PAN topology that use wireless communication technologies as Bluetooth, General Packet Radio Services (GPRS), and Universal Mobile Telecommunications System (UMTS) to perform the transmission of ECG information from the patient to the remote hospital (see Figure 12).

From the X73PHD standard's point of view, the basic devices in the HOLTIN topology are the following:

- Front-end device: This wearable device that corresponds to the agent in the X73 topology was designed having ergonomics in mind (reduced weight and dimensions, ultra low-power consumption, etc.). It is placed at the patient's chest and carries out all the functionality related to the acquisition, processing of the ECG, detection, storage and transmission of cardiac events to the manager device via Bluetooth.
- Smartphone: This device that has the role of the manager takes care of receiving the information from the Front-end and performing the storage in order to transmit later to the hospital with GPRS/UMTS technology.
- Call center: Located at the hospital it manages all data coming from the patients and service related information. It includes a monitoring server, the diagnostic applications used by cardiologists, and other service management tools.

Using HOLTIN in a patient requires a previous step of configuration. With this configuration process, that consist of filling some patient related information forms plus the adjustment of some parameters, the specialist or medical staff performs all the tasks required for the correct monitoring of the patient's health state in the system:

storage of personal details, assignment to the patient of front-end and Smartphone devices, configuration of operation parameters (limits of cardiac events detection, event storage time, etc.), among others. Once the configuration process is finished the system is ready to be used by the patient in an autonomous way.

The front-end equipped with a high grade of intelligence performs the detection and storage of cardiac events suffered by the patient in a continuous way. All the information captured by the MD is transmitted to the manager device by means of X73PHD-compliant Bluetooth technology thanks to the specific health applications Bluetooth profile called Health Device Profile (HDP). This way, HOLTIN system combines features derived from the use of Bluetooth wireless technology with characteristics as interoperability and plug-and-play. A fully X73PHD-compliant specialization for 1-3 ECG lead devices is being drafted at the moment of this writing that will be adopted in the near future once completed.

While the use of the HOLTIN service by a patient, the manager device receives not only the information about the patient's health state but several alarms and notifications related to the correct operation of the system. Examples of these alarms are: battery level of the front-end, low quality of the ECG information acquired by the device and even a wrong positioning of the front-end at the patient's chest.

All the cardiac events suffered by the patient are received at the hospital and can be analyzed by the specialist in order to make a diagnostic. This way, the patient only needs to go to the hospital when the specialist has detected some cardiac pathology that requires treatment.

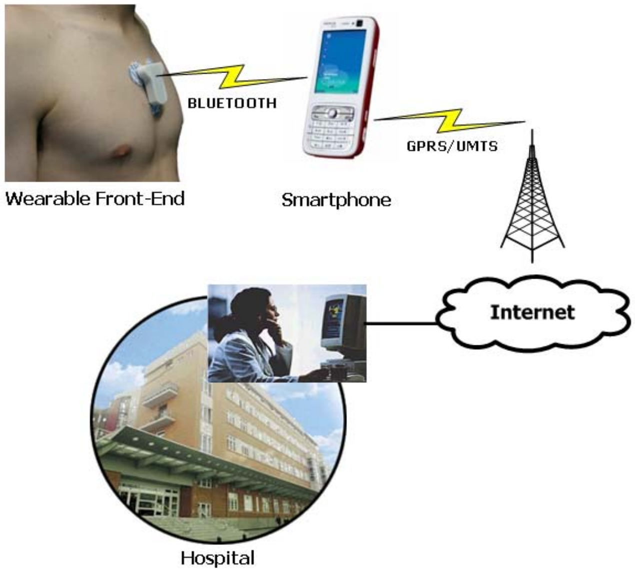


Figure 12. HOLTIN system

VI. Future trends and open points

Due to the protocol evolution and feature expansion towards a more efficient p-Health vital signs communication framework, new functionalities could now be incorporated allowing X73 to be used in a wider range of solutions. Our research group is working in two key points: enhancements and harmonization of real-time signals and implementation into microcontrollers devices.

A. Signal handling: harmonization and enhancements

Although the X73PHD profile was initially designed for simple medical devices, it would be beneficial that the standard could also consider some other biomedical signals more complex such as, for example, the ECG. This need has been already addressed by ISO/IEEE and a device specialization for the ECG has been recently announced for phase II (ISO/IEEE11073-10406 Basic ECG (1-3 Lead)). Some other standards and protocols have been covering ECG signals during the last years. In this plethora of ECG standards, SCP-ECG (European Standard), HL7 aECG (American), or MFER (Japanese) can be found among those more successful. ISO/IEEE has recently included the latest version of SCP-ECG (EN1064:2005+A1:2007) in the X73 family standard (ISO/DIS 11073-91064). However, nothing has been addressed about how to harmonize these two protocols. In order to accomplish this harmonization, there are some key issues that require further attention:

- The terminology harmonization between these two standards (as well as with other standards) is one of the most important items. It has to be investigated the correlation between the different fields defined in both standards and identify which SCP fields are already mapped in X73 and which are not.
- It is necessary to define the forthcoming ECG device specialization in a manner that complies with SCP-ECG. Due to the particular characteristics of ECG devices, the DIM of this specialization might require new classes, different from those that appear in the already defined specializations.

Nevertheless, any modification and/or creation of new fields in the X73 standard must be investigated and proposed so that the SCP standard can be supported within the framework of the X73 family of standards. On the other hand, regarding the SCP-ECG protocol itself, it is expected to extend this standard so that it could cover new aspects. The extension of the standard from diagnostic 12-lead ECG to short-term ECG or its use in telemonitoring services are some examples of possible expansions. But, in this process, the compatibility with the X73 standard has to be taken into account. In environments such as home care telemonitoring, the real-time ECG transmission is expected to be very practical. Still, the use of SCP-ECG in an X73 universe and its ability to the relevant process of ECG management in the context of patient care in and out of the hospital needs further investigation.

B. Implementation into microcontroller-based devices

There is an increasing demand of high grade of ergonomics in wearable devices and specially in the recently appeared wireless scenarios. In order to improve the ergonomics, MD developers shall increase device's autonomy and decrease its weight which usually means that the board must use both batteries as small and soft as possible and low capacity embedded processing systems in order to minimize the power consumption. In this way both MDs at the PoC and PHDs are usually built onto microcontroller-based platforms that determine the requirements of the software running on them. Also there must be selected a transmission technology (wired or wireless) which also determines the framework for the application development, the operating system and the resources left for the X73 module. For example, in the Bluetooth or ZigBee case, the framework is determined by the communications stack that usually provides a proprietary Real Time Operating System (RTOS) and a proprietary Application Programming Interface (API) to access the RTOS functions. Thus, the technical requirements have to be finally translated into software implementations that have in mind to reduce processor and memory as much as possible. As far as software is concerned, this type of devices do not require a high grade of intelligence and sources code are usually written in assembler, C, or embedded C++. Operating System (OS), in case it was used, is platform dependent and its API differs strongly from some devices to others.

