Advanced multi-sensor platform for chronic disease home monitoring*

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***Abstract*—Nowadays chronic diseases affect an ever-growing segment of population in developed countries; and the management of such kind of diseases requires a huge amount of resources. Chronic Heart Failure, Chronic Obstructive Pulmonary Disease, Diabetes, etc. are the main causes of hospitalization for elderly people, and considering the general aging of population this may lead sustainability problems in the near future. In the last years, clinicians and administrators have identified the telemedicine as strategy to improve the patient management, ensuring both a decreasing of hospital admissions and improving the patient's quality of life. This paper presents a complete system for the management of the healthcare information related to the chronic patient treatment, integrating three main elements: a configurable multi-sensor platform for the acquisition and transmission of vital signs, a dedicated server for the provisioning of centralized telemedicine service and the possibility to synchronize the electronic health record.**

Keywords—Multi-sensor acquisition; chronic diseases; telemedicine; telemonitoring.

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I. Introduction

The increasing number of people affected by chronic diseases represents an important challenge for the National Health System (NHS) in any developed countries.

The most common diseases are: Chronic Heart Failure (CHF), Chronic Obstructive Pulmonary Disease (COPD) and diabetes. These are affecting approximately 15 million people in Europe with an incidence of 3.6 million new cases every year; and they have the same trend also in US. [1] Chronic diseases represent the leading cause of hospitalization in older adult. Considering the progressive evolution of such diseases, the ideal healthcare model should rely on a continuous monitoring of vital signs, in order to recognize and attend as soon as possible the symptoms of incoming destabilizations.

Instead, the traditional healthcare model is based on periodic visits, often provided by specialized centers. This dramatically causes a high hospitalization rate because it does not fulfil the need of continuous monitoring of the health status. The consequences are a reduction of the quality of life of the patients and the increasing of the costs sustained by the National Health System due to the hospitalizations [2]. Studies have shown that a large part of such hospitalizations in chronic patients are avoidable recognizing the signs of decompensation before they become irreversible. [3]

In this scenario, a more efficient and adequate care model returns important benefits both for the patients and the NHS. Of course a frequent or continuous monitoring of vital signs is not possible with the traditional model, but instead it have to rely on new ICT platforms and devices.

This paper presents an advanced multi-sensor platform, integrating all actors involved in the healthcare of chronic patients, for the provisioning of personalized telemedicine services based on the home monitoring of vital signs and the circulation of the clinical information among all involved caregivers. This platform potentially improves the quality of life of the patients, reducing the number of monitoring visits and the hospitalization rate. It also can reduce the expenditure accounting the NHS.

Hereafter, the Section II shows an overall description of the ICT platform. Section III, Section IV and Section V describe the sensors, the gateway and the server application respectively. Conclusions are drawn in Section VI.

II. MULTI-SENSOR PLATFORM ARCHITECTURE

The modern ICT technology represents a key factor to implement an efficient remote monitoring service. It allow to reduce the distance and the time barriers, creating a framework in which all the actors can access the same information and contribute to its upgrade.

All the components of the proposed platform have been designed with the rationale to reduce the effort required to be operated, minimizing also the impact on the users (i.e. the patient, the medical personnel, etc.). The final aim of the system is to allow the automatic, transparent and safe flow of clinical information, acquired directly by the patients or by professional caregivers during domiciliary visits at home, towards an e-health service center that represents the connection hub among hospital, practitioners and territory services (e.g. telemedicine, telemonitoring, telecare, etc.).

The overall architecture (see Fig.1) consists of three main elements, interconnected exploiting the Internet network:

- The multi-sensor tele-monitoring system, usually installed at patient's home, allows acquiring and transmitting vital signs to the service center. It consists of a set of biomedical, eventually wearable, sensors and a programmable gateway in charge of reminding the personalized activities established for the patient and taking care of the data management;
- The service center server that acts as a central hub for the data and information exchange. All modules communicate through the center: its software allows the management of chronic patients and the integrated database stores all the data and information making them available for the integration into the Electronic Health Record (EHR) and the Hospital Information System (HIS);

The general practitioner module allows the family doctor to interact with the clinical information of the followed patients,

