Optimization Proposal of a Standard-Based Patient Monitoring Platform for Ubiquitous Environments

I. Martínez, J. Escayola, I. Fernández de Bobadilla, M. Martínez-Espronceda, L. Serrano, *Senior Member IEEE*, J. Trigo, S. Led, and J. García, *Member IEEE*

***Abstract*— This article describes the optimization of a patient telemonitoring platform based on the ISO/IEEE11073 (X73) standard to enable medical device interoperability. In order to achieve this, principal advantages and remaining improvements are evaluated to include in further upgrades towards the new profile evolution, oriented to ubiquitous environments and wearable devices (Personal Health Devices, X73-PHD), and opened to additional plug-and-play features and remote management. After evaluating the possibilities, we describe the platform porting process, a required step to adapt it to the new functionalities and allowing the development of end-to-end standard based systems. The paper details the implementation of the agent-manager architecture, particularized on the X73-PHD communication protocol between a Medical Device (MD) and a central gateway (Compute Engine, CE). Lastly, the obtained results are evaluated, oriented to constitute an X73-PHD tester to prove the challenges currently under discussion in the European Standardization Committee (CEN).**

ISO/IEEE11073 Standard Basic Nomenclature

BER/DER	*Basic/Distinguished Encoding Rules*
PER/MDER	*Packet/Medical Devices Encoding Rules*
CE	*Computer Engine*
DIM	*Domain Information Model*
FSM	*Finite State Machine*
MD	*Medical Device*
MDIB	*Medical Data Information Base*
MDAP/MDDL	*Medical Device Application Profile/Data Language*
X73-PoC/PHD	*X73-Point of Care/Personal Health Device*

I. Introduction

Along the 90's decade, telemonitoring services were aimed to patient control in hospitals, especially those whose vital signs had to be continuously under supervision and were allocated at the Intensive Care Unit (ICU) [1]. Each manufacturer developed medical systems with proprietary specifications thus complicating the incorporation of these devices in e-Health systems, which required of a homogeneous implementation to achieve a global and ubiquitous (u-Health) solution.

With this evolution towards the u-Health, the patient becomes the center of the entire medical care system. Technologies for ubiquitous computing, through Personal and Body Area Networks (PAN/BAN) emerge as a need for the new telemonitoring scenarios.

Interoperability between different medical systems, in terms of protocol standardization becomes, then, a main requirement to progress towards e-Health [3]. This is a long process that has been promoted by several organizations, like the European Standardization Committee (CEN) through its Technical Committee 251 (TC251) [4]. From CEN/TC251, new standards, the focus of our work, are being developed: ISO/IEEE11073 (X73) family of standards on its first version for medical device interoperability at the Point-Of-Care (X73-PoC) [5], as well as its most recent evolution oriented to BAN/PAN and wearable systems to be used over Personal Health Devices (X73-PHD) [6].

There are previous contributions [7], developed in the USA from the research group headed by Dr. Warren, but neither European contributions in this field nor proposed end-to-end solutions to cover new use cases for ubiquitous patient monitoring and design-oriented to be compatible with the new standard version X73-PHD, as it is introduced in this article. In this article, taking previous developments as a start point [8] in which a first end-to-end implementation based on standards (X73 and EN13606) was implemented, we show an optimization progress on that platform.

The new architecture has to provide a solution to those ubiquitous scenarios proposed by the X73-PHD standard, incorporating necessary changes at the agent-manager communication model, redefining the state machine for connection stage management, and designing new transport and physical layers. It is necessary then to develop an architecture which ensures its portability to other environments and use cases (geriatric services, athlete training monitoring, mobile scenarios, etc.), ease its remote management (medical information, alarms, operating scheme, etc.), add new technologies (Bluetooth, ZigBee, RFID), and propose new wireless devices (PDAs, SmartPhones, microcontrollers, etc.).

Section II describes the X73 evolution and the platform optimization. Section III shows the suggested design, its architecture and its implementation progress. Section IV evaluates the results and new functionality oriented to X73-PHD. Conclusions are commented in Section V.

This research work has been supported by projects TSI2007-65219-C02-01 and TSI2005-07068-C02-01 from *Comisión Interministerial de Ciencia y Tecnología* (CICYT) and European Regional Development Fund (ERDF), PET2006-0579 from *Programa de Estímulo de Transferencia de Resultados de Investigación* (PETRI), and FPI grant to M.Martínez-Espronceda (Res. 1342/2006 from Public Univ. of Navarre).