In order to simplify the process of development in microcontroller-based platforms some work is being done thanks to the low variability of the X73PHD messages. Our proposal is distributed on the following two steps: firstly, the set of messages that the device needs and the sequence they should follow is determined; and, secondly, an exhaustive analysis of this set of messages (typically a dozen) to obtain patterns on them is done and the resulting ones are grouped as a resource module called the patterns library. The minimal X73PHD intelligence that does the dynamical processing is given by the so called X73 kernel. It is developed using Object Oriented Analysis and Design (OOA/D) principles following a stimulus-response schema and the X73PHD specs.

Once developed, an implementation can be shared and it offers a RAD that will allow a novel X73PHD implementer to develop a MD with only a basic knowledge of X73 since the unique needed modules to be developed are the adaptation layer and the device drivers. In order to maximize interoperability it is preferable to create a framework that shall be used by all manufactures. By the time, although mechanical, an exhaustive analysis of the X73PHD standard is required to generate the patterns library and the X73-kernel. Work to develop an automation tool that provides automatic generation of X73-Kernel and patterns library is being carried out by our group.

VII. Conclusion

The need of interoperability in order to propose compatible and harmonized healthcare solutions requires the use of standard-based design for new ubiquitous and personal health environments. ISO/IEEE11073 is the European way for solving this integration lack and its implementation in new uses cases and application context will allow guaranteeing the implantation of p-Health solutions transferable to the healthcare system.

Acknowledgment

The authors wish to thank PHDWG and Melvin Reynolds, *convenor* of the CEN/TC251 WGIV, for the contributions to this research. We also appreciate the contribution of Miguel Galarraga (UPNA associate professor and researcher) and Adolfo Muñoz (researcher of the *Instituto de Salud Carlos III*, AENOR/CTN139 general manager, and CEN/ TC251 member) to the excellent results carried out during the last years in this work. This research work has been partially supported by projects TIN2008-00933/TSI and TSI2005-07068-C02-01 from *Comisión Interministerial de Ciencia y Tecnología* (CICYT) and European Regional Development Fund (ERDF), TSI-020302-2008-35/*Plan Avanza I+D* from *Ministerio de Industria, Turismo y Comercio*, and FPI grant to M. Martínez-Espronceda (Res. 1342/2006 from Public University of Navarre).

References

[1] Clemmer T. P. Computers in the ICU: Where we started and where we are now. Journal of Critical Care, 2004, vol. 19, pp. 201-207

[2] Pedersen S, Hasselbring W. Interoperability for information systems among the health service providers based on medical standards. *Inform Forsch Entwickl* 18(3-4):174-188, 2004.

[3] Comiteé European Normalisation/TechnComm251 (CEN/TC251). http://www.cen.eu – http://www.centc251.org [In Spain, Asociación Española de Normalización (AENOR/CTN139) http://www.aenor.es/desarrollo/inicio/home/home.asp]. Accessed April 09.

[4] Yao J. and Warren S. Applying ISO/IEEE11073 standards to wearable home health monitoring systems. *Journal of Clinical Monitoring and Computing*, vol.19, pp.427-36, 2005.

[5] I. Martínez, et al. Implementation of an end-to-end standard-based patient monitoring solution. *IET Commun* 2(2):181-191, 2008.

[6] Reynolds M. *et al.* Can telemonitoring systems interoperate? Review of the suitability of existing standards for adaptable telecare provision. Healthcare Comp Conf of British Comp Soc (HC), pp.104-115, 2007.

[7] DICOM. *Digital Imaging and Communications in Medicine*. http://medical.nema.org/. Accessed April 09.

[8] Zywietz C. and Fischer R. Integrated content and format checking for processing of SCP-ECG records. *Comp in Cardiology*. pp. 37-40, 2004.

[9] HL7. Health Level Seven, Devices Special Interest Group (SIG). http://www.hl7.org/Special/committees/healthcaredevices/index.cfm. Accessed April 09.

[10] EN13606 CEN/TC251. Electronic Healthcare Record Communication. Standard Parts 1, 2, 3, 4 and 5 (2006). http://www.medicaltech.org. Accessed April 09.

[11] ISO/IEEE11073 Point-of-Care MD communication standard (X73PoC). Personal Health Devices standard (X73PHD). Health informatics. *IEEE Standards Association.* http://standards.ieee.org/. http://www.ieee1073.org. Accessed April 09.

[12] Integrating the Healthcare Enterprise (IHE). http://www.ihe.net/. Accessed April 09.

[13] Continua Health Alliance. http://www.continuaalliance.org/home/. Accessed April 09.

[14] Vena platform (X73-compliant pulsioximeter). *Cambridge Consultants (Altran Technologies)*. http://www.cambridgeconsultants.com/news_ pr204.html/. Accessed April 09.

2009 Fourth International Multi-Conference on Computing in the Global Information Technology

Implementation Guidelines for an End-to-End Standard-based Platform for Personal Health

I.Martínez, J.Escayola, J.Trigo, P.Muñoz, J.García
Aragon Institute for Engineering Research (I3A/GTC)
University of Zaragoza (UZ)
c/ María de Luna, 3, 50018 Zaragoza, Spain
{imr, jescayola, jtrigo, pmugnoz, jogarmo}@unizar.es

M.Martínez-Espronceda, L.Serrano
Electrical Electronics Engineering Dept.
Public Univ. Navarra (UPNA)
Campus de Arrosadía s/n. 31006 Pamplona, Spain
{miguel.martinezdeespronceda, lserrano}@unavarra.es

***Abstract*—There is a need to develop open sensors and middleware components that allow transparent integration and plug-and-play interoperability of Medical Devices (MDs) and Computer Engines (CEs). The use of standards seems to be the internationally adopted way to solve these problems and allow implementing ubiquitous solutions, including wearable devices, focused on the new paradigm of Personal Health (p-Health). However, to the best of our knowledge, there is no experience where the full chain from personal healthcare environment to Health Centre had been implemented using interoperability standards. Even though there have been some initiatives to combine different standards, the vision of an entire end-to-end standard-based system is not yet a fact end-to-end solution. This paper presents the implementation guidelines of a ubiquitous platform for p-Health. It is end-to-end standards-based, using ISO/IEEE11073 in the patient environment and EN13606 to communicate the information to an Electronic Healthcare Record (EHR) server. The platform has been designed to comply with the last ISO/IEEE11073 and EN13606 available versions and tested in a laboratory environment to demonstrate the feasibility of an end-to-end standard-based solution.**

***Keywords*—EN13606 standard, end-to-end design, implementation guidelines, ISO/IEEE11073 standard, p-Health.**

I. Introduction

The remarkable growth of Information and Communication Technologies (ICTs) during the last decades has fostered the development of innovative healthcare applications. The traditional fixed hospital locations for these telemedicine applications (usually called e-Health) have gradually evolved to new mobile environments (m-Health), user-centered personal applications (p-Health) and finally to ubiquitous healthcare systems (u-Health). All these systems, applications and environments make use of Medical Devices (MDs) to acquire user biomedical signals and measurements that can be sent to HealthCare Information Systems (HCIS) in order to be subsequently analyzed by physicians. To fulfill the needs of the new health environments, Personal Health Devices (PHD) provides users ubiquitous and remote management and supervision by including facilities and new functionalities such as wireless technologies and high portability.

