Personal eMonitors. An open e-health, real-time mobile platform for the acquisition, analysis and processing of medical data.

Giuseppe Baroni, Flextronics Design - Barbara Tornaghi, frog design
Marco Augusto Mariani, GFM Net - Antonio Capone, Politecnico di Milano

Abstract - Personal eMonitors is an open e-health, real-time mobile platform for the acquisition, analysis and processing of medical data. Its components are fully wireless and can be scaled and personalized according to patient needs.

It also includes an innovative wearable sensor, connected wirelessly to a portable hub. The vital parameters collected from the patient via the devices can be monitored in real-time by the trained operators of a Health Center, while alarms can be calibrated for each individual through easily-applicable algorithms via the Health Centre's web platform.

This strongly innovative and highly technologically advanced project has been developed for the specific case of individuals with coronary heart disease, arrhythmia or who have undergone invasive heart surgery, but can be scaled and adapted for the remote monitoring of any disease.

This paper describes the structure and the components of this platform.

I. CONTEXT

Medical inflation is preposterously high in most developed countries. Cost-containment strategies coming from all angles are trying to improve resource allocation, intensifying health promotion and the prevention and early detection of disease.

Though life expectancy is growing, there is a constant increase in chronic disease and disability, as well as an increase in the demand for rehabilitation aids and aids for daily living, in particular in developed countries.

Shorter hospital stays, more specialist consultations outside the hospital environment, greater use of separate centers for convalescent, geriatric, and terminally ill patients, have all increased the need for effective communication and information transfer systems.

Roughly 10 years ago, the medical sphere has begun converting its paper-based archives to digitalized information, and this process is finally picking up speed and bearing its fruits. At the same time, technology is facilitating communications and generating communities all over the world, as new and improved medical devices and technologies hit the market every year.

II. PROJECT OVERVIEW

"Telemedicine, or the offering of health services at a distance, can contribute to improving the quality of life of European citizens as well as those of healthcare professionals, while tackling the challenges presented by the healthcare system" [1].

Personal eMonitors is the outcome of a 2-year partnership among three very diverse corporations (frogdesign, Flextronics, and GFM Net) together with the university Politecnico di Milano. The research program was co-funded by the Lombardy Region (Italy) and the EU Commission, the finality of the project being to "*promote technological knowledge transfer between different industries in a variety of Italian regions*"[2]. Indeed, it was multidisciplinarity and multiprofessionality (ranging from interaction design, software development, mathematics and ICT architects) which enriched the project.

As mentioned, the objective of the project was to design and develop an open and adaptable platform for the remote monitoring of a number of diseases. It was decided to focus on one single disease, specifically coronary heart disease, in order to focus our attentions during the research phase, the user-testing phase and the design and development phase.

The project began with the collecting of census material from a number of highly regarded national and international sources, in order to understand the domain, how the market was contextualised, and who could be involved in or affected by the service.

An intensive ethnographic research phase followed where all the partners worked closely alongside healthcare professionals (cardiologists, nurses, family doctors) and patients. It was through this collaboration that the overall system was defined.

The initial intent was to populate the service with already-existing and off-the-shelf products in order to prove the concept of a truly open platform. Nevertheless, the momentum towards wireless ECG (or EKG, electrocardiogram) devices was quickly picked up by the partners and it was decided to develop a new device: the Smart Patch.

III. SYSTEM OVERVIEW

As illustrated in Fig. 1, the system can be divided in three main stages. The first phase includes a number of wireless medical devices (e.g. ECG acquiring device, glucose meter, blood pressure meter, weight scale) apt for the acquisition, both continuous and episodic, of a patient's vital parameters. These devices send the data in real-time to the Health Agent. The latter is an off-the-shelf portable hub, and composes the second stage of the system. It not only analyzes the data, thus identifying anomalies, it also forwards them to an independent Health Centre (composed of trained staff and with the constant support of specialists) – the third stage. In this manner, the operators at the centre can intervene in case of an emergency by either reaching the patient directly via the Health Agent, or contacting an emergency service.

The Health Agent is a real-time touch point between caregivers and patient. A request for assistance can be sent manually by the patient by pressing a large button on the screen of the device. The Health Agent also allows for the easy update of medication, the booking of hospital visits and health exams, as well as the practical management of the patient's emotional wellbeing and medical documentation.