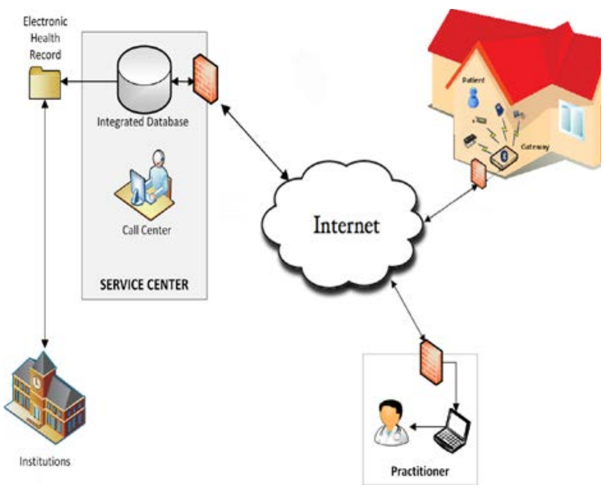

Fig. 1 The overall architecture of the proposed platform

TABLE I List of selected biomedical sensors

Sensor	*Patology*	*Technical data device*
A&D weighting scale (UC-321PBT)	CHF	Range 0-200 Kg; Resolution 100 g; Bluetooth SPP
A&D blood pressure monitor (UA-767PBT)	CHF, COPD	Pressure: 20 mmHg to 280 mmHg; Pulse: 40 to 200 pulses/minute) Accuracy ± Pressure: ±3 mmHg or ±2%, whichever is greater; Pulse: ±5%; Bluetooth 2.0 SSP/SPP
Saturimeter Nonin Onyx II 9560 Bluetooth	CHF, COPD	Oxygen Saturation Range (SpO2); Oxygen Saturation Accuracy ± 2 digits; Bluetooth 2.0
Glucometer Lifescan UltraEasy with bluetooth (BA-110) H3System	Diabetes	Range 20–600 mg/dL; Bluetooth 2.0 SPP
SPIRODOC spirometer, MIR	COPD	Flux measure: ± 16 L/s Volume accuracy: ± 3% o 50 mL Flux accuracy: ± 5% o 200 mL/s; Bluetooth 2.0 SPP
Corscience BT12 ECG	CHF	12-channel derivation; Continuous ECG measurement with wireless data transmission; Pacemaker detection; Bluetooth 2.0 SPP

realizing at distance the evolution of the disease.

III. SENSORS

The basic function of the sensing module is the acquisition, processing and transmission of the patient's vital signs to the home gateway. All involved sensors, both commercial or ad-hoc developed, are non-invasive, Bluetooth and battery-powered. They required to be used or wear only for the duration of the measurement, avoiding long-term installation of the patient's body.

The pathologies of interest are, in order of priority:

1) Congestive Heart Failure (CHF);
2) Chronic obstructive pulmonary disease (COPD);
3) Diabetes.

Table 1 summarizes the technical features of the commercial biomedical sensors selected in the presented platform to assess the clinical status of patients. Along with these devices, an ad-hoc wearable sensor to measure the movement and the energy consumption has been implemented. The rest of this Section describes the movement sensor.

A. Features of the movement sensor

For the special parameters, related to the study of body movement, it has been developed a specific sensor based on an inertial platform for the analysis of human movement. In particular the sensor is able to extract the following parameters:

- Fall detection / no movement detection
- Energy consumption
- Step detection
- Stride estimation

The goal was to design a sensor that is small and lightweight enough to be worn comfortably without obstructing normal activities, also for medium-term periods.

B. HW/SW architecture of the movement sensor

The sensor's board has a 9-axis MEMS Inertial Measurement Units (IMU) System in Package (SiP). The SiP contains a gyroscope, an accelerometer and a digital compass.

All these sensors are triaxial and an appropriate run-time algorithm allows a perfect space calibration and realignment, a typical problem that affects these particular sensors. The combination of these three sensors showed a promising design for the extraction of physiological parameters related to movement analysis.