Manufacturers of MDs all around the world have been fighting for a place in the market by creating their own protocols to transmit and manage biomedical signals. This fact causes an obvious lack of interoperability, specially suffered by end-users and healthcare system managers. Several organizations have been promoting standardization to fill this interoperability gap. The main European organization in this field is the Committee European of Normalization (CEN), specifically its Technical Committee CEN/TC251, and its countries mirrors as Spanish Normalization Association (AENOR), with its Technical Committee AEN/CTN139 (to which our research group belongs).

There are also several norms and standards for medical information interoperability that are being developed: DICOM for medical images, SCP-ECG for ECG signals intercommunication, HL7 for medical messages exchange; and ISO/IEEE 11073 [1] for MD interoperability, and CEN/ISO EN13606 [2] for Electronic Healthcare Record (EHR) exchange that are the two protocols called to solve the interoperability leak in the European context. The integration of all this plethora of standards into end-to-end solutions is still an intricate work. In this context, some private initiatives such as Integrating the Healthcare Enterprise (IHE) and Continua Health Alliance have emerged and are willing to collaborate with the aforementioned organizations to encourage standardization [3].

This paper presents the implementation guidelines for an end-to-end standard-based ubiquitous platform oriented to p-Health solutions, developed through the most recent evolutions of ISO/IEEE11073 and EN13606 and proposes a new protocol for End-to-End Standard Harmonization (E2E-SHP). In Section II the whole platform architecture is described by detailing its technical features as evolution of ISO/IEEE11073, integration with EN13606, and inclusion of E2ESHP. In Section III the proposed standard-based design and implementation guidelines are analyzed by distinguishing the specific requirements for both standards. In Section V the results of this new platform oriented to PHD are assessed and discussed for their implementation into MD by using microcontrollers. The strong and the weak points of p-Health solution are discussed as global conclusions in Section VI for its real solution transferable to the health system.

978-0-7695-3751-1/09 $26.00 © 2009 IEEE
DOI 10.1109/ICCGI.2009.26

IEEE computer society

II. Platform Architecture

One of the main challenges in the research lines for standard development and integration is its further real implementation in a telemedicine solution, transferable to the healthcare system. A survey of the standard-based paradigms for interoperability is given in [4], and previous contributions in last years have been developed for studying the viability of their isolated implementation [5]-[10]. ISO/IEEE11073 (X73) has been applied in sanitary environments, by implementing solutions to monitor patients in the Point-of-Care (X73PoC) [5]-[7], and its latest version has evolved to new approaches for Personal Health Devices (X73PHD) [8]-[9]. EN13606 has been implemented in healthcare systems for solving the interoperable exchange of EHRs [10]. Nevertheless, there are not European antecedents or proposals about global end-to-end solutions that integrates X73PHD and EN13606 oriented to p-Health, as it is presented in this paper.

The platform architecture (see Figure 1) is based in a Compute Engine (CE) that collects all the information acquired by different patient's MDs that define the ubiquitous and personal healthcare environment. This CE communicates, through the communication networks, with a Monitoring Server (MS) that manages the different CEs and gathers all the information arriving from each patient monitoring scenario to update the EHR. The characteristics of these different elements that form the system architecture are:

- *MDs*. The original medical data acquisition follows the vendor format (X73-compliant MDs are yet to be released into the market even though they include universal interfaces, USB or Bluetooth, the protocols are proprietary). Thus, this adapter creates the specific MD specification that generates the associate Domain Information Model (DIM) and establishes the Finite State Machine (FSM) to allow MDs acting as agents of X73 communication.
- *CEs*. Compute engine is designed as an X73-manager that recollects medical data from MDs through FSM. The information is stored in an X73-data file that, with the specific configuration profile, is the data input to the frame creation process for end-to-end protocol (E2E-SHP). E2E-SHP is a proposed protocol that allows CE (as client) and MS (as server) to guarantee the harmonized communication: supervision and remote control, platform updating and management, database access and user info monitoring, network status, intelligence of the system, etc.
- *MS*. Monitoring server is composed by two entities. The first one acts as E2ESHP server because it is in charge of receiving data from X73PHD, decoding E2ESHP frames and extracting the appropriate X73PHD data (distinguishing of the associated user' information) in order to store them in the database. The second one acts as EN13606 client/server because it implements a double function: acceptation of EN13606 queries for its further translation to mandatory fields to search them in database, and generation of EN13606 extracts following the archetype.

From this proposed platform architecture, the design guidelines and the implementation process have to guarantee several technical specifications regarding to the specific requirements for both X73PHD and EN13606 standards, as it is detailed in the next section of this paper.

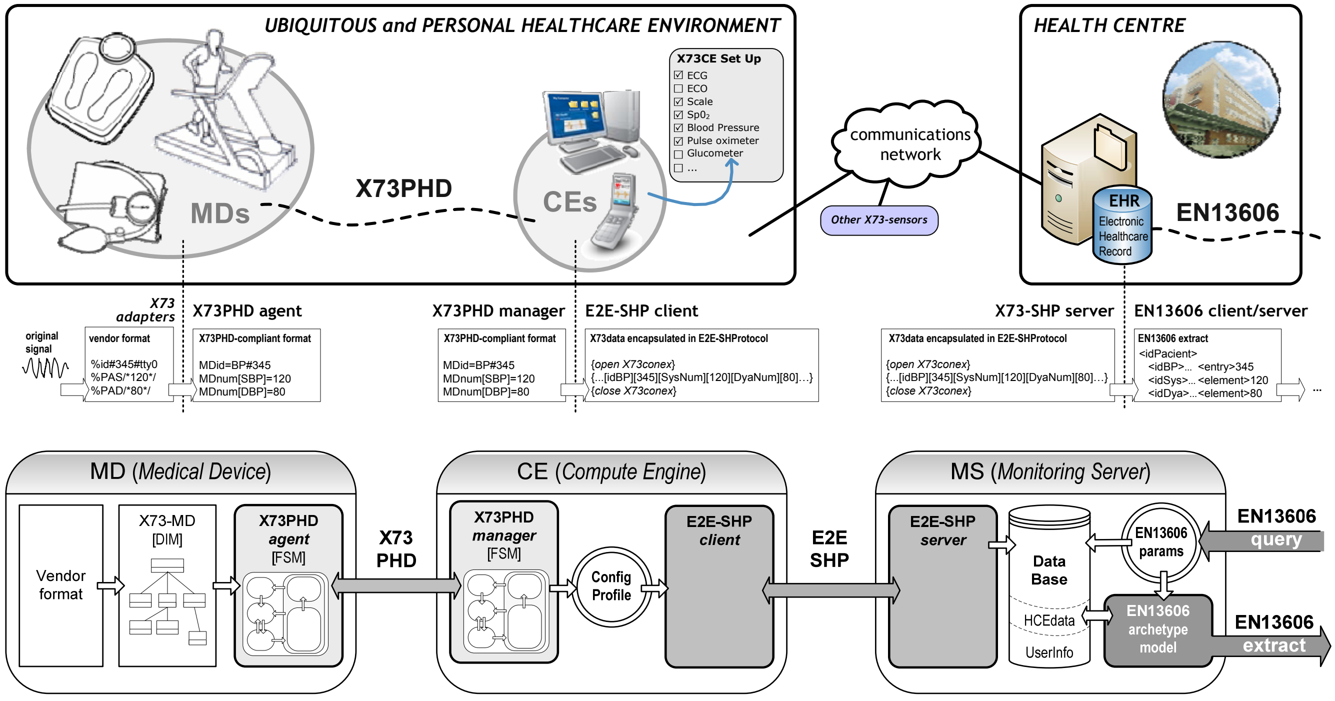


Figure 1. Implementation proposal for end-to-end standard integration in a p-Health platform

