Development of a Low Cost Wearable Prototype for Long-Term Vital Signs Monitoring Based on Embedded Integrated Wireless Module

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Abstract

The specific goal of this study is the development of a system for assisting people affected by age inconveniences, disabilities or chronic diseases through observation of vital signs and to make patient communications with physician office, hospital facilities, caregivers and device itself easier. The system can be used both for home health care (home care - telemonitoring) and communication aid for disabled persons besides research purposes.

The hardware platform is based on a custom wireless biomedical data acquisition unit, designed on an ergonomic and comfort basis to provide continuous monitoring of the electrocardiogram (ECG), respiratory motion and pulse oximetry.

To ensure more comfort we developed a sensor-belt with dry rubber electrodes for ECG pick-up and respiration motion detection.

The system has been presented to a small sample of hypothetical users to obtain ratings and suggestions for future improvements.

1. Introduction

"The next two decades will see dramatic changes in the health needs of the world's populations. In the developing regions, noncommunicable diseases such as depression and heart disease are fast replacing the traditional enemies" World Health Organization [1].

There has been an increasing interest in telemonitoring thanks to the availability of new technologies for data transmission and processing, with better performances and lower costs. There are many examples of telemedicine systems based on mobile phones or PDAs [3,4]. Both of these approaches have drawbacks in some situations (e.g. a mobile phone can be difficult to be used by the elderly due to the small display). We consider personalization as a way of maximizing the cost/performance ratio. For example, we can use a PC based system when the user is at home and switch to a mobile phone based when the user is out.

The specific goal of this study is to develop a system for assisting people affected by age inconveniences, disabilities or chronic diseases through observation of vital signs and to make patient communications with physician office, hospital facilities, caregivers and device itself easier.

This paper focuses on the hardware framework needed for continuous patient monitoring, comfortable long term usage and easy communication between the instrument and the patient. The system has been developed to be economically affordable for hypothetical industrial production and designed to be customized for users' needs. With the customization, the same hardware platform can be used to help a wider number of people. Some auxiliary inputs can be used to connect devices for augmented communication in people with disabilities. Integration of devices for communication extends the range of hypothetical users to about 50% of home assistance services [2].

The actual system is a proof of concept for checking various technical solutions and to test the prototype.

2. Methods

2.1. System architecture

The system is based on a biomedical signal acquisition unit (UPAD *Unità Portatile Acquisizione Dati*, portable data acquisition unit), wirelessly connected to a processing unit that can be a PC, a smartphone, a PDA and so on.

Splitting the 'acquisition and processing' problem into two physical units allows realization of a less expensive and lightweight device suitable for long-term signal acquisition. Signal processing, long range data transmission and user interface are performed by an external unit with looser constraints about weight and dimensions. The data acquisition unit can also be used to integrate both biomedical signal acquisition features for health status monitoring and custom interfaces for disabled people communications.

2.2. Features details

Inputs currently available with UPAD are a 2-channel ECG, a respiratory signal from a chest piezo belt, a pulse oximetry signal and 3 analog inputs available to connect communication devices for disabled people.

The ECG front-end is based on a balanced impedance bridge scheme. This allows maintenance of a high CMRR and a high input impedance in an AC-coupled configuration [7]. ECG and respiratory signals are analogically processed for SNR enhancing and anti-aliasing filtering. Pulse oximetry signal is provided in digital form by a commercial OEM pulse oximeter (XPOD from NONIN Inc.).

Auxiliary inputs can be connected to devices needed for patient communication augmentation. These devices are to be chosen upon individual needs analysis as in the Assistive Technology philosophy [8].

The UPAD version is constituted by a board with analogical stages and power circuitry and connected with a Toothpick [14] module. This embeds a PIC18f6270 microcontroller that can be reprogrammed and a BlueTooth class 1 transceiver. AD conversion is performed by PIC internal converter.

The nominal Bluetooth coverage area is 100 meters open field. Coverage area is reduced by walls or obstacles, but empirical tests have shown that it is suitable for a "normal" house environment. Bluetooth protocol also embeds encryption and error correction features in a full transparent way. For a stronger security, a further encryption could be applied to data before transmission.

A custom communication protocol enables the device to carry different kinds of data and to reconfigure the device runtime. This allows use of different techniques to save energy, for example by reducing the sampling frequency (for "slow" signals as SPO2 and respiratory or in case of poor signal quality in case of patient movement), or transmitting some channel only every few minutes, or transmitting parameteres extracted by signals instead of raw data. We can also obtain further savings by enabling the power management features of Bluetooth modules.

The power management module is based on a double step-up converter (based on MAX756 integrated circuit) with one for the digital part and one for analogical circuitry to avoid power line noise due to the bluetooth transmitter and digital circuitry. This allows energy saving by turning off the analogical stage when it is not needed. Step up modules allow use of a wide variety of power source, from 1.5 to 5V. UPAD can be powered with rechargeable NiCd / NiMh batteries, a disposable alkaline battery or a high-efficiency Li-Po battery to meet different cost/performance/weight requirements.

UPAD contains a pushbutton and LEDs allowing users to interact with the unit (e.g. to turn on and off, to signal a dangerous situation, or to manually start a recording session).

The main user interaction is performed by the processing unit. This interface, designed to help the user with textual and graphic instruction, is characterized by a limited number of buttons, and can be used with a TV remote controller.

2.3. Dry rubber ECG electrodes

The ECG signal is acquired by dry rubber electrodes [6] placed on a thoracic belt, carrying all electrodes and respiratory piezo sensor. We chose to use dry rubber electrodes for comfort and easiness of use. Normal holter electrodes have to be placed individually by a skilled person. They also are usually adhesive, which can be problematic with skin humidity and they require adequate preparation. Rubber electrodes placed on a belt solve these problems because they do not require preparation, allow acquisition also in case of skin humidity (humidity also improves rubber electrodes performance), and can be easily applied.