The device uses a STM32 ARM microcontroller for embedded applications requiring a high level of integration and low power dissipation and is powered with a single Li-Ion 150 mAh battery.. Communication with the gateway exploits a Bluetooth 4.0 LE chipset, integrated into the device. The aspect of the sensor board is shown in Fig.2. Two built-in algorithms run on the device: the first computing the step detection, stride estimation and energy consumption; the second determining the fall detection or no movement revelations.

First tests of the device showed a battery life (with the algorithms running and the radio interface active) of about 48h.

C. Detailed design of the movement sensor algorithms

The algorithm implemented for step detection consists of the four stage [4]. In the first stage, the magnitude of the acceleration a_i for each sample i captured by the accelerometer is computed. In the second stage, the local acceleration variance is computed to remove gravity. The third stage uses two thresholds: firstly, (T_1) is applied to detect the swing phase, whereas the second (T_2) is applied to detect the stance phase (B_{2i}) in a single step while walking. The fourth stage is detected in sample i when a swing phase ends and a stance phase starts. The estimating the Stride Length (SL) is necessary, at every detected step, in order to calculate the total forward movement of a person while walking. Here, SL depends on the person, its leg length, and its walking speed and the nature of the movements during walking, etc. The

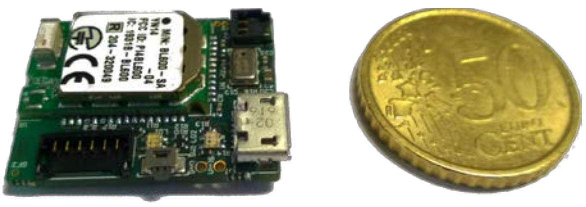

Fig.2 The movement sensor board

algorithm proposed by Weinberg [5] assumes that SL is proportional to the bounce, or vertical movement, of the human hip. This hip bounce is estimated from the largest acceleration differences at each step. The algorithm implemented for SL estimation consists of the following steps [4]. The first step computes the magnitude of accelerations a_i. The second step estimates the SL using the Weisberg expression:

$$SL = K\sqrt[4]{max_{j=(i_p\pm w)}^{\widetilde{a_J}}} - min_{j=(i_p\pm w)}^{\widetilde{a_J}}$$

where the maximum and minimum operations are applied over the filtered accelerations in a window of size $2w+1$ around the sample $i_{(p)}$ corresponding to the p stance detection. K is a constant that has to be selected experimentally or calibrated. If the length *SL*, estimated by the method above, and the frequency of the *step* is known, it is possible to derive the velocity of each step as the ratio of the two sizes. The velocity of the single step is the basis of the estimation of the energy consumed during the walk. Depending on the velocity, the *MET* (Metabolic EquivalenT: one MET corresponds to an energy consumption of about 1 Kcal / Kg / h.) can be computed.

Note that from the level of METs [6] it is possible to estimate the energy consumption (EC in Kcal) of a walk, knowing the mass of the patient and the corresponding walking velocity.

$$EC = MET\ x\ m\ x\ \Delta t_{step}$$

where m denotes the mass of the patient in kg and Δt_{step}, in seconds, corresponds to the time for the step p stance detection.

The algorithm implemented to determine the fall detection is based on the controls of the thresholds. A fall-like event is defined as an acceleration peak of magnitude greater than 3g followed by a period of 2500 ms without further peaks exceeding the threshold. The accelerometer-sampling rate has been set at 50 Hz, a trade-off between resolution and power consumption [7]. Threshold values around 3g (in general, ranging from 2.5g to 3.5g) have been widely used in other fall detection systems [8]. The value 3g is small enough to avoid false negatives, since real falls are likely to present an acceleration pattern containing a peak that exceeds such a value.

Several sensor placements have been already tested, e.g. the waist, trunk, leg, hip and foot. In this paper the sensor is mounted on the hip. Although data from all locations provided similar levels of accuracy, the hip was the best single location to record data for activity detection. It provides better accuracy than the other investigated placements [12]. This location is optimal for the implementation of more efficient algorithms, as it allows having a cleaner signal from the IMU. However the exact position and orientation of the platform on the hip is not important, because many algorithms only work with the magnitude of sensor readings.