III. STANDARD-BASED DESIGN AND REQUERIMENTS ANALYSIS. IMPLEMENTATION GUIDELINES

The implementation process implies the analysis of the specific requirements for both X73PHD and EN13606 standards in order to guarantee their technical specifications.

A. X73PHD requirements

X73PHD-based solutions rely on a communication star network topology defined by several MDs (agents) and a CE (manager). The manager will receive agent's association requests and decide either to accept them (operation stage) or reject them. As different transmission technologies can be used in X73PHD, the following key points should be followed in order to obtain a successful overall application:

- *MD adaptation*. Due to the lack of availability of X73PHD-compliant MDs, even though they include universal interfaces, proprietary MDs without X73PHD output are used including an X73 adapter.
- *MD integration*. The system should be able to incorporate new devices even if they make use of several transport technologies, both wired and wireless. At this point, X73PHD also defines a set of quality parameters and protocol payload that must be met, regardless of the type of transport technology used.
- *CE mobility*. The manager might be running on a mobile platform (Smartphone, PDA) in those cases where patient requires a monitoring while not being at home, like travelling, doing sports, etc. All kind of hardware and software solutions should be evaluated prior to any development. Battery autonomy, complexity of usage, stability, user's interface design, as well as programming issues, etc. are some of the facts to consider.
- *CE optimization*. It is necessary to analyze the protocol traffic efficiency so that new optimizations can be added to the protocol. Although a specific MD Encoding Rule (MDER) was designed for X73PoC, X73PHD and the additional features could require a revised version of MDER and the data type defined in ASN.1.
- *MD-CE communication*. The entire protocol stack should be implemented in both agent and manager to evaluate its layers independently. As X73PHD standard is relatively new and it is in draft status, new devices could still have protocol frame errors that would lead the system to a critical failure. This test-bed environment can be used as a verifying tool for new implementations with X73PHD to check the stability of the protocol, as well as timeouts, etc.

PHD devices are designed to be provided with limited hardware/software specifications and resources. This applies to both agents and managers when used in mobile solutions. Optimizing as much as possible the code is one of the development restrictions, and for that the platform reference is based on a microcontroller. This requirement being satisfied, upgrading to a higher platform with more resources available (interfaces, multimedia, and other services) should be feasible with minor changes.

Data transmission technology has to be selected based on different aspects. The signal's features should make some technologies more favorable against others, as data size, frequency, robustness against transmission errors, delivery priority, to name a few, may differ. On the other hand, wireless transmission might not be used, for instance in hospital environments without a proper EM-isolation, and wired technologies will significantly reduce the mobility of the equipment and patient/users. Nevertheless, some other real implementation issues should be taken into account as well, as some technologies may not have modules that meet the device design.

Same programming language (C++) has been used to develop the new platform like the two previous solutions. The main reasons have been:

- The use of pointers in order to easily manage object tree, efficient memory use and data frames.
- Already acquired programming skills with C/C++ and Integrated Development Environments (IDE) like Visual C++.
- Low level hardware access to control buffers and communication drivers.
- It can be used to develop solutions for embedded systems (embedded C++).
- Easily integrated into Windows application either for PC or Windows Mobile by including the Microsoft Foundation Class (MFC).

Microsoft Visual Studio C++ and Microsoft embedded Visual C++ have been used as Development Environments allowing to target two different platforms while keeping the code (especially the X73PHD communication library) as close as possible between them. While X73PHD library has been entirely programmed by using C++ and standard libraries, the application layer, Graphic User Interface (GUI) and other wrappers needed to access other services have been developed with the MFC libraries. These libraries can encapsulate both the protocol code and the required service functionalities in simpler classes. It also provides useful tools to create easily window-based applications adding a wide range of controls like buttons, information fields, graphics, etc. Despite of obvious graphical differences, interfaces can be created to Desktop environments as well as Mobile with these libraries.

For X73PHD protocol development, the *ISO/IEEE P11073-20601/D20 Draft Standard for Health informatics - Personal health device communication - Application profile - Optimized exchange protocol* has been followed, released on May, 2008. Although some minor changes have been included since then, none of them has been critical enough to consider some parts of the overall system to be short-time modified. In other words, it was stable enough to base a solution development on it.

The implementation process requires a selection of the main protocol features because all its characteristics are not be applied depending on the type of device. Nevertheless, our project attempts to develop, at the same time, a protocol implementation as close as possible to the one described in the draft. The reason of this is because the previous solution adopted a fragment of X73PoC enough for a proof of concept, but not for a multi-purpose application. Thus, in the design proposed in this paper, X73PHD FSM has been completely implemented from the beginning, as well as ASN.1 and MDER encoded data types. Other X73PHD features like *Permanent Metric* and *Enumeration* have been included later as new use cases have been brought into the application scenario.

In order to reduce the system complexity, the protocol stack and data structure models from X73PHD have been modified. While previous platforms incorporated all the layers from OSI model as well as both functions and packets needed to be processed by all of them, this time just the header is processed. Once the header is analyzed a field content chart will be followed to simplify the FSM operation. As the frame structure is known previously, it is possible to access certain information byte locations without need to read the whole packet. A comparison chart between the two approaches is shown in Figure 2.

All the data types are defined in X73PHD using ASN.1. The result is an abstract declaration of the data to be used later in the protocol, that is, name and type. Then, this complex data has to be mapped into a byte-frame in order to be manipulated by a computer and lately sent over a transmission medium. This byte-representation is achieved using MDER, a more efficient version of the classic Basic Encoding Rules (BER). Although BER, along with Packet and XML Encoding Rules (PER and XER), has available C++ compilers for conversion, MDER required some additional modifications and code arrangements to obtain C++ encoding functions. This approach raised the complexity of the previous solution, as well as memory requirements. That is the reason why in this solution direct byte-encoding technique has been used in order to provide transparency to the frame creation process as well as reduce the memory requirements (aiming microcontroller-based hardware). At the same time, special precautions have to be taken while defining the frame creation within the code to avoid critical protocol errors.

Frame processing is done in a similar way like the previous solutions, although in this case it is more atomized due to MDER features. As information fields within a frame are constant in location, like protocol-definition headers, lengths or segment indicators, measure-containing fields are updated with patient signals from the MDs.

