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Biomedical Electronic Systems to Improve the Healthcare Quality and Efficiency

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1. Introduction

The most recent developments of electronics, informatics and telecommunications let imagine applications in the biomedical engineering field to improve the healthcare quality (She et al., 2007). In particular a number of systems has been developed in the telemedicine and home care sectors which could guarantee an efficient and reliable home assistance allowing a highly better quality of life in terms of prophylaxis, treatment and reduction of discomfort connected to periodic out–patient controls and/or hospitalization for the patients afflicted by pathologies (such as cardiac decompensation or obstructive chronic bronchopathy), and allowing considerable savings on sanitary expenses.

In this chapter we present a review of our principal projects in biomedical electronic field, developed at the Electronic Device Laboratory of Polytechnic of Bari, Italy.

Firstly we propose a medical electronic-computerized platform for diagnostic use, which allows the doctor to carry out a complete cardio-respiratory control on remote patients in real time. The system has been patented and has been designed to be employed also to real-time rescue in case of emergency without the necessity for data to be constantly monitored by a medical centre, leaving patients free to move. For this purpose the system has been equipped with highly developed firmware which enables automated functioning and complex decision-making. In fact, when an emergency sign is detected through the real-time diagnosing system, it sends a warning message to people able to arrange for his/her rescue. A Global Positioning System (GPS) also provides the patient coordinates. All this occurs automatically without any intervention by the user. The system might be useful also to sportsmen. Thanks to its characteristics it can help to reduce hospitalization rates and length of stays thereby improving health costs and quality of life. Moreover the system, in its version for diagnostic use, has been verified by the heart specialists of the Institute of Cardiology in the General Hospital (Polyclinic) of the University of Bari.

We also propose a low-cost, electronic medical device, designed for the non-invasive continuous real-time monitoring of breathing functions. It diagnoses respiratory pathologies by the electronic three dimensional (3-D) auscultation of lung sounds, performing a correlation between lung sounds and diseases.

Moreover we present a new system for acquiring simultaneously some health parameters which are strongly correlated: breathing rate and kinetic activity. The system is based on a

couple of sensors, which are very light, absolutely non- invasive and compatible with every day life.
For breathing sensing we use an already known method involving a belt to sense the thorax dilatation, but we apply a new kind of dilatation sensor on the belt based on a conductive rubber, which is new in breathing detection, quite cheap and sensitive.
Breathing rate observation is quite useless when no information is available on patient activity that could cause breathing rate change. Therefore we present also a kinetic activity sensor based on commercial accelerometer. Signals from these sensors are amplified filtered and elaborated and feed to the ADC of a micro-controller. Experimental results have shown a clear correlation between these signals, inducing us to stress the importance of coupling breathing and kinetic activity monitoring, particularly in patients with lung and heart diseases.
At last we present a new system for cardioholter applications, characterized by the possibility to send an ElectroCardioGram (ECG) by Bluetooth to 6 or 12 leads. Moreover it is also equipped with GPS module for the patient location in real time. Particularly it proves useful indefinite places such as nursing homes and rest homes for elderly people. However by using a mobile phone the system also allows transmission within a long range by GPRS/GSM.
All designed systems, prototyped and tested, are characterized by originality, by plainness of use, as they planned with a very high level of automation (so called “intelligent” devices).

2. Heart and lung auscultation system for diagnostic use on remote patients

Although there are already available instruments for the remote monitoring of ECG (Prolux et al., 2006), the contemporary Cardiac and Pulmonary tele-Auscultation (ACP) is not carried out yet for the lack of adequate instruments and clinical validation of the methods.
However the known tele-electrocardiographs are able to transfer the electrocardiograms only after the acquisition, not in real time and are mostly and strongly orientated towards the sanitary emergencies. In fact they are typically installed on ambulances and need a skilled staff for the utilization (Woolard et al., 2005) (Kyriacou et al., 2002).
On the other hand it is essential to observe the electrocardiogram is not the only source of information useful to evaluate the patient health.
It is obvious, therefore, that there is a rather limited offer of the current market with regard to the requirements which a health service should meet, if it is in the lead with regard to the effective potentialities offered by the present technology.
Particularly we recognize deficiency or total absence of reliable and valid telemedicine platforms which allow the follow up of patients and the execution of all the main vital parameters, such as electrocardiograms, spirometry, oximetry, cardiac tones, lung sounds, with a doctor in a different place regard to the patient.
In this paragraph we describe (Convertino et al., 2009) a medical electronic-computerized platform for diagnostic use, which allows the doctor to carry out a complete cardio-respiratory control on remote patients in real time. The system has been patented (Italian patent n.0001354840, 2009) and has been designed to be employed also to real-time rescue in case of emergency without the necessity for data to be constantly monitored by a medical centre, leaving patients free to move.
As if the doctor is present personally near the patient, the system allows him to receive in real time the following data:

1. auscultation of cardiac tones and broncho-pulmonary sounds
2. electrocardiogram
3. arterial blood pressure
4. oximetry
5. respiration frequency
6. phonocardiography
7. spirometry
8. image and audio of the patient with high quality.

