

Implementation Experiences of ISO/IEEE11073 standard Applied to New Use Cases for e-Health Environments

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Abstract—Recent advances in biomedical engineering and continuous technological innovations in last decade are promoting new challenges, especially in e-Health environments. In this context, the medical devices interoperability is one of the interest fields wherein these improvements require a standard-based design in order to achieve homogeneous solutions. Furthermore, the spreading of wearable devices, oriented to the paradigm of patient environment and supported by wireless technologies as Bluetooth or ZigBee, is bringing 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. In this paper, several implementation experiences based on ISO/IEEE11073 standard are detailed. These evolved e-Health services can improve the quality of the patient's care, increase the user's interaction, and assure these e-Health applications to be fully compatible with global telemedicine systems.

I. INTRODUCTION

A great progress has been achieved through the last decade on healthcare applications due mainly to the advances in biomedical engineering. The application environment has been extended from hospital-located healthcare services to the patient/user's context creating the new Personal and Body Area Networks (PAN/BAN) and evolving the concept of telemedicine to new e-Health [1]. All of these scenarios rely on specific Medical Devices (MDs) based on sensors to acquire the user's biosignals (blood pressure, pulse, weight, temperature, ECG, etc.) so they can be monitored by the same user and later evaluated by the professional healthcare service providers [2]. Personal Health Devices (PHD) attempt to allow the user to manage the measurement process not only at any point when possible, but also while travelling, making use of wireless technologies and portable computing devices in order to report signal and events to remote supervision [3].

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Such a freedom in elaborating high quality sensors combined with user's centered features raises the number of MDs introduced by manufacturers in the market. But the interoperability problem arises because a specific e-Health application has to be developed and implemented to every use case. That usually forces the system designer to use a unique set of devices. It leaves out others MDs with similar or probably better specifications, avoids updates or changes because of system failures, and it is the main reason why a standardization effort is necessary [4].

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. But the standard that reached the highest development level as well as consensus and acknowledgment has been, in the European context, ISO/IEEE11073 (X73) [5]. Its previous versions were originally focused on the Point-of-Care of the patient (X73PoC). With the emerging of new transmission technologies (like USB, Bluetooth, WiFi, or ZigBee) and wearable devices, it has evolved to the most recent version for PHDs oriented to e-Health (X73PHD). Furthermore, all the X73PHD development has been carried out by the PHD Working Group (PHDWG) [6], where our research group works within numerous companies and institutions. In parallel, private initiatives such as Integrating the Healthcare Enterprise (IHE) [7] and Continua Health Alliance are willing to collaborate to integrate and harmonize the different standards in a homogeneous context [8]. Recently, the results of PHDWG has been adopted by Continua Health Alliance as standard *de factum* for MDs interoperability, and in further works it will be accomplished one of the main alliance objectives: 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 devices of the system, as long as they all implement X73PHD.

This paper analyzes the most recent innovative advances in biomedical engineering applied to the standard-based design through several implementation experiences of X73-compliant solutions for the new e-Health use cases. In Section II the results of PHDWG for achieving new MDs X73PHD-compliant specializations, new use cases and interoperable application environments are detailed. Section III presents several implementation experiences following the X73-based design rules. Finally, the future trends related to standard harmonization and its integration in homogeneous solutions are discussed in Section IV.

II. NEW E-HEALTH USES CASES AND MEDICAL DEVICES

When an e-Health service is being defined and its implementation is based on X73 conformance, following the standard features and specifications, it is necessary to define a set of closed use conditions. These conditions are called Use Cases (UCs), and they try to collect both standard's potential application and end-user's requirements. The traditional UCs, X73PoC-based, have been initially focused on Intensive Care Units (ICUs) applications or bedside, mainly concerned about monitoring, pre- and post-surgery and bedside disease management. In short, the MDs used were mostly fixed, wall powered, and not designed to be wearable or portable. Advances in both biomedical engineering and telemedicine potential users forced the need of a new standard, as mentioned earlier, and therefore new UCs emerged [9].

In order to determine the initial set of MDs that were intended to work with X73PHD, a survey was conducted to gather the opinion of manufacturers and stake-holders. The final decision was taken based on the interest of PHDWG experts in developing the standard or providing help for that during the process and the availability of the working group. At this moment, this classification is composed by the following MDs (indexed in X73PHD as 11073-104XX [5]): 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. The last PHDWG voting results for further MDs has been: breathing rate, spirometer, basic ECG (3-leads), peak flow meter, INR-blood coagulation, physical activities of daily living monitor, CO₂ meter, insulin pump, fetal monitor, body composition analyzer, and simple EEG (1-lead). So far, a pulse-oximeter with X73PHD over Bluetooth as transmission protocol has been already developed [10] and successive X73PHD MDs are expected to be developed soon.

