Design and implementation of a standardised framework for the management of a wireless body network in an Mobile Health environment

Alejandro Talaminos[1] ✉, David Naranjo[1,2], Gerardo Barbarov[1], Laura M. Roa[1,2], Javier Reina-Tosina[2,3]

[1]*Biomedical Engineering Group, Faculty of Engineering, University of Seville, Seville 41092, Spain*
[2]*Biomedical Research Networking Center in Bioengineering, Biomaterials and Nanomedicine (CIBER-BBN), Madrid 28035, Spain*
[3]*Department of Signal Theory and Communications, Faculty of Engineering, University of Seville, Seville 41092, Spain*
✉ *E-mail: atalaminos@us.es*

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The design and implementation of a framework that facilitates the development of Mobile Health applications to manage the communications with biomedical sensors in compliance with the CEN ISO/IEEE 11073 standard family are presented. The framework includes a set of functional modules that are responsible, among other tasks, of the communication of sensors and the processing and storage of data. The mobile terminal acts as an intermediary or hub, collecting and presenting the data received in a standardised way, regardless of the sensor type used. In this context, as proof of concept it is presented a mobile app built on the top of the framework to manage the communications with a smart fall detector.

1. Introduction: The concept of eHealth [1] emerges in industrialised countries in response to problems of ageing population, increase in prevalence of chronic disease, inefficient care processes and high health costs. To address these challenges, eHealth comprises a new health ecosystem based on citizen empowerment [2], where the patient is more responsible for and involved in her/his treatment and healthcare. This new model of care extends the care process, which has traditionally been located exclusively in hospitals and medical centres, to expand and cover other services within a scenario of ubiquitous computing.

From the technological point of view, this change has given rise to new lines of research related to the study of methods and techniques that allow the continuous monitoring of physiological parameters of the citizen. In this context, the paradigm of Mobile Health (mHealth) arises [3] included within of the eHealth ecosystem, but focused mainly on prevention and clinical diagnosis of patients regardless their geographic location and using mobile technology. Currently, the rate of adoption of mHealth applications in healthcare is being slowed due to some shortcomings, as the complexity associated with the integration of multiple non-interoperable technologies and the difficulty of adapting the graphical interfaces to different physical and cognitive limitations of the users [4].

Among mHealth applications, those that use the so-called personal health devices (PHC) and/or wearable sensors to monitor the physiological variables of the users [5] stand out. In this sense, the reduction of costs, the electronic miniaturisation and the rapid evolution of the wireless communications have led to a growing interest in the development of this type of biomedical devices. Moreover, biomedical sensors are playing a significant role in prevention-oriented healthcare [6] including those caused by age-related conditions, for which the empowerment provided by technology is still limited [7].

Wireless body area networks are responsible for coordinating communications between all these biomedical sensors through the wireless transmission to a hub of all the information collected from the sensors. In this sense, the great proliferation of these devices is giving rise to a great heterogeneity of semantics and proprietary communication protocols that are delivered as black boxes and, therefore, as non-interoperable devices. In this way, manufacturers or system integrators are guaranteed exclusivity in the market and force users to be technology dependent. The inherent increase in complexity of these systems also handicaps small developers, who face an additional workload in the deployment of sensor platforms that have different communication protocols. Finally, the problem is further aggravated when the data processed have to be integrated into a health information system.

To address the interoperability problems in the context of mHealth, the manufacturers of biomedical devices proposed the adoption of the European Committee for Standardization, International Organization for Standardization (CEN ISO)/IEEE 11073 standard family (also known as X73) [8]. Originally, the X73 standard was defined to describe the interoperable exchange of vital signs between medical devices (agents) and central equipment (managers). Eventually, the standard was extended with the X73PHD, an evolution of the X73 to satisfy the current needs, which are focused on the new personal or portable devices at the point-of-care scenario. Although there are several cases of interoperability success between biomedical devices using X73 nowadays [9], integration problems still exist because this family of standards allows the extension of the norm and sometimes sensor manufacturers add proprietary protocols with the objective of protecting their technological innovations [10].

