Architecture for Lifestyle Monitoring Platform in Diabetes Management

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Abstract. Diabetes management has no patterns in the actual health industry. Many models have been presented for monitoring its behavior focusing only in glycemic values and basing patient evolution on diary records. The presented system describes the architecture for fully monitoring diabetes patients through a platform of sensors and a mobile device. Nowadays there is a lack of interoperability standards between sensors and managers, for this, the architecture has been split out into three layers that mask main functionalities and allow adaptation for incoming 11073 standard and certified sensors.

Keywords: Diabetes, eHealth, Sensors, 11073.

1 Introduction

Information from WHO (World Health Organization) reveals the alarming rise in the number of population affected by any type of diabetes mellitus. The fact sheet [1] indicates that in 1985 there were around 30 million people with some type of this metabolic disorder. In 2000, this number increased to 171 million and predictions point that it will reach 366 million people in 2030, drawing this disease as an epidemic.

Nevertheless, some authors have considered the direct cost of diabetes mellitus in Spain oscillating between 2,400 and 2,675 million Euros per year [2]. Hospitalization expenses and the cost of other drug different from insulin figure as the heaviest batches. These studies show the importance of investing in prevention and also affirm the huge cost for managing associated diabetes complications, which can be avoided keeping a good control of the disease [3].

As a matter of fact, rising both micro/nano mobile computing technologies and biomedical sensors development open a wide spectrum for monitoring complex diseases such as diabetes mellitus. Literature has several proposals in this line [4] [5], reporting evidences for improvements in glycemic values.

Diabetes patients are expected to register the results of blood sugar and insulin intake in a notebook diary, which is shown to the specialist each appointment. Compliance and diligence on completing this basic information to the caregiver is variable and erratic. Large data collections would allow physicians to improve their diagnosis and treatment set-up.

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Healthcare industry is progressively focusing on putting standards for a new era of m-health and e-health systems. But till nowadays it is still missing the real implementation of a full-standardized system. Nonetheless there are many companies working together [8] to overcome this hurdle for the development; but so far only "AND" and Nonin companies offer certified devices compliant with 11073 standard.

This paper presents two monitoring strategies for diabetes patients. On the one hand, it describes the Application Hosting Device (AHD) of the patient station that manages the sensor platform and allows sending IHE-PDC messages that will be compliant with Continua Health Alliance [8] at a WAN level. On the other hand, it also describes a mobile application for monitoring patient lifestyle.

The whole system provides a metabolic profile that integrates information were other systems do not provide. The patient application gathers multiple physiological data from the sensors, for instance, blood pressure, level and duration of performed physical activity, weight, height, consumed energy, values of glucose as well as insulin bolus. In addition patient lifestyle information is recorded in a mobile device.

Evaluation results regarding usability and improvement on the diabetes management will be gathered by two pilots in different focus groups in Spain (Madrid) and Italy (Parma).

2 Methods

The principal purpose was to create a system that gives the opportunity for both the patient and also to physician to check the current status of the disease and its evolution.

The applied methodology that has been used is goal-oriented and carried out in five different stages described below:

2.1 Research Phase

At the beginning of this phase interviews with the different actors involved in the system have been carried out: endocrinology specialized physicians and diabetic patients.

Afterwards, a state of art regarding the selection of sensors used in the system has been made; Chosen sensors are based on the following requirements:

- Fulfillment of European Union regulation.
- Available Application Programming Interface(API)/SDK (Software Development Kit)/Controls
- To be intuitive and user friendly handling.
- Provide data output/interface

The sensors must provide data regarding glycemic values, blood pressure, weight and performed physical activity.

2.2 Modeling Phase

Different types of information acquired from several data sources must be stored in a homogeneous database. The system core must contain the database and the Patient Mobile Device (PMD) should work as a data collector.