From this, a solution design based on frame patterns is developed storing previously designed byte-patterns on memory, and filled up with the necessary parameters prior to be sent. This method will simplify the processing required on, for instance, a microcontroller as there is no need to process a new frame. In case of agents, from the received frame and based on the state-tables some of the reply-frame fields can be automatically completed from a pattern, and add finally the required information.

From previous considerations, it is desirable to perform a study of the real environment in order to develop applications and go into improving its specifications in depth. The main purpose is to discover all the standard potential applications and suggest modifications to those aspects believed to bring a better overall system's performance. A methodology followed in our work is described as follows:

- Find and analyze health services based on telemedicine.
- Enumerate, for each one of them, the MDs from the application and find out if the devices implement automatic signal acquirement.
- Study the medical services in which these devices are being used and, if use cases are defined, classify them.
- Propose, at this point, an X73 based solution. When selecting the kind of MD to be incorporated to the system, the compatibility/interoperability factor should be considered the last while other features like quality, price, versatility and efficiency should be taken into consideration first. Design objectives should be to provide the system with more reliability (reducing human error), allow the user/patient to move or make use of portable devices (ubiquitous) and simplify the set-up/replacement process in case it is necessary.

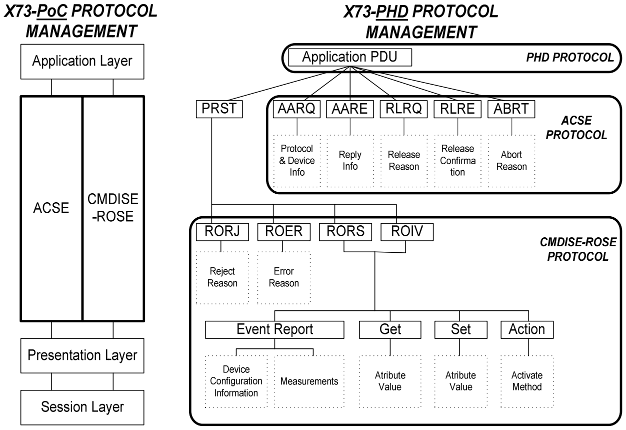


Figure 2. X73PoC and X73PHD protocol stack comparison

Following this methodology, the design of the X73PHD FSM (see Figure 3) is the key issue of any solution based on X73PHD since it defines the behavior procedure. In the design, the following states defined in X73PHD must be taken into account: DISCONNECTED, CONNECTED, UNASSOCIATED, ASSOCIATED, CONFIGURING and OPERATING. The operating procedure would be as follows:

- When both devices are turned on, the local initialization procedure is executed (MDIB and other state parameters).
- From that initialization, a connection is established through the transport layer; if it has been successfully driven, then both devices enter into CONNECTED state (but UNASSOCIATED). In order to get 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 because the manager has the configuration stored from previous operations, they enter into the ASSOCIATED state and they will be ready to operate. If not, then the manager will ask previously for the agent configuration (CONFIGURING) and store it for future connections (this facilitates the plug-and-play functionalities).
- In the OPERATING state, the sending of measurements begins. They can be directly sent by the agent or on demand by the manager. Under this mode, the agent can perform either a single sending or successive, during a period of time which can be limited or not.

At any time both agent and manager can get disassociated because of error situations, end of measurements, or because of other circumstances. To do so, there is a disassociation request [RLRQ], followed by a confirmation on the other side [RLQE], or a direct disassociation [ABRT].

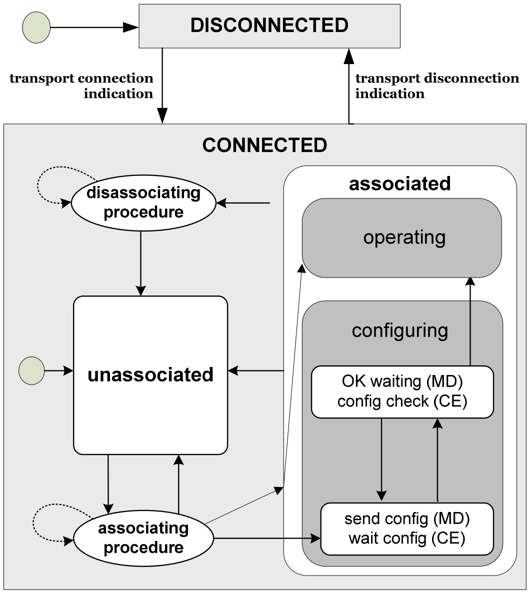


Figure 3. X73PHD Finite State Machine (FSM)

B. EN13606 requirements

EN13606 standard [2] has been developed in order to represent any information included in the EHR, as well as its communication between EHR systems, managing semantic interoperability of the transmitted data. The main objective of that standard is to normalize the way EHR (the whole EHR or part of it) is interchanged to make them interoperable. Thus, EN13606 is not intended to specify the internal architecture of EHR system or the way data are stored or consulted, but the way the clinical information must be transmitted. To do that, EN13606 is based on a dual model: Reference Model, which supports information, and Archetype Model, which define "knowledge" (an archetype is a pattern that represents the specific characteristic of the clinical data). In this way, if the knowledge changes (or we need to represent additional characteristics) only the archetype under data are represented will change: for example, one patient's blood pressure would be expressed as the Reference Model but the fact of blood pressure is composed by systolic pressure and diastolic pressure is represented by the Archetype Model.

The standard is divided into 5 parts: 1-Reference Model, 2-Archetype Specification, 3-Reference Archetypes and Term lists, 4-Security, y 5-Interface Specification. Though EN13606 does not specify how data has to be stored, to transmit an interoperable EHR, we have to be able to represent several kinds of structures (see Figure 4). Briefly, those are the logic blocks the transmitted clinical data would consist of:

- *Extract*: The top-level container of part or all of the EHR of a single patient.
- *Folder*: The high level organization within an EHR (i.e.: episode of care, compartments of care, etc.)
- *Composition*: a single clinical encounter or record documentation session (Reports, test results, etc.)
- *Section*: clinical headings reflecting flow information (i.e.: Subjective symptoms, Findings, Treatment, etc.).
- *Entry*: Clinical Statements.
- *Cluster*: The means to organize nested multi-part data structures (tables, time series, etc.)
- *Element*: A container of a single data value. It is the leaf node of the hierarchy.