Given the monolithic nature of the existing protocol implementations in terms of interoperability and communications, several works have tried to simplify the process of integration between different biomedical sensors that are compatible with the X73 standard. For example, in [11] middleware architecture is proposed where sensors and protocols can be loaded dynamically, focusing mainly on the process of communication start-up. On the other hand, another integration effort is presented in [12], integrating stationary medical devices in isolated clinical scenarios and excluding the role of mobility. Finally, a modular middleware for the on-demand integration of medical devices is exposed in [10], introducing the concept of Open Services Gateway initiative device, which describes the basic communication mechanisms of sensors with the platform.

All these works show the need to facilitate the integration and propose solutions in the form of middleware, providing a management platform for a wide range of sensor types and including an automatic adaptation of the device. However, in most cases, a communication example between a biomedical device and the middleware is not presented. Besides, the use of these software solutions implies that the application developer should have knowledge of the X73 standard and the underlying middleware technology. Finally, considering the wide range of possible scenarios, communication may be restricted to only a single sensor with a hub or reduced set of sensors such as in the context of wearable devices [13] or monitoring of chronic patients [14]. In these cases, these middleware solutions can add complexity.

Considering this context of sensors heterogeneity, complexity of integration and absence of interoperability, this Letter presents a framework designed and implemented with the aim of providing a simple management tool that allows the communication with portable biomedical sensors that are compatible with the X73 standard through a hub device, for example, a mobile phone. The framework has been designed and developed from a modular and extensible point of view, facilitating the scalability and integration of new sensors, as well as the addition of other complementary functionalities.

Considering that falls are a serious public health issue in elderly persons [15], as proof of concept it is presented the implementation of a mobile app built on the top of the framework to manage a smart fall detector.

The work is divided into three sections: the methodology followed is presented in Section 2, as well as the software design patterns on which the framework is based. This section also includes the design of the communication module and how it is integrated with the X73PHD standard, considering the Bluetooth Health Device Profile (HDP). Afterwards, results and discussion are presented in Section 3, detailing each one of the modules contained in the proposed framework and describing a specific use case of the mobile application to manage a smart fall detector. Finally, conclusions are exposed in Section 4.

2. Materials and methods: The methodology followed in the construction of the framework is based on the so-called systems development life cycle (SDLC), a classic process of software development in systems and software engineering. SDLC consists of a series of stages including: requirements analysis and definition of technological specifications, design, implementation, testing and evaluation. From the point of view of design, a modular architecture methodology has been used to build the application, defining all the functional elements of the application as scalable and reusable components.

The framework architecture is designed in a modular perspective through an application programming interface (API) that provides an abstraction layer to ease communication with the sensors and access to the monitored data. At the programming level, the API provides instances to the sensors that are intended to be controlled, where each instance is constituted by a set of functional modules with their respective interfaces.

All the constituent modules of the framework have been made following the model–view–controller (MVC) software design pattern [16], widely used in web applications. In this case, it has been extended and adapted to communication, management, processing and presentation of the data collected by the sensors. In this context adapted from MVC, the controller component will be responsible for interacting with the sensors including not only the collection of biomedical data from the user, but also the management of the sensor configuration. On the other hand, the model is responsible for the data processing including the storage in a database and forwarding to an external location. Finally, the view implements the graphical user interface (GUI) and presents the information in a standardised way based on some configuration criteria that can be previously established by the user.

Regarding the communication between the modules of the framework, an event-driven architecture [5] has been used, where an event is triggered when a specific change or variation occurs on a particular state or variable of a module. Once the event is generated, it is propagated through a communication bus to which all the modules are attached. This perspective of event-oriented design allows for a low decoupling between the different components of the framework, making them less dependent on platform, language and operating system. Finally, once all the functionalities, interfaces and events of the modules are established, each module is formally modelled using a class diagram of the unified modelling language.

Table 1 Types of biomedical sensors, measurements and bit rate

Sensor	Measurement	Bit rate
electrocardiogram	cardiac activity	72 kb/s
electroencephalogram	cerebral activity	86.4 kb/s
electromyography	muscular activity	1536 Mb/s
pulse oximeter	oxygen saturation	< 10 kb/s
thermometer	body temperature	< 10 kb/s
glucometer	glucose in blood	< 10 kb/s
bioimpedance meter	body composition	< 10 kb/s
Galvanic skin response (GSR)	electrodermal activity	< 10 kb/s
accelerometer and gyroscope	physical activity	< 10 kb/s

With respect to communications with the sensors, the concentrator element of the personal area network (WPAN) of sensors is the mobile terminal. This device is the one that integrates the framework proposed in this work. At the level of biomedical sensors, there is a large number of wireless devices such as pulse oximeters, monitors of cardiac activity, blood pressure, thermometers, glucometers etc. Typically, most of them use Bluetooth-based communications and sometimes they also implement the X73 standard. The data collected by these sensors may contain medical parameters, but also other information such as the geographic location of the user or the configuration of the device. The transmission rates supported by the Bluetooth standard allow communication with the vast majority of existing biomedical sensors [17], as presented in Table 1.