The system is classified into three interconnected subsystems:

1. Tablet/UMPC PMD.
2. PDA PMD.
3. Central Server Unit (CSU).

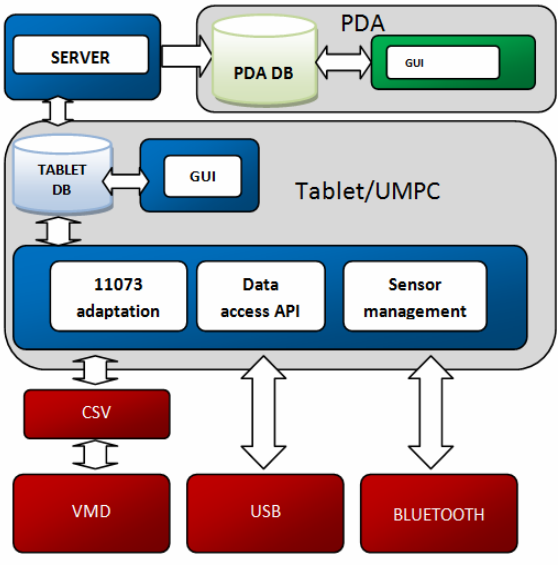

Fig. 1. Stack overview

Tablet/UMPC PMD hosts the subsystem to acknowledge data from medical sensors. PDA PMD subsystem has been modeled as set of forms and questionnaires where the patient will be able to register daily information related to his lifestyle and evolution of the disease. Central Server Unit behaves as a data assembler and service provider. Figure 1 shows the basic structure of the whole system and the access point of each module to its correspondent module.

Regarding the proposed Tablet/UMPC subsystem, an architecture of three modules has been constructed to isolate different functionalities related to Data Access Layer (DAL) and Business Layer (BL). These three modules are 11073 adaptation, Data Access API and Sensor Management.

BL lies into the Sensor Management module. Here, constants and methods are defined for setting up the communication interface over Virtual Medical Device (VMD), USB and Bluetooth physical layer.

Once the sensor has been recognized by the Sensor Management module, Data Access API module retrieves information such measurements and configuration parameters from the device. This module is the layer that masks the methods, protocols and indispensable commands to carry on data exchange between sensors and the system.

After insuring that the data has been received properly, invalid values are discarded and filtered before being stored in the database locally into the Data Storage Unit (DSU) named Tablet DB. Thus, values can be shown as feedback for the patient using graphs and been transferred to the CSU using web services whenever internet connection is available through x73 WAN messages.

11073 adaptation module was designed to encapsulate stored data into x73 WAN messages compliant to Continua Guidelines v1.5 that may be sent to the upper layer in the CSU.

2.3 Requirements Phase

Due to the limitations found during research phase and explained in Results chapter, it has been mandatory to add a Tablet/UMPC device to the architecture to host the module that enables collecting data from the sensors.

The portable device persists in the system because it is the simplest way the user can introduce real-time notifications regarding insulin intake, food ingestion as well as, the daily life events related to the diabetes.

2.4 Development Phase

Both resident tool in the portable device [Compact Edition] and the application that works on the Tablet/UMPC, has been developed using Visual Studio 2008 environment with C# and Framework 3.5, since it provides Web Service support and easy access to Windows Operative System resources. In addition, SQLServer 2008 has been selected for data base engine.

Design and performance for GUI elements have been developed using Photoshop CS4.

2.5 Evaluation of the Test

Two pilots still taking place in Spain and Italy to tests the system. The idea is to have an individual diagnosis of a group of selected patients before the finalization of the implementation of the system. These pilot experiences will help to obtain valuable results and adapt the platform to patient and professional needs.

An in-depth interview is carried out to acknowledge the opinion of a focus group; the procedure will consist of a set of open interviews before, during and after the test of the system.

The technique consists of a semi-structured open interview subject that may not necessarily follow a previously set sequence. The sequence will be determined by the response of the patient interviewed. This methodology focuses over the speech analysis, and will address also usability questions.

In the theoretical sampling the number of studied cases will not affect as the potential of each case, to help in the development of theoretical understandings about the study area. After completing interviews with volunteers, the sample will be diversified depending on the type of people interviewed to cover the entire range of perspectives of people in which we are interested.

3 Results

After the research phase, it has been possible to state that the implantation of standard 11073 has not become general in the commercial sensors. In addition, most of the manufacturers are reluctant to share any API or SDK for third party purpose.