IV. GATEWAY

The gateway is the element of the platform in charge of acquiring data from the sensors wirelessly and providing all the necessary computation and communication resources in order to allow the automatic transmission of data towards the centralized server.

The Fig.3 describes the context in which the gateway system operates. On one side there are a number of heterogeneous diagnostics tools for data acquisition. These tools can be used in different contexts having the need of a dedicated concentrator for their transmission towards the reporting physicians. On the other side there are a number of vertical clinical data management tools, each of them is dedicated to a different clinical context but clinical data are often the same or similar, certainly come from the same instruments. Between these two elements, to act as a bridge between the world of tools and management platforms there is the gateway of clinical data. In order to close the gap between data acquisition and data management, and to implement a flexible solution, it leverages a specific software layer called Gateway Integration Engine.

The gateway has three main features:

- acquire data from instruments with different communication channels;
- send them to the data center;
- distribute them to different platforms.

The results of this analysis show the decomposition of this element in two main parts.

- Client Gateway (Acquisition);
- Server Gateway Integration Engine (Distribution).

The first element is the point of contact with the patients or the caregiver assisting them.

From the analysis of requirements and need to make a product that might be used in different application contexts it was decided to develop the Client gateway on the Android 4.2.2 platform in order to have a reusable system on various instruments:

- Set-top-box;
- Tablet;
- Smart Phone.

The use of mobile and wireless technologies to support the achievement of health objectives has the potential to transform the face of health service delivery across the globe [9] [10].

From the functional point of view, the client gateway has the following macro-functionality:

- intuitive User Interface;
- several communication interfaces (Bluetooth, Serial, Wi-Fi, Ethernet);
- business logic for data acquisition, processing, transmission and management of the personalized agenda of activities defined by the caregiver;

The user interface is a module that can be adapted for the different platforms. In any cases it has to be very intuitive and easy to use considering the target user. It consists of:

- Status LEDs to alert the user of the states related to the hardware component of the box (e.g. power on/ off, channel network, etc.)
- Communication LED to give the application messages to the user. It is in RGBW technology and, properly controlled provides messages to tell about the status of the acquisition and to implement the reminder functionality using a color-code approach;
- Speaker to help the user with sound messages (including voice) that convey information about the measures to be performed or already performed.
- TV connector to connect the set-top-box client gateway, optionally, to the home TV (if near and if equipped with HDMI interface) and obtain a richer user interface. Part of this user interface is the same available in the Tablet version of the client gateway.

The part of communication bus is dedicated to the interface with the various diagnostic tools and it is able to acquire data from instruments connected to different communication channels.

Business logic acts as a link between the transmission, data acquisition and user interface. In particular:

- encapsulate the data acquired by the instruments in an XML format that contains the data in raw format (which allows to maintain the medical certification of the platform when both sensors and medical server are both certified);
- transmit data with the communication channel available to the server gateway integration engine;
- control the user interface;

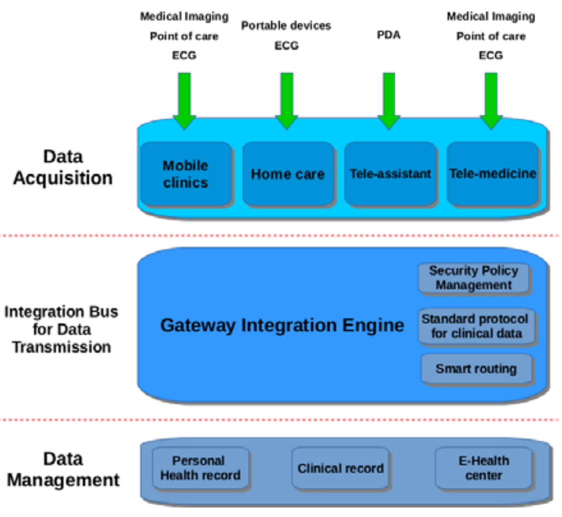

Fig.3 Operating environment of the gateway

- manage the security of data transmission;
- manage the agenda of the patient (received from server);

From the point of view of interfacing with personal medical devices, the application handles the communication essentially via the Bluetooth interface, in particular using the RFCOMM protocol and the profile HDP (Health Device Profile) [11].