The system consists of two parts: a patient station and a doctor position, both compact and light easily transportable, both are composed of committed laptop, hardware and software.
The patient unit is equipped with miniaturized diagnostic instruments and is suitable also for paediatrics use. Many patient stations can correspond to one doctor position.
The system is modular and allows to select and to install some of the suitable diagnostic instruments, even though it is prearranged for the plug and play installation of the others (for example only the electrocardiograph can be installed and then also the phonendoscope, etc.).
The electrocardiogram could record up to 12 derivations and the software is able to interpret the data and to automatically carry out the reading and the diagnosis of the trace which should be confirmed by the doctor. It is possible to carry out monitoring without time limits and always in real time. This makes possible the capture of uneven heartbeats or also intermittent ones of other nature. The acquire trace is registered and filed.
The tele-phonendoscope is of electronic kind and obtains biological sounds in the [20 Hz, 1 kHz] frequency range and can be used in three modes in order to improve the cardiac and pulmonary auscultation: membrane, bell and extensive modality. Moreover, it allows the 75% suppression of the external noise.
It is equipped with software for the real time spectrum analysis and it starts automatically at the beginning of the auscultation procedure. The positioning of the phonendoscope is led by a remote doctor thanks to the full time audio/video communication and the biological sounds can be simultaneously heard either by the patient (or by an operator helping the patient in the examination) or by the doctor in remote.
The biological sounds are also registered during the acquisition with significant advantages for diagnosis accuracy and for possibility of carrying out diagnostic comparisons with previous records.
The tele-spirometer allows to carry out the FVC, VC, MVV tests and to determine the respiratory frequency and it is autodiagnostic.
The finger (optic) tele-saturimeter allows to carry out the monitoring (check without time limit) of the SpO_2 value as it is equipped with plug-in which permits the tracing of the saturation values curve that will be presented in real time to the doctor.
The filing of the data concerning the carried out examination occurs in a dynamic database both on the patient position and on the doctor position; the data will be filed by ordering them for each patient.
Thus to each patient a clinical record will be associated containing all his data. This kind of filing is very useful to carry out diagnostic comparisons on the evolution of a disease or on the outcome of a therapy, and it eases him of the burden of having the record documentation regarding him personally. In the patient database there is also a filed schedule containing the personal details of the patient, the case history in addition to various notes, values of blood tests, the outcome of other diagnostic tests, treatments undertaken during the time, therapy in course, etc.

This system also makes possible to transmit echograms, X-rays radiograms and other tests in digital form to the doctor and also their filing in the patient data base.
The doctor can also prescribe other subsequent clinical tests advised and/or treatments to undertake.
The system does not present connectivity limits of any kind find and requires a 320 Kb/s minimum band or a UMTS Mobile telephone.
The system has a user friendly software interface very easy to be used, which implements the one touch philosophy, and requires extremely reduced operating costs.
The patient can ask for a medical examination and the doctor can accept or refuse to examine him if busy. As a result of the doctor's availability, the medical examination can start and the doctor can ask for the necessary tests through a simple "click".
This system has been planned/designed in the observance of the current regulations for medical devices, informatic safety and privacy.
The system, therefore, is marked by three distinct and basic fundamental characteristics:

1. the real time data transmission by assuring the remote doctor the simultaneous control of the data during their acquisition;
2. the possibility to carry out a complete telematic medical examination, including the tele-auscultation, all the operations the doctor performs when he examines the patient directly at home or at the surgery and even more, since the system is equipped with typically diagnostic instruments not available at the family doctor but at hospital units;
3. the possibility to establish a continuous audio/video communication during the examination, in order that the same doctor can interact with the patient, verifying the correct positioning of the sensors and having also a very high quality image of the patient, which can be useful for diagnostic aims.

Among the most evident and important applications we can indicate the following ones:

1. home tele-assistance of cardiac patients in decompensation or of chronic patients with pathologies attributed to the cardio-circulatory or respiratory apparatus;
2. mass prophylaxis with complete cardio-respiratory control, frequently and at low cost;
3. tele-consultation;
4. follow-up of patients discharged early (precociously) and in need of tele-protection;
5. closed-circuit monitoring of the health of patients waiting for hospitalization.