I. Martínez, J. Escayola, I. Fernández de Bobadilla, J. Trigo, and J. García are with the Communications Technologies Group (GTC), Aragon Institute for Engineering Research (I3A), Univ. of Zaragoza (UZ), c/ María de Luna, 3, 50018 Zaragoza, Spain (correo e.: imr@unizar.es). M. Martínez-Espronceda, L. Serrano, and S. Led are with the Electrical and Electronics Engineering Dep., Public Univ. of Navarre, Campus de Arrosadía s/n, 31006 Pamplona, Spain (correo e.: miguel.martinezde espronceda@unavarra.es).

II. X73 EVOLUTION AND PLATFORM OPTIMIZATION

The development of new personal and wearable devices have brought X73 to an optimized version, X73-PHD, which describes the landscape of transport-independent applications and information profiles for personal telehealth. These profiles define data exchange/representation and terminology for communication between Medical Devices (MDs, as glucometer, thermometer, etc.), and Compute Engines (CEs, as cell phones, personal computers, etc.). In X73-PHD communication model, MD and CE are named as agent and manager, respectively. As shown in Fig.1, the architecture is divided into three main protocol blocks:

- **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 MDs are continuously being added, by developing its MDS.
- **Optimized Exchange Protocol**. The main part of the standard consists of a medical and technical terminology framework (Domain Information Model, DIM) which will be encapsulated inside the Protocol Data Unit (PDU). The communication model describes a point-to-point connection based on manager-agent architecture through a Finite State Machine (FSM). The first version of X73 defined this part as the Medical Device Data Language (MDDL). Next, a Service Model defines a set of messages and instructions to retrieve data from the agent based on the DIM. In addition to this, it provides a data conversion from an Abstract Syntax Notation (ASN.1) to a Transfer Syntax, using an optimized Encoding Rules (ER) denoted as Medical Device ER (MDER), as well as standard Binary ER (BER) and even more effective Packet ER (PER) support. Service Elements (SE) taken from the previous X73 version for this purpose are: Remote Operation (ROSE, Optimized for MDER), Association Control (ACSE) and Common Management Information (CMISE).
- **Transport Layer**. Data transmission will be held over a transport technology caused by X73-PHD identifies assumptions that require direct support by this layer, allowing various transports to be implemented (X73-PoC established higher dependency between transport and upper and lower layers). Thus, transport specifications are out of the scope of the X73-PHD standard, while other Special Interest Groups (SIG) are working towards profile definition for Bluetooth, USB, etc.

Following this evolution, migration from the previous platform [8] (known as *platform1.0-*α) to a new *platform1.5-*β was necessary. A snapshot of the overall process is shown in Fig. 2. Main objectives for these challenges are:

- Use case evolution from fixed systems to mobile, and the addition of plug-and-play or hot-swap features, forced to move from IrDA or RS-232 to new technologies like USB or Bluetooth.
- The new MDs, because of upgrading from X73-PoC to X73-PHD, required an important change in the communication scheme with the CE, which implies a new FSM design. This new FSM is somehow too complex to be implemented in the *platform1.0-*α due to new methods that need to be incorporated.
- The new X73-PHD base standard does not specify a concrete transport level. Nevertheless, *platform1.0-*α introduces a specific complex model to add modularity to the implementation. The Optimized Exchange Protocol replaces the previous X73 protocols to define PDUs.
- X73 adapter evolution towards more versatile systems able to be used in microcontroller-based systems, wireless CEs, new use cases (from fixed to ubiquitous), and multimedia environments of Graphic User Interfaces (GUIs) that require a simpler high-level encapsulation (*platform1.0-*α is too complex at the low level development).

From this basis, the requirements that will state the design specifications for the new implementation will be evaluated.