3. Results

A pre-serie UPAD (Figure 1) prototype has been used as a test-platform for refining design and developing software on the processing unit. This allows also us to test interactions with processing unit software.

The prototype is small (13 x 6.5 x 3 cm) and light (130 g with batteries) therefore it can be used under dresses for a long time.

ECG signal bandpass and amplification are set in regard to international recommendations [5], as verified from simulations and tests on the circuit. Both filtering for diagnostic (0.05–100 Hz) and holter-like monitoring (1 - 30Hz) has been tested. Sampling frequency can be set runtime up to 1000 samples/second. Transmission protocol can manage resolution up to 32 bit, but actual resolution is limited to 10 bit by the internal ADC on Toothpick.

The requirements of the sensor for breath measurement are loosen. We tested a cut-off frequency of 1Hz (low pass filter, II ordered Sallen-Key) which allowed detection for normal breathing (usually 0.1-0.3 acts / second) and rapid breathing (rarely exceeding 2 acts per second). This signal can be sampled at low frequency (e.g. less than 10 samples/second) to reduce the amount of data transmitted.

Figure 1: UPAD acquisition unit with ECG dry electrode belt and pulse oximeter.

The Nonin XPOD pulse oximeter is connected digitally and the quality of the data is certified by the manufacturer. Data can be forwarded to the processing unit or unpacked locally for on-board processing (e.g. for Pulse Wave Transit Time PWTT computation [12]).

The communication protocol appears robust. There have been no cases of data loss, except during loss of radio link (units too far) or battery failure. The tests were carried out for a total time exceeding 10 hours.

The power system has been only partially tested, since an error in the printed circuit board pinout forced us to mount the step-up chips "flying". This type of assembly led to a degradation of performance of the step-up circuit and a loss of efficiency due the raised tracks resistance. In this configuration, without adopting techniques for energy savings, we can still obtain autonomy exceeding 3 hours with 2 AAA alkaline batteries. The use of AA batteries, if compatible with comfort and size requirements, would triple the amount of energy available. Further improvements could be achieved with Li-Ion or Li-Poly batteries, allowing a greater energy density.

Since a large part of power is drained by data transmission, the exact consumption depends on the data transmission parameters and environmental conditions (e.g. type of disease to manage, presence of obstacles in the house and habits of the patient). Thus, we have only evaluated consumption in the "worst case" and will carry out surveys on real consumption when we perform a field trial.

We estimate there will be 20 hours of battery life with normal use.

The U3 algorithm for QRS complex detection is the basis of on board ECG signal segmentation and classification. It allows good recognition performances with a low computational load (a comparison with the well known Pan and Tompkins on the MIT-BIH Database had an error rate 0.85% U3, 0.71% P & T on about 109,809 beats [11]). Within the present study the U3 algorithm has been implemented successfully on the microcontroller leading the UPAD. This allows on board recognition of cardiac rhythm and, together with pulse oximetry data, blood pressure variation detection through PWTT technique.

The processing unit can run real time algorithms for health status identification. For instance, a PCA based algorithm, tested on signals from MIT BIH database, showed 98% sensitivity and 100% specificity in detecting ischemic episodes [6].

The prototype has been presented to a small group of potential users (12 persons, 14 to 76 years old) to verify how the product is perceived and to obtain information for further development. A trainer showed each volunteer how to set up and use the system. Then, the user had to perform the operation himself, using only the contextual suggestions from the analysis program interface.

The interaction with the user was based on a graphical panel displayed by a computer monitor or a TV, showing textual and graphical instructions and allowing navigation between various steps of the analysis set-up. The user employs a TV remote control to give inputs. This is easier to use compared to a standard PC keyboard, in particular for older people that can get confused by too many keys and are more familiar with TV remote controls.

The software interface has been rated 10.33/12. Also the comfort (2.83/3) and the easiness in wearing the device (2.17/3) seem to be good. The time requested for starting a test session is about 120 seconds (of which 90 are for wearing the ECG belt) on the first try, while a trained person can do it in about 10-20 seconds. It is interesting to note that none of the subjects failed to wear and start the system.

4. Discussion and conclusions

We have presented a prototype of a system for helping people with chronical illness or disability in monitoring their health status and in communicating with health care professionals.

The hardware platform allows monitoring of some cardio-respiratory related biosignals (ECG, breathing, pulsi oximetry) and interface with assistive technology devices for disabled people communication. A smart biosignal telemetry unit is the bridge between the patient personal area network and a processing unit that performs the heaviest computations and interfaces user with the system and assistance personnel.

Both hardware telemetry unit and software interface have been tried by possible users, from 14 to 76 years old. In all cases the volunteers were able to set up the system properly for a monitoring session. Simplified user interface, based on text and images with a limited number of buttons, has been rated as easy to use.

The system has been rated as easy and comfortable to use, since most parts of the sensors are hosted by an elastic belt. This contains dry electrodes for the ECG in a conductive rubber that is easily placed and also suitable in presence of skin humidity.

Questions to the volunteers that tested the prototypes led to some suggestions to improve the comfort and usability that included minor modification to the sensor belt, use of animations in the user interfaces and some changes in the interface layout.

Other improvements to be evaluated are the use of different transmission standard like ZigBee instead of Bluetooth, the use of different batteries (like LiPo or LiIon), integration of other kinds of sensors (accelerometers, more ECG leads and spirometry) to extend the number of pathologies covered by the instrument.

We are planning, in the next months, to start a clinical trial of the system to test performance and to refine the design.

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