IV. SYSTEM DETAILED DESCRIPTION

The present architecture of Personal eMonitors is composed by the following sub-assemblies:

- Smart Patch: an *ad hoc* wireless medical device with sensors, able to collect and transmit ECG data;
- Device Node: an *ad hoc* Radio Frequency (RF) device which receives and stores data coming from the Smart Patch, and forwards them to the Health Agent;
- Blood pressure meter: a commercial wireless device, able to communicate blood pressure levels directly to the Health Agent via a Bluetooth connection;
- Pulse Oximeter: a commercial wireless device, able to communicate the levels of oxygen in the blood directly to the Health Agent via a Bluetooth connection;
- Health Agent: a commercial portable hub containing an *ad hoc* application able to receive, analyze and temporarily store the data coming from the Device Node and other medical devices, forwarding them to the Health Center;
- Health Center, an independent center composed of trained staff and medical professionals, which receives and stores data in a dedicated database. Other professionals can have access to the data via a secure *ad hoc* web or smart phone interface.

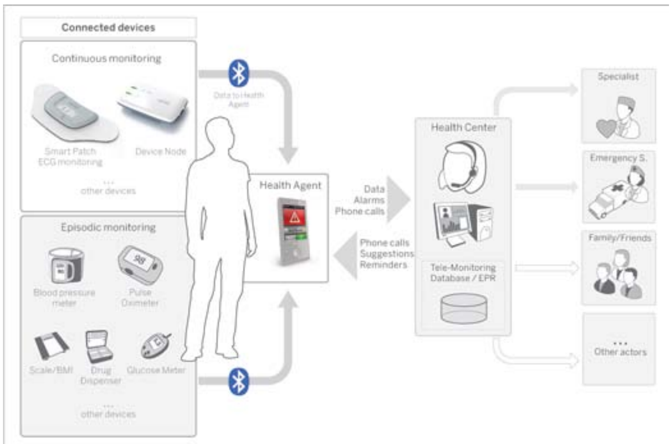

Fig. 1. System overview.

Since some sub-assemblies which compose the platform are represented by already-existing products, the following paragraphs will describe in detail those components that were developed by the partnership for the project.

A. *Smart Patch*

The Smart Patch is a small and very discreet fully wireless device. Its ergonomic and intuitive shape allows the individual to position it correctly under the left pectoral muscle, in the area of V4, V5, V6 ECG derivations. Several prototypes with different shapes and sizes were developed and user-tested. These prototypes underwent ECG acquisition testing in order to validate the distance between electrodes and the position on the patient's body. Fig. 2 shows the working prototype of this part of the system.

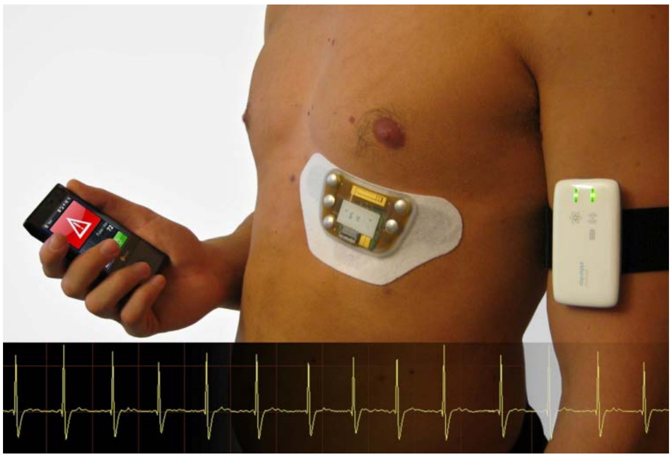

Fig. 2. Working prototype of Smart Patch, Device Node, Health Agent.

The data collected are transmitted to the Device Node using a low-power wireless technology, based on a proprietary protocol. The data are then forward via a standard Bluetooth connection to the Health Agent.

The Smart Patch consists of two parts, as shown in Fig. 3: the Durable, which includes the flexible electronic board and a display, and the Disposable containing the battery and electrodes. Five asymmetrically placed snap buttons allow for the patch to be assembled without error. The Patch turns on only when the two parts are connected, and a plastic display shows that the patch is functioning correctly by illustrating the patient's Heart Rate.

The electronic board of the Smart Patch is designed on a double-sided flexible board (as shown in Fig. 4), connected to a plastic display. The RF antenna is routed on the flexible board as well. All these elements are enveloped in soft, FDA-approved silicon material.

The Disposable part develops on four layers: a top gauze, a flexible single-sided board, an adhesive bottom gauze and a protective bottom layer. The disposable includes three ECG electrodes and a flexible battery (Fig. 4). The purpose of inserting the battery in the Disposable is to avoid the use of an external charger, thus simplifying the interaction between patient and device. At the same time the Durable, which is the most technologically developed part of the device, lasts longer by simply replacing the disposable.