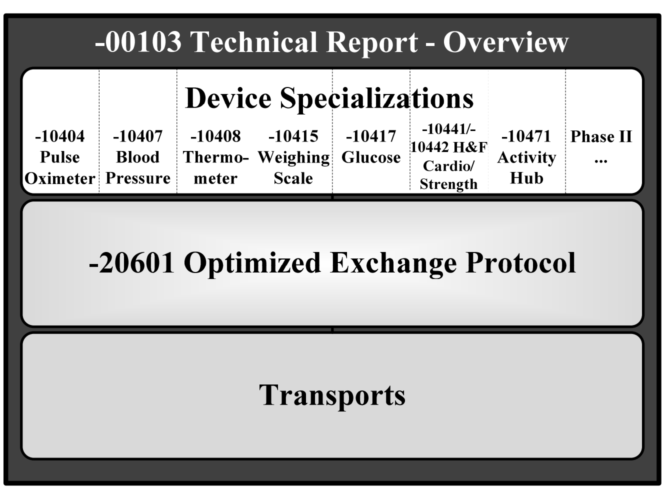

Fig. 1. ISO/IEEE11073 Personal Health Devices (X73-PHD) protocol map

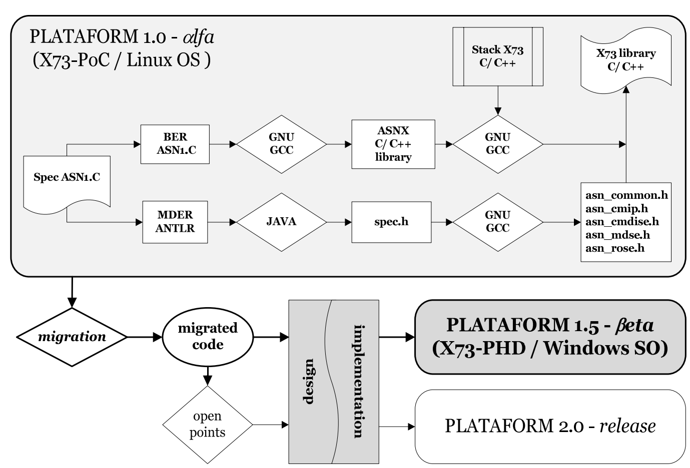

Fig. 2. X73-Platform evolution scheme

III. Proposal of Design and Implementation

After the technical analysis that justifies the platform migration; the solution architecture, design rules, and implementation development are described below.

A. Migration architecture. Design rules

The proposed new architecture has to cover a group of main commitments or design guidelines.

First, it should look for a functional design in compliance with X73. To do so, the dependence on transport technology has to be removed by looking for a generic and configurable solution: transport layer manager or *handler*. Thus, the acquired data are first translated to X73, and refreshed with every new measurement (but in an episodic way, not periodically as in *platform1.0-α*). Then, the data transmission is initiated (already X73-compliant) from the previous X73-adapter to CE, under user request. Therefore, it is up to the developer to include the files capable to give support to the appropriate transport technology for each MD.

Secondly, the design of generic X73 stack has to be kept. However, the code has to be optimized and the definitions library ASN1.C (ASNX for X73) has to be introduced in order to successfully connect in the communication link from the development environment for each resource. The abstract classes for MD and CE have also to be modified to implement the new FSM defined by CEN for X73-PHD.

Finally, since no transport technology is incorporated, the data encapsulated through the different layers become into a layout based on a structure of buffers that collect the set of PDUs of the different stack layers. These *buffers* have to be properly managed so that they can response to the communications protocol designed by X73.

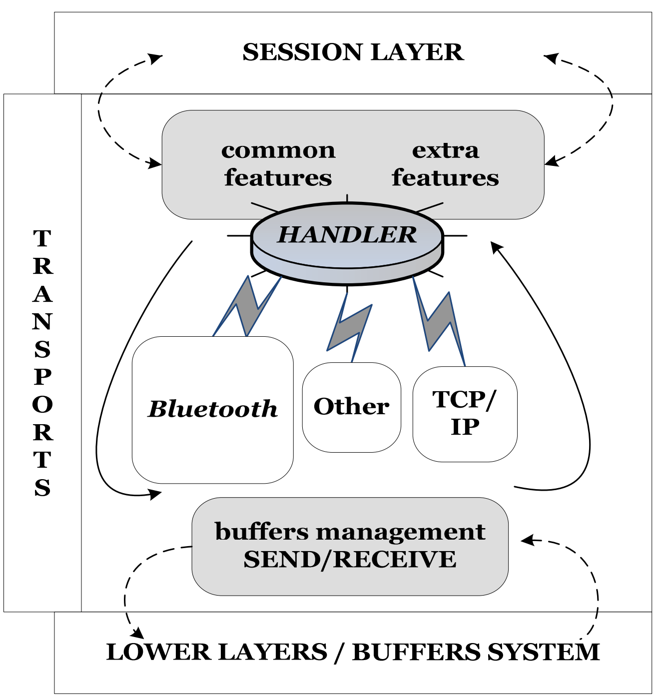

Fig. 3. Transport protocol handler for the new X73-PHD platform.