The software architecture of the client gateway is based on five main modules, in order to simplify future upgrades, also aiming at increasing the number of connectable devices. The first module provides the user interface and includes the various graphics and multimedia resources (movies for the use of the devices, audio for feedback etc.) to communicate with the user. The second module manages the connections with medical devices, creating communication channels suitable for sending and receiving data. Third module (interaction between the application and the hardware) performs the low-level functions for the activation of the LEDs and the speaker. These functions are implemented in C with Arduino IDE. The fourth module has the task of interpreting the data received from sensors to make them readable. The fifth and last module takes care of sending safely the raw data embedded into XML tags by exploiting cable or Wi-Fi external Internet connection.

The other main element of the architecture is server gateway integration engine. This element is the link between data and the large set of heterogeneous management platforms on which the telemedicine services are based on.

The technology used for the development of this part of the system is Java 2 Enterprise Edition (J2EE). The strategic decision to use J2EE technology provides extreme flexibility concerning the configurability. In fact, with increasing the architectural complexity in terms of data volumes and actors, some application services can be configured to predict whether or not the presence of cluster of application server. J2EE also guarantees to the products developed, outstanding portability and integration via XML.

From the functional point of view this module:

- Receive raw data embedded into XML tags from the client gateway;
- Transmit to the client gateway the agenda of the configured patient;
- Allow the complete management of patients;
- Transmit data to the server of the service centers with specific adapters;
- Receive agenda by external clinical data management tools.

With reference to the model in Fig.4, the server gateway integration engine receives the data from the client gateways encapsulated in an XML envelope. Those data are the ones collected by the patients using the assigned sensors. The configuration module allows the remote configuration of the client gateway in terms of agenda of activities to be suggested to the patient, indication to perform the routing of messages to the platform and other configuration of the behavior of the single client gateway. Agendas and configuration in general can either be generated by the patient management module in the standard format or received from external platforms (and eventually adapted) before be pushed to the client gateway. In case of external clinical data management tools the messages coming from the client gateway are forwarded to the collection service. This task can happen without further intermediate steps or, on the contrary, if the exchange protocol is different from that defined and not compatible with the XML envelope defined, a specialized module is responsible for adapting the format of the data.

The hardware architecture of the client gateway is based on a Freescale iMx6 CPU. This CPU hosts a full set of peripherals in order to match the features mentioned above. The block diagram of Fig.5 shows them. This set of peripherals is divided in two main parts:

- User interface;
- Communications.