Fig. 3. Smart Patch exploded view.

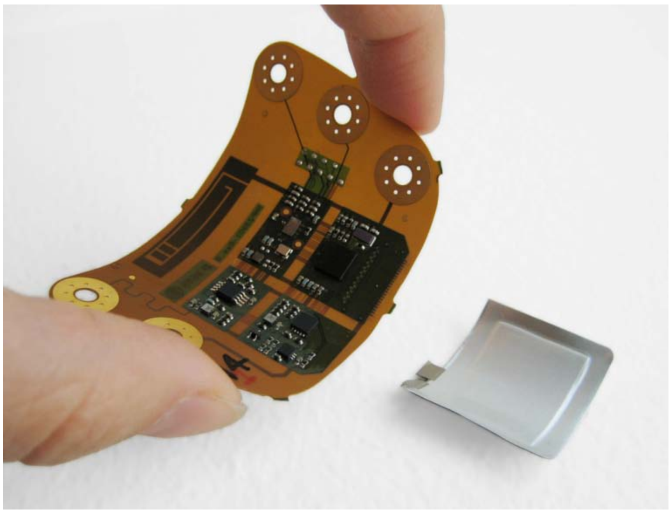

Fig. 4. Double-sided flexible board and flexible battery.

In synthesis, the main characteristics of Smart Patch are:

- Usability: the Durable part can be easily connected and disconnected from the Disposable via five simple and familiar snap buttons. The Smart Patch is designed to be assembled, positioned and disassembled with simple gestures;
- Wearability: both the Disposable and the Durable are thin and flexible in order to be as comfortable and as unobtrusive as possible;
- Minimum dimension and weight: the dimension of the device is 145x75x11mm. Its weight is less than 30g;
- Easy Turn-on button: the button is designed as a capacitive sensor and the activation parameters are a minimum distance of 0-6mm and a time of 3sec.
- Biocompatibility: the Disposable is designed using materials in compliance with biocompatibility international standards, so as to minimize skin irritation;
- Clear Display: it shows the Heart Rate, the RF connection and the battery level of the Smart Patch.
- Easy Cleaning: the Durable can be cleaned using alcohol or water.

B. *Device Node*

The Device Node is the small intermediary between the Smart Patch and the Health Agent. Its role is to receive the proprietary, low power RF signals from the Smart Patch and re-transmit these securely to the Health Agent using a Bluetooth standard channel.

The Device Node was introduced to optimize the battery-life of the Smart Patch, otherwise limited because of the power consumption of standard Bluetooth transmissions.

The status of the connections between the Device Node, the Health Agent and the Smart Patch (as well as the Node's battery level), are easily visible through two LEDs. The Device Node monitors Patch-Node-Health Agent errors and malfunctions, communicating anomalies immediately to the Health Agent. These errors are also visualized by the two LEDs.

From an electronic point of view the device node includes the following features:

- flash memory;
- non volatile memory
- computational capacity (MCU and memory)
- customised low power wireless connectivity
- standard RF connectivity (Bluetooth)
- power supply management
- rechargeable battery

The flash memory acts as volatile storage to securely maintain the data in case the connection with the Health Agent fails, while the non volatile memory can store specific parameters such as the device's serial number and the alarm thresholds.

The Node is designed to be worn by the patient via easy-to-use straps or other fastening mechanism which slip through a designed opening.

C. *Health Agent*

The Heath Agent is an off-the-shelf smart phone with an *ad hoc* application running on it (Fig. 5). The application is designed to provide feedback to the patient regarding the state of the system and its sub-assemblies, and as a means for the patient to interact with the system and more specifically with the Health Centre's operators.

Fig. 5. *Ad hoc* application and user interface.

The Health Agent receives all the vital parameters from the paired devices and is able to temporarily store them. The data are then sent in compressed packages, via a mobile phone network, to a web server, where it can be visualized and consulted using any sort of browser. Data received by the Agent are analyzed for anomalies, with parameters set by Health Centre specialists. In the specific case of the analysis of ECG data the algorithm of So and Chan [3] [4] [5] [6] is implemented.

Triggers can be set to identify parossistic arrhythmia (tachycardia and repeated extrasystole) and bradyarrhythmias. In the case that an alarm is sent by the Agent, the latter connects to the server in real-time and forwards data continuously to the Health Center.