Regarding the evolution of the Bluetooth standard in recent years, version 4.0 (Bluetooth LE or low energy) has been widespread, which is supported by the majority of sensors in the market and by the modern mobile terminals [18]. This Bluetooth enhancement offers significant advantages regarding energy consumption and supports a simpler device discovery procedure, point–multipoint reliability, additional encryption features and a greater number of concurrent connections with respect to previous versions of the standard.

The standard that defines the communication protocol to ensure communication between any type of biomedical sensor and the mobile device is the X73 standard of interoperability between medical devices. In the past few years, X73PHD has emerged, an evolution of X73 to meet the current needs focused on new personal or portable devices in the point-of-care scenario. This new version is mainly defined within the optimised exchange protocol (ISO/IEEE 11073-20601) and within the specific standard for the sensor device (ISO/IEEE 11073-104xx). The X73PHD standard defines the agent and the manager as fundamental elements in communication. The agent represents the personal health equipment (sensors), while the manager is the intelligent processing terminal (mobile terminal).

The main function of the X73 middleware is to provide a standardised communication interface for the exchange of information between these two elements. To that aim, the standard describes an abstract model constituted by three elements:

- *Domain information model (DIM):* It particularises the information that an agent sends as a set of objects with their respective attributes. The attributes are used to define medical data, also representing different states and behaviours of the agent. In addition to these attributes, objects can also have a set of *get* and *set* methods that can be invoked by the manager to communicate with the agent.

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• *Service model:* It defines an efficient and flexible protocol used by the agents and the manager to exchange the data defined in the DIM.
• *Communication model:* It defines the interaction model in the communication between the agent and the manager through a finite state machine.

The integration of X73PHD with the Bluetooth specification becomes a reality through the Bluetooth HDP profile. Other communication profiles that include the X73PHD are the personal universal serial bus (USB) Health Device Class (PHD) and the ZigBee Health Care, which have not been considered in this Letter, since Bluetooth technology is the one that has greater support in the majority of biomedical sensors currently available in the market.

The layered structure of the X73PHD protocol stack is composed of the lower layers, which match the layers 1–4 of the open system interconnection model and define the transport technology. On the other hand, the upper layers comprise the communication protocol X73-20601 and the specialisation of the X73-104xx sensor. Fig. 1 shows the Bluetooth layer model on the agent side and the integration with the framework proposed in this Letter.

In this sense, at the lower level of the layer model, the logical link control and adaptation protocol (L2CAP) is located. It is responsible, among other tasks, for the management of the quality of service and the segmented, and also for the assembly of the frames.

Different communication channels can be established via L2CAP using the protocol service multiplexer through the registration of a unique identifier. The multi-channel AP is the one that provides a connection to manage several devices simultaneously. In this way, it offers different control and data channels for each connected device, depending on the requirements of the device.

Additionally, each type of biomedical sensor has a particular multi-channel adaptation protocol data end point (MDEP) data type associated. Depending on its value, a logical function sink (or source instead of sink for the specific agent side) is established within the device data specialisation level. This logical function sink is modelled from a hierarchy of elements associated with the DIM and it is based on the information that the device handles and on its behaviour.