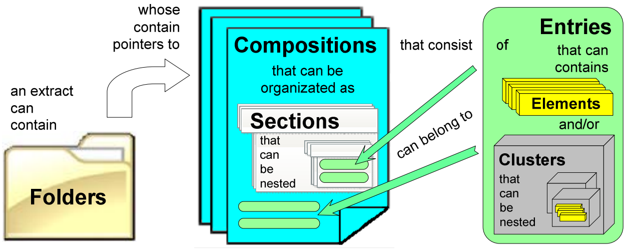


Figure 4. EN13606-compliant EHR extract structure (*published in* [2])

EN13606 standard is not completed yet. In the beginning of 2009, Part 5 had not been ratified and Reference Model has several differences with the previous version (ENV13606) of 2004. These main differences, in order to adapt the concepts that are needed to transmit in an EHR query/extract are:

- Sensitivity is not a mandatory parameter, and now it is represented by an integer. If sensitivity is not transmitted, a default value is supposed to determinate who is allowed to access that information.
- Attribute used to group a set of COMPOSITIONs (*contribution_id*) goes from AUDIT_INFO class to COMPOSITION class, so its meaning is more related to clinical information rather than context information.
- CLINICAL_SESSION class and its attributes are now included by RECORD_COMPONENT and FUNTIONAL_ROLE classes; in this way, COMPOSITION class contains now optional attributes as *session_time* (time interval of the session) and *territory* (country where the extract is created), and FUNTIONAL_ROLE class contains *healthcare_facility* (organization at which the role was performed) and *service_setting* (type of service location at which the role was performed).
- Attribute representing who is legally responsible for the care of the patient at the time COMPOSITION is committed (*hca_legally_responsible_for_care*) disappears.
- Optional attribute *composer* is replaced by a mandatory association with *committal* belonging to AUDIT INFO class. In this way, context information is higher because of it must be said who sends, when was send and from which EHR system. In addition, it can be made difference between who send it and who created it, which can in fact be different people.
- Attribute *version_specific*, which makes reference to the target of a link was a RECORD_ COMPONENT or a version of it, is deleted. Because of every version of a record component have a unique identifier, is logic to make reference to that identifier giving no importance if it is a version or not.

After studying the evolution of these fields in the standard and the inheritance between classes, the main fields to be transmitted with EHR are shown in Table I, as well as the *data types* (in brackets) and their meaning in the standard. Those fields are mandatory in transmission, but if we include additional (optional) ones that are not mandatory but takes singular relevance in telemedicine applications, other relevant information could be expressed like if the extract has been automatically generated by a machine and the doctor who authorized that transmission, if it is attached a view of the screen when the test was made, even the date and the time interval at which the item occurred.

TABLE I
EN13606 REFERENCE MODEL. RELEVANT FIELDS

EHR_ EXTRACT	Header of the container. After that, all compositions are transmitted
ehr_id [*Instance Identifier*]	The unique EHR identity (from which the EHR_EXTRACT was created for that EHR provider system for this subject of care)
ehr_system [*Instance Identifier*]	The identity of the EHR provider system from which the EHR_EXTRACT was created
rm_id [*String*]	The identity and version of the Reference Model standard under which the EHR_EXTRACT was created
subject_of_care [*Instance Identifier*]	Unique identifier of the subject of care
time_created [*Time Point*]	Date/time at which data from this subject of care's EHR was queried/exported to create the EHR_EXTRACT
EXTRACT_ CRITERIA	Optional parameters specified in the EHR Request. They are not mandatory to repeat
all_versions [*Boolean*]	Indicator if it includes all historic versions
archetype_ids [*Set Instance Id*]	Set of Archetypes if they were used as a basis of selecting data to include in the EHR_EXTRACT
max_sensitivity [*Integer*]	Used sensitivity for EHR_EXTRACT generation
multimedia_included [*Boolean*]	If multimedia data have deliberately been excluded from the EHR_EXTRACT
other_constraints [*String*]	additional criteria that were used to generate the EHR_EXTRACT
time_period [*Interval TimePoint*]	Date or time interval to which the EHR_EXTRACT is limited
RECORD_ COMPONENT	Abstract class that introduces those mandatory fields
name [*Text*]	Name of the record
rc_id [*Instance Identifier*]	Unique identifier of the record
synthesised [*Boolean*]	TRUE if this RECORD_COMPONENT was created in order to comply with this standard
COMPOSITION	Inherited attributes of RECORD_COMPONENT and a mandatory association with *commital* (from AUDIT_INFO), which contains those attributes:
committer [*Instance Identifier*]	The party responsible for committing the RECORD_COMPONENT
ehr_system [*Instance Identifier*]	EHR system in which the RECORD_COMPONENT was committed
ehr_id [*Instance Identifier*]	The unique EHR identity (from which the EHR_EXTRACT was created) in which the RECORD_COMPONENT was committed
time_committed [*Time Point*]	Date/time at which the RECORD_COMPONENT was committed within the identified EHR system
ENTRY	Inherited attributes of RECORD_COMPONENT
uncertain_expressed [*Boolean*]	If it contains data that indicates some degree of uncertainty
ITEM	Abstract class (CLUSTER and ELEMENT inherits from it). It introduces *optional* fields:
<*obs_time*>	Date and time (interval) at which the ITEM occurred
<*emphasis*>	A way of denoting that the composer wished to mark this ITEM (*optional*)
CLUSTER	Inherited attributes of RECORD_ COMPONENT, and:
structure_type [*Code SimpValue*]	Time/spatial organization of data within this CLUSTER
ELEMENT	Inherited attributes of RECORD_COMPONENT and ITEM
value [*Data Value*]	DATA_VALUE containing the value, unless this is indicated as absent by a *null_flavour* attribute

Furthermore, an EN13606 implementation would require a MS from which we would be able to generate a valid EHR extract, as shown in Figure 5. As we can see, this example contains additional fields like *meaning* to bind the measurement meaning to a clinical terminology and *archetype_id* to identify the pattern data which is transmitted after. In this example, CEN Data types (TS14796) has been used meanwhile the definition of a new data type, common to ISO, HL7 and CEN, would be carried out.

```
EHR_EXTRACT
ehr_system.extension = HospitalServet
ehr_system.assigningAuthorityName = Salud
ehr_system.valid_time = 1/1/1900 – 1/1/3000
ehr_id.extension = ExtractoHCE.120025022008
ehr_id.assigningAuthorityName = Salud
ehr_id.valid_time = 1/1/1900 – 1/1/3000
subject_of_care.extension = 441003686941
subject_of_care.assigningAuthorityName = Salud
subject_of_care.valid_time = 1/1/1900 – 1/1/3000
time_created.time = 15/02/2009 17:32
rm_id = EN13606-1.0
  COMPOSITION
  rc_id.extension = 0003
  rc_id.assigningAuthorityName = MiguelServet-Salud
  rc_id.valid_time = 1/1/1900 – 1/1/3000
  name = Listado de datos de telemedicina
  sensitivity = 3
  committal.ehr_system.extension = HospitalServet
  committal.ehr_system.assigningAuthorityName = Salud
  committal.ehr_system.valid_time = 1/1/1900 – 1/1/3000
  committal.committer.extension = Dr. Perez
  committal.committer.assigningAuthorityName = Salud
  committal.committer.valid_time = 1/1/1900 – 1/1/3000
  committal.time_commited = 10/01/2009 17:32
    ENTRY
    rc_id.extension = 0004
    rc_id.assigningAuthorityName = MiguelServet-Salud
    rc_id.valid_time = 1/1/1900 – 1/1/3000
    archetype_id.extension = CENArch.Entry.TMWeightMeasure.v1
    archetype_id.assigningAuthorityName = MiguelServet
    archetype_id.valid_time = 1/1/1900 – 1/1/3000
    name = Medida del peso
    meaning.codingScheme = 2.16.840.1.113883.6.96
    meaning.codingSchemeName = SNOMED
    meaning.codingSchemeVersion = 7
    meaning.codeValue = 301333006
    meaning.displayName = Medida del peso corporal
    synthesissed = FALSE
    sensitivity = 3
      ELEMENT
      rc_id.extension = 0005
      rc_id.assigningAuthorityName = MiguelServet-Salud
      rc_id.valid_time = 1/1/1900 – 1/1/3000
      name = Medida del peso
      meaning.codingScheme = 2.16.840.1.113883.6.96
      meaning.codingSchemeName = SNOMED
      meaning.codingSchemeVersion = 7
      meaning.codeValue = 301333006
      meaning.displayName = Medida del peso corporal
      sensitivity = Clinical
      synthesized = FALSE
      value.PQ.value = 77
      value.PQ.units = kg
      value.PQ.property = Weight
```