Finally, the most relevant e-Health environments in last years are: healthy living, wellness & fitness, imminent disease management, assisted ambient living, elderly patient care, diabetes and home monitoring of single cardiac patient. And these environments have been grouped in three main UCs, as it is shown in Table I, which also includes the associated MDs to be standardized to X73PHD.

TABLE I.
USE CASES CLASSIFICATION FOR STANDARDIZATION TO X73PHD

UC	disease management	health&wellness	elderly monitoring
MDs	pulse oximeter, heart rate, blood pressure, thermometer, weighing scale, glucose meter.	heart rate, thermometer, weighing scale, cardiovascular fitness equipment, activity monitor.	blood pressure, heart rate, thermometer, weighing scale, independent living activity hub, medication dispenser.

III. RESULTS OF IMPLEMENTATION EXPERIENCES OF X73-COMPLIANT SOLUTIONS FOR E-HEALTH ENVIRONMENTS

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. Within our work, the e-Health environments and UCs that have been selected for an X73-compliant implementation experience are described below [11].

A. Intensive Care Units (ICUs)

ICUs represent the clearest example of local patient monitoring with a subsequent data report to a central computer. For each patient, full monitoring equipment is set, and the data coming from all the patients are observed in the central computer. Within every patient's box, several MDs can be found, such as 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 a proprietary protocol 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 some data needs to be retrieved from the EHR of the patients, HL7 is the protocol normally used.

A system's improvement can be achieved by incorporating X73 to the communications. As noted before, MDs are chosen according to the overall monitoring application compatibility. The optimal solution should permit 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 by another device that, even if it has more complexity or the rest of specifications are unnecessary, it will be able to meet the minimum requirements for monitoring. At the same time, parameter reporting could be achieved and system status can be received not only on the supervision system but also on PHDs (see Fig. 1). With this solution, ICU personnel can attend other issues while receiving real-time updates.

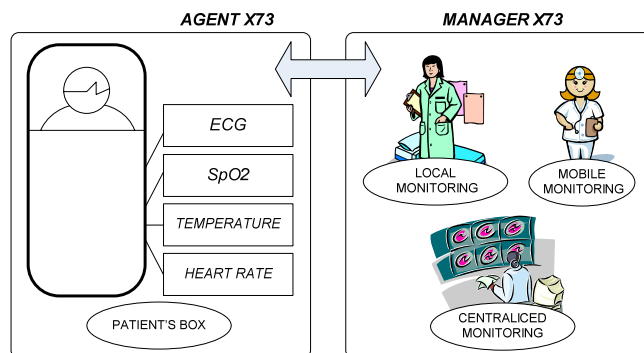


Fig. 1. ICU distributed monitoring through X73PHD standard

B. Hospital Admission

Another potential application for X73 is 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, SpO₂, blood pressure and heart rate are measured, using a single multi-parameter monitor (see Fig. 2). Once the values are stabilized, they are transferred to the patient's EHR. Although this device allows data transmission, it is not used due to protocol incompatibilities. Instead, the nurse simply checks the data and incorporates them 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 a feasible solution, different applications and different data formats coexist inside the computer. Even if compatibility issues are solved, some events like replacing a MD by another (because of malfunction, for instance) illustrate its reduced versatility.

Adding X73 to the process has many advantages compared to 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 to the MD in a specific manner (sockets, COM port, etc.), the X73 library can provide all of them, since it has being designed to support several transport technologies. Finally, it allows the possibility of adding wireless transport to the process (see Fig. 3).



Fig. 2. Multi-parameter monitor for hospital admission

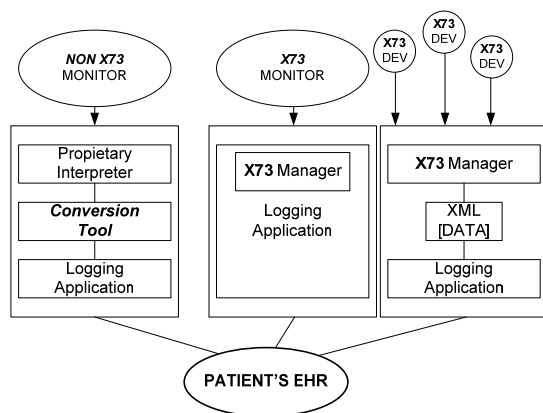


Fig. 3. X73-based design of a multi-parameter monitor

C. Blood Donor Centre

In general, donors have to be checked prior to the donation process. This includes incorporating the personal information along with biomedical measurements such as blood pressure, heart rate, hemoglobin level, weight and height (the latter two are usually provided by the donor himself). At present, all the values are introduced manually 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 accesses to the next room where the blood extraction begins. One of the typically used blood collection monitors is *Biomixer-330* with a Bluetooth module that reports the donation log (blood flow, time duration) once is finished. Such information is attached into 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 for devices that 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 will need to be changed to another provider. This proves the need for incorporating standardized devices.