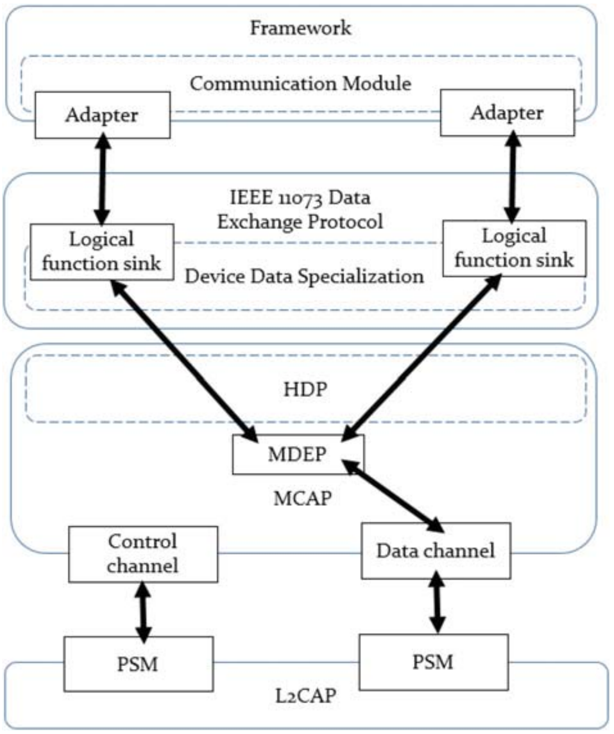

Fig. 1 *Layering scheme for the Bluetooth communication at the agent side and integration with the framework using adaptors*

The framework adaptors (integrated within the communications module) represent a software component that maps the DIM data types of the device data specialisation level to the JavaScript Object Notation (JSON) format. This JSON format is technology-independent and is widely used today in all types of systems due to its ease of being processed, stored and sent remotely. Similarly, the adaptors also inform on the possible states of communication between the agent and the manager through the different phases of the communication process:

• *Association:* It occurs when the agent sends an association request message in order to establish a session with the manager. The manager analyses the message, verifies its integrity and approves or does not approve it depending on whether an acknowledgment of acceptance or refutation is sent, according to the configuration offered by the agent.
• *Configuration:* In this phase, the agent transmits more specific information about the configuration and the types of data handled. The manager stores all this relevant information and immediately responds with an acceptance to the agent.
• *Operation:* In this phase, a physiological measurement of the user is sent to the manager from the agent periodically or on request. The manager sends a validation to the agent through the *get* message.
• *Release:* Finally, the communication of data between the agent and the manager is released to finish the communication. The agent sends an association release request to terminate the current session and the manager responds with an acceptance message.

With respect to security, HDP secures data channel and control channel communications through encrypted links with authentication between the agent and the manager. Once the information is propagated to the framework, data is stored in the local SQLite database using symmetric-key encryption.

Finally, a GUI is integrated in the framework through the presentation layer (MVC view) in order to complete the development of the mobile application for the end user. The presentation layer is built on the top of the framework and gives a user the possibility of configuring and interacting with the mobile application through graphical interface components. Given the iterative nature of the design of mHealth technologies, two thematic constructs emerge pertaining to practises and considerations in the design of a GUI: user-centred design and interdisciplinary team approach. In this sense, the design of the graphical interface of the framework was based on a conventional methodology that has as a basis a user-centred design, and it is composed of four main phases: study, design, construction and evaluation [19]. The participation of a multidisciplinary group in some of these stages contributed to the personalised adaptation of the main graphic constituents of the interface including typography, colours, position of components and interaction, among other. On the other hand, the end users of the application were grouped according to their physical and cognitive limitations, as well as to their computer knowledge and the technological barriers imposed by the hardware they have been using. This allowed the adaptation of the navigation flow of the graphical interface to the different groups taking into account these restrictions, and presenting a friendly, simple and personalised visual environment based on continuous user feedback from the early stages of development.

Currently, the framework has been implemented for Android devices. However, modular design allows an easy integration in other mobile platforms such as iPhone operating system (iOS) and Windows Phone. Several source-free libraries and tools for Android that have been used in the implementation of the framework in order to facilitate the development of certain tasks are as follows: GraphView, Gson, Java-Websocket, OrmLite, Eventbus and Antidote.

3. Results and discussion: A modular approach to develop the framework has been considered through an API which provides a set of flexible modules selected depending on the sensor used. This way, Table 2 summarises the three MVC components on which the framework is based, and the modules that have been implemented.

Regarding the nature of the modules, there are three different types: mandatory modules, optional modules and specific modules. Mandatory modules are the core of the application and are present in all instances of any sensor device. The four mandatory modules are:

- *Communication module:* This is responsible for the transmission/reception of data to/from the sensor device via Bluetooth, abstracting all the complexities of the communication to the upper layers.
- *Database module:* This module stores all the data collected from the sensors, as well as the configurations of the sensors and logs in an SQLite database.
- *Log module:* This monitors all activity and events that occur in the framework and stores them in registers (information, errors or warnings).
- *Data management configuration module:* This module provides an access interface to configure some aspects of the data handled by the framework, concerning the database, the communications, the logs or other issues.