Figure 5. Example scheme of an EN13606-compliant EHR extract

IV. Implementation into Medical Devices

Following the standard-based design and proposed development guidelines in previous section, the results of the implementation into MD are presented and discussed. As patient's data are usually collected via wearable PHDs, a key point in these MDs is ergonomics since it improves patient's quality of life. In order to improve the ergonomics, MD developers shall increase device's autonomy and decrease its weight which usually means that the board must use both batteries as small and light as possible and low capacity embedded processing systems in order to minimize the power consumption. Typical components in a board are a microcontroller, a communication module and a sensor, but sometimes the unique component in the board is a System-on-Chip (SoC) module that integrates all these components in a single chip. Once the hardware has been selected, the required software solution has to be developed. The software framework for such a task is commonly determined by the hardware involved. For example in the Bluetooth or ZigBee case, the framework is determined by the communications stack that usually provides a proprietary Real Time Operating System (RTOS) and a proprietary Application Programming Interface (API) to access the RTOS functions. Typical features of medical device hardware used in medical applications are a few Kilobytes of Random Access Memory (RAM), a few tens of Kilobytes of non-volatile solid-state memory (typically flash or Read-Only Memory, ROM), and a few Megaflops processor. All these requirements are finally translated into software implementations that have in mind to reduce processor and memory as much as possible. As far as software is concerned, this type of devices do not require a high grade of intelligence and sources code are usually written in assembler, C, or embedded C++. Operating System (OS), if used, is platform dependent and its API differs strongly from some devices to others.

This section proposes general software architecture to implement MDs. It must be noticed that X73PHD defines completely a point-to-point communication between agent and manager. That means that both syntaxes (the contents of each message, byte to byte) and semantics (the meaning of the message contents and its dynamics: what action to execute, how to respond, etc.) are defined for each transaction that usually entails any of this processes: a state change in the FSM, modifications in some of the DIM objects, and/or execution of some actions.

Based on our implementation experiences, a guideline to incorporate X73PHD into MDs and how to proceed with a MD implementation based on the concept of pattern, is given below. A pattern is defined as a model that can be used to produce a copy exactly equal to a reference. The concept can be applied here to interchanged messages between a specific MD and its CE. Taking an X73PHD specific type of message it can be seen that there are some sections or blocks that keep constant and unchanged during all MD life.

These similarities appear because in each transaction one or more ASN.1 structures are transmitted and its attributes are nearly always the same as they are needed only to enable interoperability and plug-and-play and do not transmit information. Blocks of bytes that do not differ can be extracted for a specific type of message, following X73PHD. We have coined each of them as pattern since they allow building X73PHD messages. All of the patterns needed to construct a message in a point-to-point communication between a MD and its CE are stored into what we call patterns library. Starting from the patterns library, each of the messages interchanged between MDs and its CE can be reproduced with a minimum of code lines. An example of the process is shown in Figure 6 in which the message of interest is filled with patterns from patterns library, and a few program variables, such as *Invoke-Id* or an *ObservedValue* (obtained, for example, from the last blood pressure measurement). Messages generated in this way can be compared with incoming ones, or transmitted.

The architecture of components for software development is proposed in Figure 7 and it is composed by the patterns library [11], the X73-kernel, the drivers, the adaptation layer, and the transports. The X73-kernel is the task that copes with pattern assembling, processing, comparison and transmission. It also manages the state of the FSM, the state of objects in the DIM, and some system signals. The signals managed include data sent or data received signals, connection established, connection lost, timer signals for scanners (such as *PeriCfgScanner*), etc. Drivers provide basic functions that depend on the MD specialization that allow the X73-kernel manipulate the hardware. The adaptation layer provides services that allow the X73-kernel managing peer-to-peer communications through the transport.

The guidelines above can be used to produce MD implementations. Each of these implementations can be shared between more than one MDs but only when both devices share the same communication profile and specialization. For example, it is possible to use the same implementation in a Bluetooth bathroom scale and a RS-232 laboratory weigh scale when both of them use polling profile (since both of them use the weigh scale specialization and the polling mode communication profile), but is not possible to use that implementation in a Bluetooth bathroom scale that use the baseline or PHD profile. These platforms usually use a common multiplatform programming language, such as C, to program the X73-kernel so it can be easily ported.

Untying these MD specialization-MD communication pairs gives great optimization in memory space. Most of the memory required by this solution is non-volatile type. Consequently, the low memory consumption makes possible to use the same X73-kernel and library of patterns in a big number of MDs that, at the same time, allows sharing it between different manufacturers improving interoperability.