As a proof-of-concept, we developed a X73PHD-demo testbed (see Fig. 4) that checks the X73PHD communication process between a CE/*manager* and the corresponding MDs (weighting scale, blood pressure device, and pulse-oximeter) in order to obtain the required vital signs for blood donor centre: blood pressure and heart rate, hemoglobin level, weight and height. The designed testbed allows implementing several MDs (as long as their X73PHD specifications are included into the libraries) for protocol and e-Health service testing.

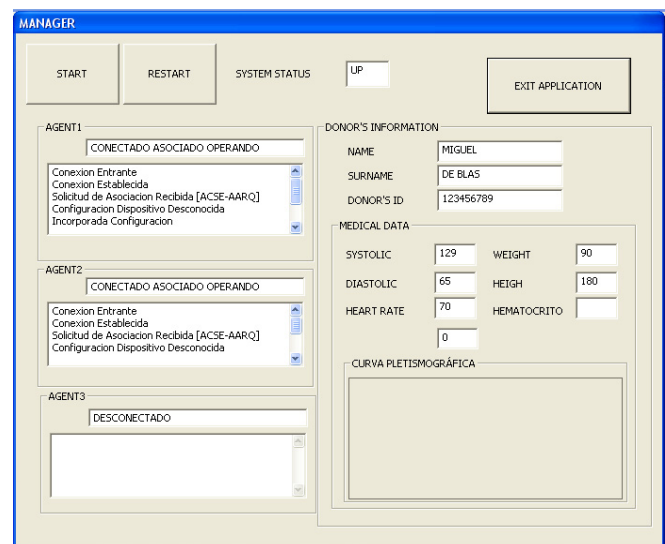


Fig. 4. X73PHD-demo testbed for Blood Donor Centre

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 (such as blood pressure, SpO₂, etc.) and report them to hospital. In this context, our group has developed X73-compliant solutions for heart failure patient's follow up called INtelligent HOLTer (HOLTIN) [12]. 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 syncope 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 Fig. 5).

The wearable 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 a SmartPhone device by means of a X73PHD-compliant Bluetooth technology. This way, HOLTIN system combines Bluetooth features with interoperability characteristics as plug-and-play. Furthermore, during the use of the HOLTIN system, all the cardiac events patient-suffered are received at the hospital and can be analyzed by the specialist to make a diagnostic. Thus, the patient only needs to go to the hospital when the specialist has detected some cardiac pathology that requires treatment. Recent tests about performance, usability or patient acceptance is being currently developing and its results will be detailed in further publications.

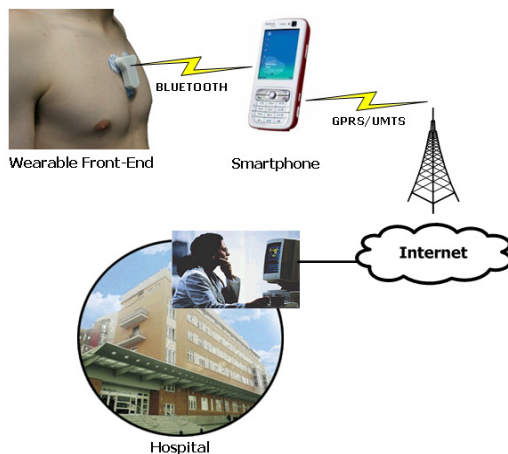


Fig. 5. HOLTIN system

IV. CONCLUSIONS AND FUTURE TRENDS

The need of interoperability in order to propose compatible and harmonized healthcare e- solutions requires the use of standard-based design for new Health environments. ISO/IEEE11073 is the European way for solving this integration lack and its implementation in new uses cases and application contexts guarantees the implantation of e-Health solutions transferable to the healthcare system. This standard is 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, possibility of operational parameters updating on demand, multi-patient enhanced compatibility, etc.

Furthermore in our current work, we are working towards two of the PHDWD priority tasks: making X73PHD interoperable with other standards for health informatics (like SCP-ECG, DICOM or HL7 within the researching work of the aforementioned initiatives IHE and Continua Health Alliance), and solving the end-to-end implementation since the medical data has been acquired from MDs (automatically or with minimal user's interaction), managed by a Compute Engine (CE) through the X73PHD communication model, externally transmitted through a new protocol for End-to-End Standard Harmonization (E2ESHP), and stored into a EHR server for their further interoperable exchange through EN13606 standard.

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