The patient can also receive reminders, suggestions and notifications from the Health Centre via the Health Agent. These are set by the patient's specialist and are personal to the individual's state of health.

Each wireless device is paired to the Health Agent by a Health Centre technician prior to their delivery to the patient. The patient needs only to switch on a device for a Bluetooth connection to be established between the device and Health Agent. The patient can also send an Alarm directly to the operators of the Health Centre, by pressing the large red button at the top of the screen.

D. *Health Center*

The Health Centre provides individuals with a service designed around them and for their specific needs. Technicians configure and pair devices to a designated Health Agent following medical specifications, and set up a patient profile on the Centre's database which can be associated to the patient's medical records. All the data coming from the various Health Agents are stored in a database, visible via a web interface (Fig. 6).

It is via the Health Centre that the platform can be configured to receive data from the Smart Patch in different modes: on demand or hybrid acquisition. In the `on-demand` mode, to target for example symptomatic patients, the ECG acquisition is executed only after the user explicitly requests this, by pressing a button on the Health Agent. In the `Hybrid mode`, useful for asymptomatic patients, the platform is configured to automatically execute ECG acquisition at set intervals. All episodic acquisitions, such as those executed using a blood pressure meter or oximeter, always require the active involvement of the user to be performed.

Fig. 6. Web interface.

Access to the Health Center is protected by username and password. Each stakeholder has a personal profile, therefore allowing for different levels of information to be accessible to different people.

Most important, operators intervene should an alarm reach the Health Centre. Alarms are shown on a video touchpoint alongside the anomalous data received via the Health Agent. The operator, a trained nurse, calls the patient via the Hub and forwards the data to an on-duty specialist, who provides immediate diagnosis.

V. System Application

Within the field of Cardiology, the service could serve as:

- a pre-diagnosis tool for family doctors, reducing significantly accesses to Emergency Rooms;
- a differential diagnosis tool, for those difficult-to-detect symptoms;
- a monitoring system for patients waiting for surgery;
- an improved wearable and totally wireless telemetry system in hospitals;
- a remote monitoring system during the rehabilitative stage following an acute heart event or surgery, allowing for earlier dismissal and the reduction hospitalization costs;
- a monitoring system for patients during a change in their pharmacological therapy, thus avoiding hospitalization;
- a valuable service for people to rent who need to be reassured and encouraged in order to return to a normal life following an acute event;
- an apparatus used by paramedics on ambulances for the quick acquisition of data and real-time transfer to the ER.

VI. Conclusions

Personal eMonitors represents a solid step towards a new generation of tele-medicine platforms composed of discreet and fully wireless devices, alongside open-source communication protocols.

Future scenarios, enriched by new elements such as smart drug delivery devices, improved multimode localization system, low power communications technology (e.g. low power Bluetooth), low-consumption batteries and new ergonomic solutions for wearable sensors, will open other possibilities for the implementation of innovative health care services.

The most relevant future scenarios where Personal eMonitors could be applied are: tele-assistance, remote healthcare, continuous medical monitoring and real-time mobile medical platforms. Such implementations will without a doubt improve patients' quality of life as well as making "medical structures" more compatible with everyday living.

References

[1] AA.VV., "Comunicazione della commissione al parlamento europeo, al consiglio, al comitato economico e sociale europeo e al comitato delle regioni sulla telemedicina a beneficio dei pazienti, dei sistemi sanitari e della società", Brussells, Nov. 2008.

[2] AA. VV., "Bando Metadistretti 2007".

[3] C.-C. Chiu, T.-H Lin and B.-Y. Liau, "Using correlation coefficient in ECG waveform for arrhythmia detection", in *Biomedical Engineering Applications: Basis & Communications*, vol. 17, no. 3, June 2005.

[4] A. L. Goldberger, L. A. N Amaral, L. Glass, J. M. Hausdorff, P. Ch. Ivanov, R. G. Mark, J. E. Mietus, G. B. Moody, C.-K Peng e H. E. Stanley, "PhysioBank, PhysioToolkit, and PhysioNet: components of a new research resource for complex physiologic signals", in *Journal of Circulation*, vol. 101, no. 23, pp. e215-e220, June 2000.

[5] H. H. So and K. L. Chan, "Development of QRS detection method for real-time ambulatory cardiac monitoring", proceedings from the 19th annual IEEE International Conference of Engineering in Medicine and Biology Society (EMBS), Chicago, pp. 289-292, Oct. 1997.

[6] P. Kligfield, "Value and limitations of 12-lead ECG monitoring", Clinical Window, Sept. 2001.