B. Solution implementation

First, and due to the need of a generic transport layer, the communication between both ends at that level is up to the developer. In the *plataform1.5-β*, the new generic layer TRANSPORTS (Fig. 3) is included. The communication with the session layer is carried out through the generic stack interface for each end (MD and CE), and with the physical layer through a system of buffers. This function is implemented by means of a generic transport layer manager interface (*handler*), transparently to the protocol.

Second, it is essential that the platform be X73-compliant in all its versions, following rigorously the design of the new state machines FSM at both ends of the system: agent (MD) and manager (CE). That design philosophy has been a key issue in the design, along with the implementation of the states carried out by the communication MD/CE in both stack models. A continuous loop has been created in order to design these machines. That loop includes the following states (Fig. 4): DISCONNECTED, CONNECTED, DISASSOCIATED, ASSOCIATED, CONFIGURING, and OPERATING. The operation process is detailed in [6].

Finally, as it occurred with the transport layer, it is up to the developer to implement any physical layer. This physical layer is in charge of receiving and sending the [*st_buffer*] structures that MD and CE send through the *handler*. The *st_buffer* structure is a data container in memory. The bits coded in each PDU of each layer follow this structure, being that way easier to manage.

From all this, *platform1.5-β* is obtained. This platform controls the bits *on the wire* (bits that form the *st_buffer* and that are sent by both stacks through its interface), enabling flow and error control, which is a goal pursued by the CEN and it will enable the system management.

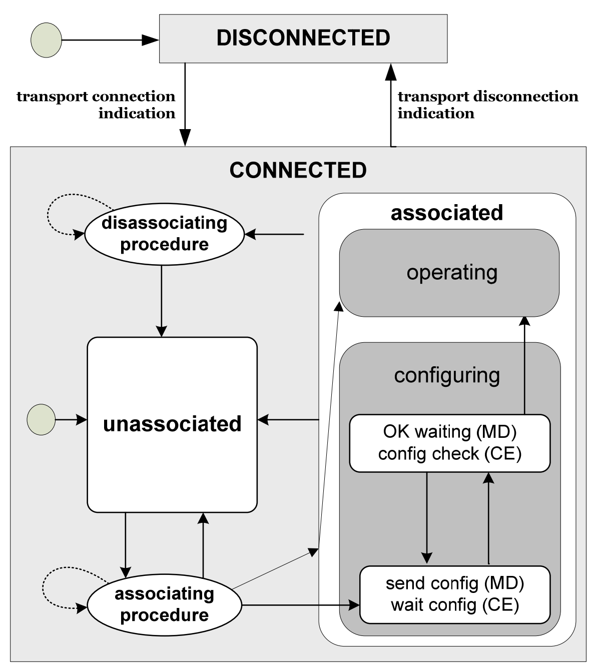

Fig. 4. Generic Finite State Machine for the new X73-PHD platform.

IV. RESULTS AND OPEN POINTS

The *platform1.5-β* implementation is a testbed model of the X73-PHD-compliant communication. Besides, its forthcoming *platform2.0-release*, which will include the open points detailed in IV.B, will allow the platform to become a solution transferable to the health system.

A. X73-PHD tester

The X73-PHD tester starts asking the user which MD wants to be used from an available list. After the selection of MD, its information, the measures types that can be acquired, and a menu to control the FSM are shown. FSM goes through the ends of the X73-PHD communication (MD-CE). From here, MD is initiated and the stack layers, operating interfaces and Medical Data Information Base (MDIB) structure are created: MDS object and its sub-branches.

Later, the transport system that supports the communication is required, getting the handler ready to support corresponding protocols. Moreover, information of the execution is shown in the screen, helping the engineer to know the methods of the layers. It is also shown how the buffers send the X73-PHD information and the other configuration parameters of the events and responses interchanged between MD and CE.

After association, MD enters to the configuration point; CE sends the MDS object to the MD, without measurements yet. In CE a context of data reception is created (episodic or polling, regarding MD model). Thus, MD is now ready for the measurement acquirement (always under user request), and enters into the OPERATING state of the FSM.