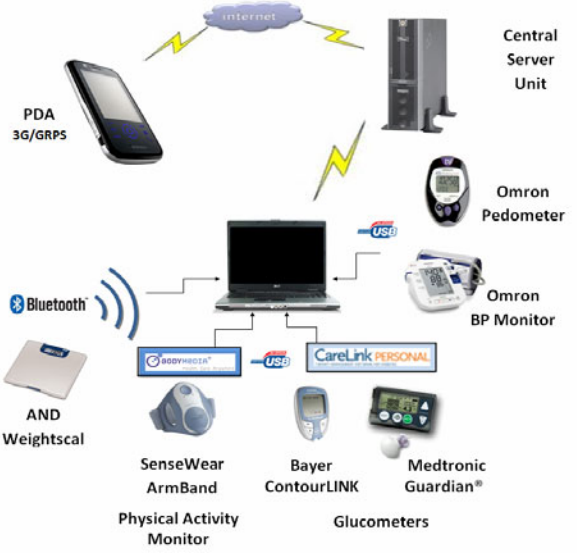

Fig. 2. System overview

Bluetooth interface is available in a quite large number of sensors and PMDs (PDA, Tablet/UMPC) but they may use different Bluetooth stacks depending on the manufacturer. Also to this, most of evaluated PDAs do not support USB hosting, an indispensable capability to enable communication interface of USB sensors.

Figure 2 shows an overview of the complete system.

The sensors of the system are shown in table 1.They have been classified according to their interface to data:

Table 1. Sensors of the System

Sensor	Group
Medtronic Guardian CGMS- Continuous Glycemia Monitoring System	2
Bayer Contour-Link Glucometer	2
SenseWear ArmBand – Physical Activity Sensor	2
OMRON HJ-720IT Pedometer	1
OMRON MT-10T Blood pressure	1
AANDD Weight Scale	3

Group 1: USB-HID access

Communication protocol of the sensor is deployed by a software module that uploads the collection of measurements using USB connection between the device and the Tablet/UMPC. These devices behave as Human Interface Device, a generic group of USB family.

Group 2: VMD access

Virtual Medical Devices (VDM) are devices than cannot be reached directly either through USB and Bluetooth Interface. Through manufacturers own driver, data is exported in a CSV (Comma Separed Value) file. This file is parsed by the VMD software module and measurements are ready for processing.

Group 3: Bluetooth access

Using Bluetooth hardware access libraries, such 32feet, the communication protocol of the sensor is deployed. Then, the measurements are acknowledged by the application.

PDA PMD subsystem consists of a structure of forms based con custom User Controls performed for this purpose. The patient will be capable to register:

- Physical Activity events, describing the activity carried out, the level and the duration.
- Food intake events, specifying the menu and CHO quantities.
- Blood pressure, weight and glycemia measurements manually.
- Medication intakes such insulin and other drugs.
- Special events such stress at work, holiday and birthday party.

These records are gathered in a Diary application that allows seeing all-day events sorted by date.

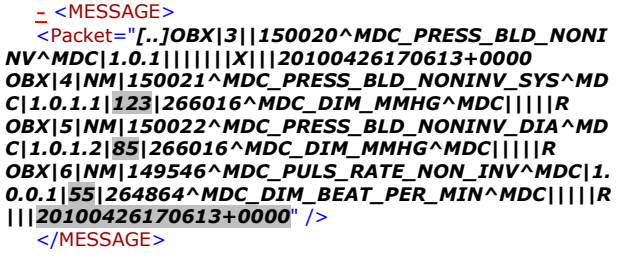

Fig. 3. BP Encapsulated Message Sample

Data which comes from the sensors it's gathered and stored for reviewing whenever patient or doctor wants to do it. Also it gives the possibility of introducing commentaries and sending the report to the physician.

Measurements are encapsulated on x73 WAN messages according to Continua Guidelines v1.5. In figure 3 an example of a blood pressure message is shown.

This schema is based on HL7 v2.6 Unsolicited Observation Result and IHE-PCD public standard.

4 Discussion and Conclusion

The work presented in this paper shows the first approach for diabetes monitoring system split out in modules. Each of these modules may be replaced as technology and the implantation of standards and interoperability rules takes over in health care industry. The new generation of healthcare systems must be based on user-transparent platforms and Machine to machine protocols (M2M), and also provide a continuous stream of data from patient squeezing ICT possibilities. Healthcare sensors interfaces to transmit data and manufacturers policy regarding the communications protocols have been two of the mos important limitations for the realization of this study.

Acknowledgement

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