User interface is mainly dedicated to allow the user's

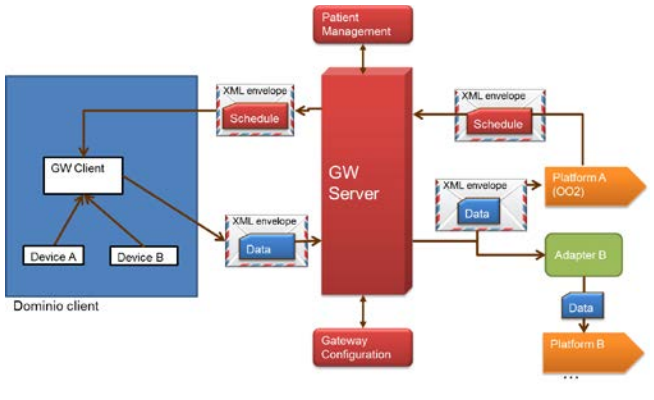

Fig4. Architecture of the communications among client and server gateways

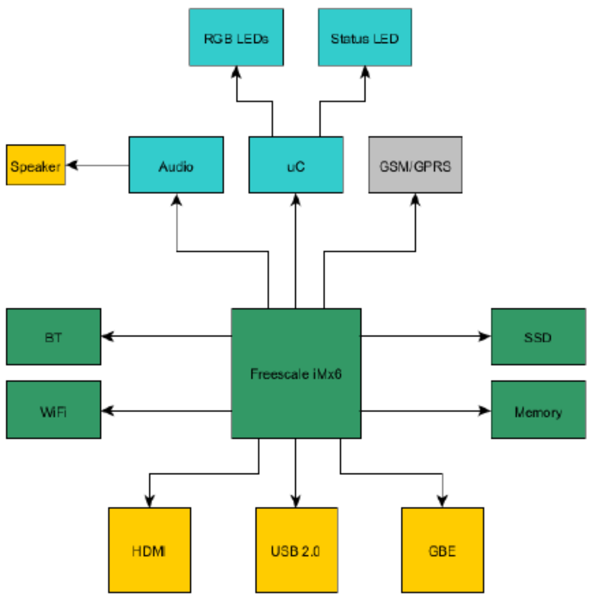

Fig. 5 Block diagram of the hardware architecture of client gateway

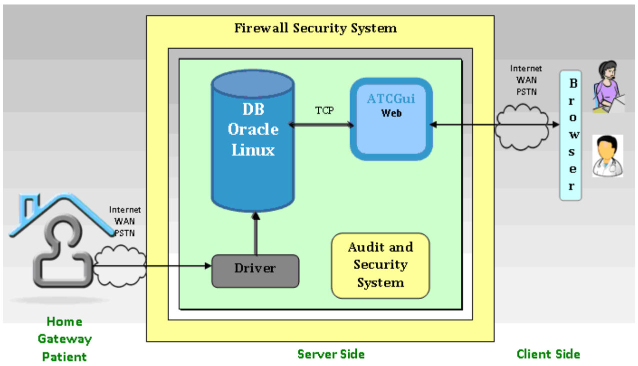

Fig. 6 E-Health center server application

interaction with the data acquisition system and its minimal set is made by Signaling Lights and Audio Speakers. Moreover, an advanced Gateway configuration will allow also Video and Keyboard/Mouse interaction like a standard PC.

The Communication section gives connectivity to the client gateway on both sensors and server sides. Sensors side is covered with a Bluetooth 4.0 interface while the Server side could be covered alternatively by Wi-Fi or Ethernet interfaces. For instance in the typical domestic application, the client gateway is connected to the server gateway integration engine through a common ADSL/Wi-Fi router provided by the ISP.

V. SERVER

The server components implements the e-Health Center, a certified medical software for the remote monitoring of the health condition of patients affected by chronic diseases that require a daily or systematic measurement of some vital physiological parameters.

Patients use the wireless medical devices assigned to them, and the data is sent automatically to the e-Health Center through a gateway. The data are received in raw format wrapped in XML and they are parsed by the e-Health Center itself, in order to allow their use for medical purposes (diagnosis, therapy, etc.). In this way, even in case the intermediate gateway is not CE-marked as medical devices, the whole chain maintains the certification.

The e-Health Center is a multi-disease, multi-device, multi-parameter, multi-language, multi-tenant, web platform for the management of patients and the remote monitoring of their vital parameters. An alarm is signaled every time a parameter is not received within the patient's schedule, and also if a parameter falls outside the ranges. Each patient has different ranges for red, yellow and cyan alarms on each parameter.

Specialized operators receive the alarms and handle them with appropriate protocols that typically include contacting in a defined order one or more of: the patient, his/her caregivers, agreed neighbors and relatives, the general practitioner, emergency services as ambulance, fire brigade, etc. The operator performs further calls as needed and monitors the situation until resolved, recording in the e-Health Center all his/her activities and their outcomes.

Patients can also have emergency ("panic") buttons to directly dial and call the operators for remote assistance.

The server application for the e-Health Center (see Fig.6), is composed by the following software components:

- Oracle database: stores all the data and contains most application logic – including object-oriented PL/SQL data models, patient schedules and alarm triggers. It is in charge of enforcing users permissions;
- C++ web application server: implements and publishes the AJAX-based web 2.0 interface;
- Driver: receives the RAW data sent by gateways, parses them and inserts the parsed measurements into the database;
- Audit and Security System: monitoring component that detects and reports any malfunctioning. It also records the system activity.

VI. CONCLUSIONS

The proposed platform is a flexible means to implement advanced multi-parametric home monitoring of patients affected by chronic diseases. It integrates the in-hospital care of acute syndromes with the out-of-hospital follow-up.
The effectiveness of the platform will be assessed in a technical pilot of three months, involving 10 chronic patients.

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