By submitting data, MD updates the MDS object with the acquired measurements, and sends them to CE to be also updated. The received measurements are shown, detailing the X73-compliant identifications (in this example: 19230, 19229 and 18442; corresponding to a blood pressure device: diastolic pressure, systolic pressure and pulse, respectively), as shown in Fig. 5. Finally, it is asked if more measurements are going to be made or, on the contrary, a menu is used to disassociate MD and CE or disconnect them regarding FSM.

```
AVAILABLE DATA
Diastolic Pressure:   7.0
Systolic  Pressure:  12.0
Pulse (/per minute): 62

X73 INFORMATION REPORT
NuObsValue: metric_Id integer: 19230
            unit_code integer: 799
            value real:        e( ) m(70)

NuObsValue: metric_Id integer: 19229
            unit_code integer: 799
            value real:        e( ) m(120)

NuObsValue: metric_Id integer: 18442
            unit_code integer: 799
            value real:        e( ) m(62)
```

Fig. 5. X73-PHD demonstrator: X73 measurement sending from MD to CE

B. Open points: platform2.0-release

As told before, some technical advances remain opened to achieve the definitive version of the platform:

- Implementing each stack in a microcontroller-based adapter inside a MD and in a wireless CE, with their transport and physical layers technologies (TCP/IP, USB, Bluetooth, etc.) in the *handler*. Besides, designing private methods that strengthen the management by means of *sockets* and *threads*, and incorporate priority models to attend certain MDs (under consideration by CEN).
- Supporting the multiple MDs connection with one or multiple CEs, optimizing the creation and management of the different MDIBs, and implementing a state manager of FSM (to read MD configuration parameters and add them to a database to guarantee the plug-and-play features).
- Migrating the console interface to an interactive GUI, adaptable to the device type (miniPC, mobile, SmartPhone, PDA, etc.), interface (Java, .Net, Web 2.0, etc.), or OS (Windows Mobile, Android, Symbian, etc.).

V. CONCLUSION

The evolution of X73-PoC to X73-PHD has derived to an optimization of the end-to-end platform, allowing to achieve an ubiquitous, plug-and-play and standard-based solution. Besides, it can be seen as a X73-PHD demonstrator to prove the challenges currently under discussion in the CEN: flow and errors control, errors and alarms management, multiple MD connection with one or multiple CEs, or implantation in micro-controllers, wearable and wireless devices.

ACKNOWLEDGMENT

The authors wish to thank X73-PHD Working Group, CEN, and Mr. Melvin Reynolds, *convenor* of the CEN TC251 WGIV, for the contributions to this research. We appreciate the contribution of Miguel Galarraga to the excellent results carried out during the last years, and also Adolfo Muñoz (*Instituto de Salud Carlos III*), Paula de Toledo (*Univ. Carlos III*), y Silvia Jiménez (*Univ. Politécnica de Madrid*).

REFERENCES

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

[2] R. Kling, "Learning about IT and social change: The contribution of social informatics," Information Society, vol. 16, pp. 217-232, 2000.

[3] S. Pedersen and W. Hasselbring, "Interoperability for information systems among the health service providers based on medical standards," *Informatik - Forschung Und Entwicklung*, vol. 18, pp. 174-188, 2004.

[4] CEN. [13] Comiteé European de Normalisation. http://www.cenorm.be. CEN/Technical Comitee TC251. http://www.centc251.org/. Last visit: 04/08.

[5] ISO/IEEE11073 Point-of-Care Medical Device Communication standard (X73-PoC). Health informatics. [Part 1. Medical Device Data Language (MDDL)] [Part 2. Medical Device Application Profiles (MDAP)] [Part 3. Transport and Physical Layers]. http://www.ieee1073.org. See also the previous standards: IEEE13734-VITAL and ENV13735-INTERMED of CEN/TC251, http://www.medicaltech.orgh. Last visit: 04/08.

[6] ISO/IEEE11073 - Personal Health Devices standard (X73-PHD). Health informatics. [P11073-00103. Technical report - Overview] [P11073-104xx. Device specializations] [P11073-20601. Application profile - Optimized exchange protocol]. IEEE Standards Association webpage: http://standards.ieee.org/. Last visit: 04/08.

[7] J. Yao and S. Warren, "Applying ISO/IEEE 11073 standards to wearable home health monitoring systems," *Journal of Clinical Monitoring and Computing*, vol.19, pp.427-36, 2005.

[8] I. Martínez, J. Fernández, M. Galarraga, L. Serrano, P. de Toledo and J. García, "Implementation of an End-to-End Standards-based Patient Monitoring Solution," *IETCommunications.Special Issue on Telemedicine and e-Health Communication Systems*, vol. 2, pp. 181-191, 2008.