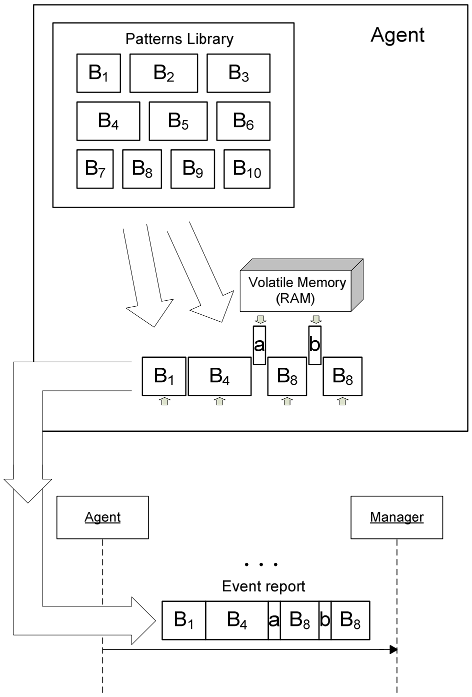


Figure 6. X73 messages synthesis from patterns

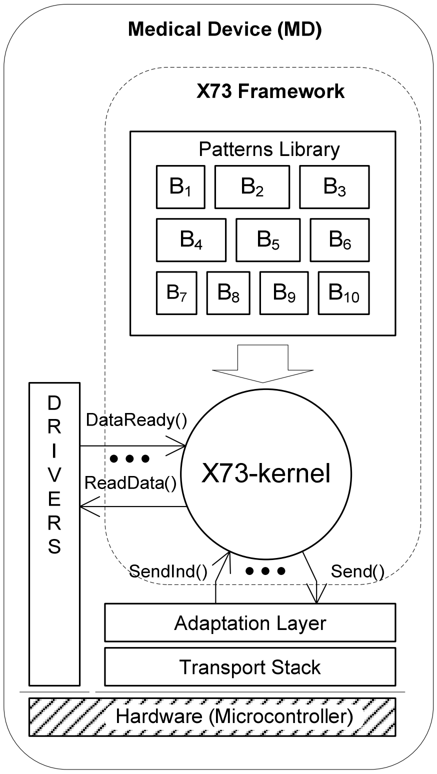


Figure 7. Architecture proposed for X73 MDs implementation

An exhaustive analysis of the X73PHD standard is required to generate the patterns library and the X73-kernel. Our proposal is depicted in Figure 8. Two-steps analysis is need: Firstly, to determine the set of messages that the device needs and the sequence they should follow, and, secondly, the analysis of this set of messages (typically a dozen) to obtain patterns. Once obtained, they are stored in the patterns library. Duplicated ones are discharged in order to reduce memory consumption. Once the patterns library has been generated, the X73-kernel that provides all the functionalities is developed using Object Oriented Analysis and Design (OOA/D) principles following a stimulus-response schema.

Once developed, an implementation can be shared and it offers a Rapid Application Development (RAD) that will allow a novel X73 implementer to develop a MD with only a basic knowledge of X73 since the unique needed modules to be developed are the adaptation layer and the device drivers. For example, in the case of a heart rate monitor, device drivers must provide with a signal that informs the X73-kernel when a new *sample-array* is ready, and a method to access the data. In order to maximize interoperability, it is preferable to create a framework that shall be used by all manufactures. To create this framework, the help of X73 world experts, experiences of other implementations, and the expertise of Special Interest Groups (SIG) is a key point.

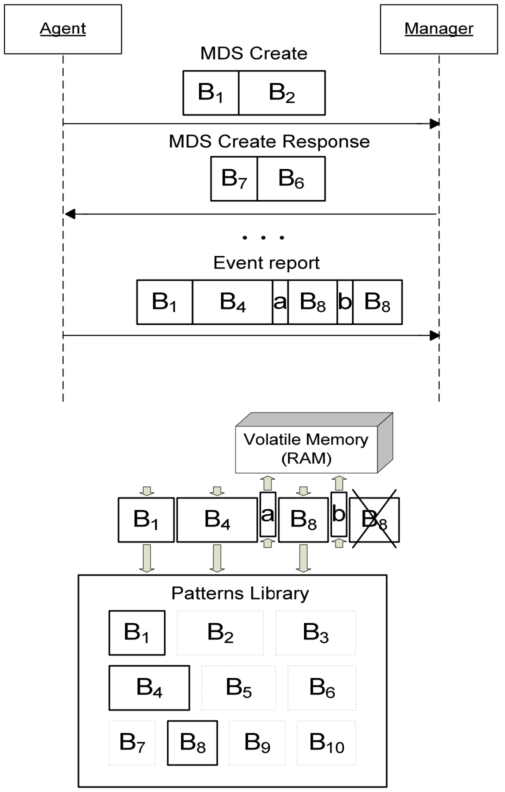


Figure 8. X73 library synthesis for microcontroller-based design

V. Conclusion

The need of interoperability and standard integration for the proposal of harmonized healthcare applications have derived to the implementation of an end-to-end standard-based platform that allows achieving a ubiquitous and personal health solution. The followed design guarantees the specific requirements for the two main standards in this context, ISO/IEEE11073 and EN13606 (both adopted as European way of medical interoperability), and opens new challenges currently under research as the implantation on micro-controllers or the development of a new protocol for end-to-end standard harmonization (E2E-SHP).

Acknowledgment

The authors wish to thank PHDWG and Melvin Reynolds, *convenor* of the CEN/TC251 WGIV, for the contributions to this research. We also appreciate the contribution of Miguel Galarraga (UPNA associate professor and researcher) and Adolfo Muñoz (researcher of the *Instituto de Salud Carlos III*, AENOR/CTN139 general manager, and CEN/ TC251 member) to the excellent results carried out during the last years in this work. This research work has been partially supported by projects TIN2008-00933/TSI and TSI2005-07068-C02-01 from *Comisión Interministerial de Ciencia y Tecnología* (CICYT) and European Regional Development Fund (ERDF), TSI-020302-2008-35/*Plan Avanza I+D* from *Ministerio de Industria, Turismo y Comercio*, and FPI grant to M. Martínez-Espronceda (Res. 1342/2006 from Public University of Navarre).

References

[1] ISO/IEEE11073.CEN/TC251-Health Informatics.www.cenorm.be - www.centc251.org. Point-of-Care MD Communication standard (X73-PoC). Personal Health Devices standard (X73-PHD). www.standards.ieee.org/ - www.ieee1073.org. Accessed April 09.

[2] EN13606-CEN/TC251. Electronic Healthcare Record (EHR) Communication. Parts 1, 2, 3, 4 and 5. http://www.medicaltech.org. Accessed April 09.

[3] Integrating the Healthcare Enterprise (IHE). http://www.ihe.net/. Continua Health Alliance. http://www.continualliance.org/home/. Accessed April 09.

[4] Reynolds M. *et al*. Can telemonitoring systems interoperate? Review of the suitability of existing standards for adaptable telecare provision. Healthcare Comp Conf of British Comp Soc (HC), pp.104-115, 2007.

[5] Yao J. and Warren S. Applying ISO/IEEE 11073 standards to wearable home health monitoring systems. *J Clin Monit Comput* 19(6):427-436, 2005.

[6] Warren S, Lebak J, and Yao J. Lessons learned from applying interoperability and information exchange standards to a wearable point-of-care system. *Conf Proc Transdisciplinary Conf Distr Diagn Home Healthcare*. doi: 10.1109/DDHH.2006.1624807, 2006.

[7] Clarke M, Bogia D, Hassing K, Steubesand L, Chan T, and Ayyagari D. Developing a standard for personal health devices based on 11073. *Conf Proc IEEE Eng Med Biol Soc*, pp.6175-6177, 2007.

[8] Martinez I. *et al*. Implementation of an end-to-end standard-based patient monitoring solution. *IET Commun* 2(2):181-191, 2008.

[9] Galarraga M. *et al*. Standards for medical device communication: X73PoC-MDC. *Stud Health Technol Inform* 121, pp. 242-256, 2006.

[10] Muñoz A, Somolinos R, Pascual M, Fragua J A, Gonzalez M A, Monteagudo J L, and Salvador C. H. Proof-of-concept Design and Development of an EN13606-based Electronic Health Care Record Service. *J Am Med Inform Assoc* 14:118-129, 2007.

[11] Martinez-Espronceda M, Serrano L, Martínez I, Escayola J, Led S, Trigo J D, and García J. Implementing ISO/IEEE 11073: Proposal of two different strategic approaches. *Conf Proc IEEE Eng Med Biol Soc*, pp.1805-1808, 2008.