The optional modules can be integrated or not in the sensor instance, depending on the needs of the application being developed. Currently, two modules of this type have been defined:

- *Sensor configuration module:* This module informs about aspects related to the sensor device associated with the instance, for example, calibration, misplacement, if the device is locked or the current state of the battery.
- *Cloud module:* It is responsible for the data communication to an external location.
- *Presentation module:* This implements the graphic elements of the GUI.
- *Graphical interface configuration module:* This module allows to establish the location of the graphic components depending on the type of sensor and/or the data monitored.

Finally, the specific modules are those applying only to a particular type of sensor. An example of a module of this type is the processing module associated with the fall sensor, which is responsible for discriminating whether a particular impact corresponds or not to a fall.

Fig. 2 shows the layer architecture of the developed API, where two instances of sensors and the modules they include are presented. As it can be seen, the mandatory modules are present in both instances and are highlighted in red, while the optional and specific ones are in white.

Table 2 Modules implemented of the framework, grouped according to the components of the MVC pattern

MVC components	Modules
model	1. storage module
	2. processing module
	3. cloud module
	4. log module
	5. data management configuration module
view	1. presentation module
	2. graphical interface configuration module
controller	1. communication module
	2. sensor configuration module

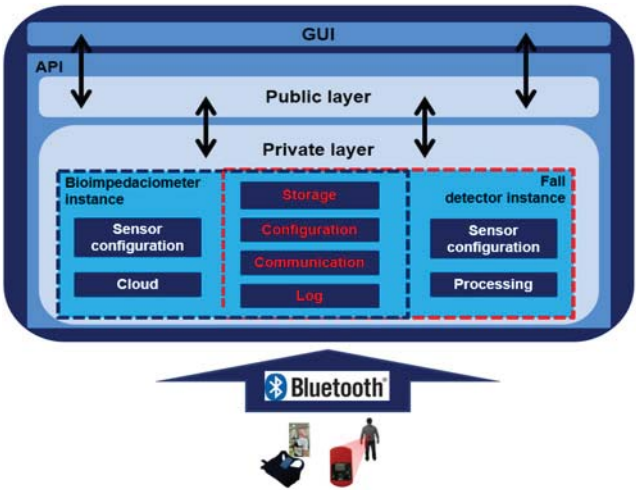

Fig. 2 *Layered architecture of the framework proposed*

For a preliminary test of the developed application, a smart fall detector [20] has been used. For the design of the graphic interface of the application, several questionnaires and interviews have been made to the final users with the objective of detecting possible needs or requirements. Under this perspective of design, the graphic interfaces have been constructed to be adapted to any type of device, screen and resolution, considering also the technological capabilities and knowledge of the final users as well as the possible physical or psychic limitations thereof, facilitating in this way the accessibility and usability of the application. Fig. 3 shows a screenshot of the application mobile when a fall is detected and an appropriate emergency service is alerted.

In summary, the present framework proposes a software solution addressed primarily, but not exclusively, for simple communication environments with a single sensor or for a reduced set of sensors. Thus, it allows the developer to focus on data collection, omitting the complexity about the underlying communications architecture. The modularity of the framework permits the software to be scalable to more complex scenarios.

Currently, the design and development of the framework is involved within the context of a research project on long-term care, so the fix of bugs and future upgrades are guaranteed. Finally, the developed software is still in a testing phase, but the

Fig. 3 *Snapshot of the application mobile when a fall occurs*

authors plan to free the code of some modules from the framework for the scientific community after the finalisation of the validation stage of the project. This is planned to take place throughout the next year and under lesser general public licence. The next steps of the framework software will consider more complex scenarios and will integrate other types of sensors in compliance with the X73 standard family.

4. Conclusions: A framework has been designed and implemented that facilitates the implementation of mobile applications for the management of a WPAN based on the ISO/IEEE 11073 standard. The design of the application is based on specifications that guarantee the reusability, interoperability and scalability of the functional modules, forming a system that meets the characteristics of open architectures. The tool allows the user to configure the final information in a standardised way regardless of the sensor being used. As a case of use, a mobile application has been developed that integrates the proposed framework for the management of a fall detection sensor.

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