The reduction of hospitalization time, using home tele-protection, and the avoided hospitalization of patients in decompensation monitored at home imply large economic saving. The shorter patient presence in hospitals reduce the waiting lists in a remarkable way.
Moreover there is today a growing need for inexpensive and reliable health monitoring devices (Jovanov et al., 2003). able to record data, to analyze them in real time and, if possible, to transmit them to a receiving unit by exploiting wireless technology, but the market still does not seem to offer any reliable GPRS or Bluetooth-based, effective and low-cost health-monitoring telemetric systems.
Although telemetric systems are already used in hospitals, they do not seem to fully exploit all the potential of modern technology and seem to suffer from some important limitations. In fact, many devices are specifically intended for emergencies (Pavlopoulos et al., 1998) and can transmit ECG results, as well as those from the monitoring of some other parameters. Such systems are inadequate for continuous health monitoring, not easy to use and have to be managed only by qualified operators, which makes them unsuited for personal use and domestic applications. Moreover one of the limitations of existing devices lies in the fact that they are not wearable and allow only to monitor ECG, saturation and some other

parameters separately, otherwise extraordinary bandwidth would be needed in order to transfer all data, especially via GSM (at the limited speed of 9200 kbit/s). GPRS and UMTS technologies result from the development of GSM transmission of packet data.
The combination of the latest suitable telecommunication solutions (GPRS and Bluetooth) with new algorithms and solutions for automatic real-time diagnosis, cost-effectiveness (both in terms of purchase expenses and data transmission/analysis) and simplicity of use (the patient will be able to wear it) can give the designed system useful for remote health monitoring, allowing real-time rescue operations in case of emergency without the necessity for data to be constantly monitored.
For this purpose the proposed system has been equipped with highly developed firmware which enables automated functioning and complex decision-making. It is indeed able to prevent lethal risks thanks to an automatic warning system. All this occurs automatically without any intervention by the user.
Each monitored patient is given a case sheet on a Personal Computer (PC) functioning as a server (online doctor). Data can also be downloaded by any other PC, palmtop or smartphone equipped with a browser. The system reliability rests on the use of a distributed server environment, which allows its functions not to depend on a single PC and gives more online doctors the chance to use them simultaneously.
The whole system consists of three hardware units and a management software properly developed. The units are:

- Elastic band: the sensors for the measurement of health parameters are embedded in an elastic band to be fastened round the patient's chest.
- Portable Unit (PU), which is wearable and wireless (GPRS/Bluetooth). This PU allows, by an Internet connection, the transmission, continuous or sampled or on demand, of the health parameters and allows the GPS satellite localization and the automatic alarm service, on board memory. Moreover PU has an USB port for data transfer and a rechargeable battery.
- Relocable Unit (RU): GPRS/Bluetooth Dongle (on PC server, i.e. online doctor).
- Management Software: GPS mapping, address and telephone number of nearest hospital, simultaneous monitoring of more than one patient, remote (computerized) medical visits and consultation service, creation and direct access to electronic case sheets (login and password)

Fig. 1 shows a picture of the PU. The very small dimensions are remarkable, even if it is only a prototype, realized at the Electronic Devices Laboratory of Polytechnic of Bari, and more reduction in dimensions is still possible.
The system, in particular the PU, collects data continuously. These are stored in an on-board flash memory and then analyzed real-time by an on-board automatic diagnosis software. Data can be sent to the local receiver, directly to the PC server (online doctor), or to an internet server, which allows anyone to download them once identified with his/her own login and password.
Data can be transmitted as follows:

1. real time continuously
2. at programmable intervals (for 30 seconds every hour, for example)
3. automatically, when a danger is identified by the alarm system
4. on demand, whenever required by the monitoring centre
5. offline (not real-time), downloading previously recorded (over 24 hours, for example) data to a PC.

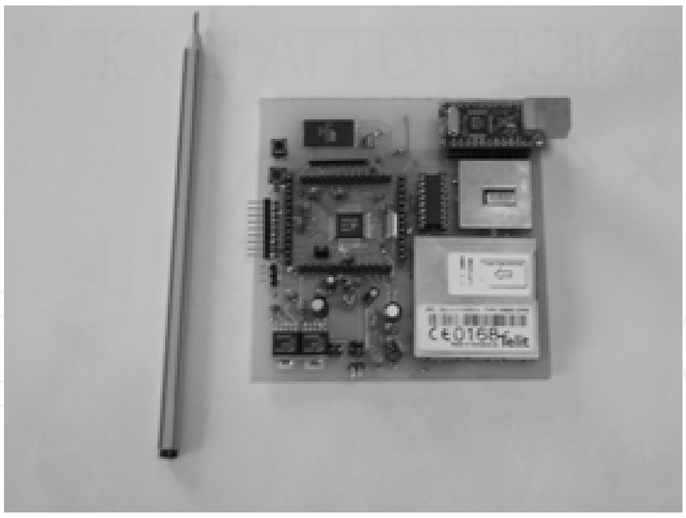

Fig. 1. A picture of the Portable Unit.

In all cases patients do not need to do anything but simply switching on.
When an emergency sign is detected through the real time diagnosing system, the PU automatically sends a warning message, indicating also the diagnosis, to one person (or even more) who is able to verify the patient health status and arrange for his/her rescue. In order to make rescue operations as prompt as possible, the PU provides the patient's coordinates using the GPS unit and the Management Software provides in real time a map indicating the position of the patient, as shown in Fig. 2.

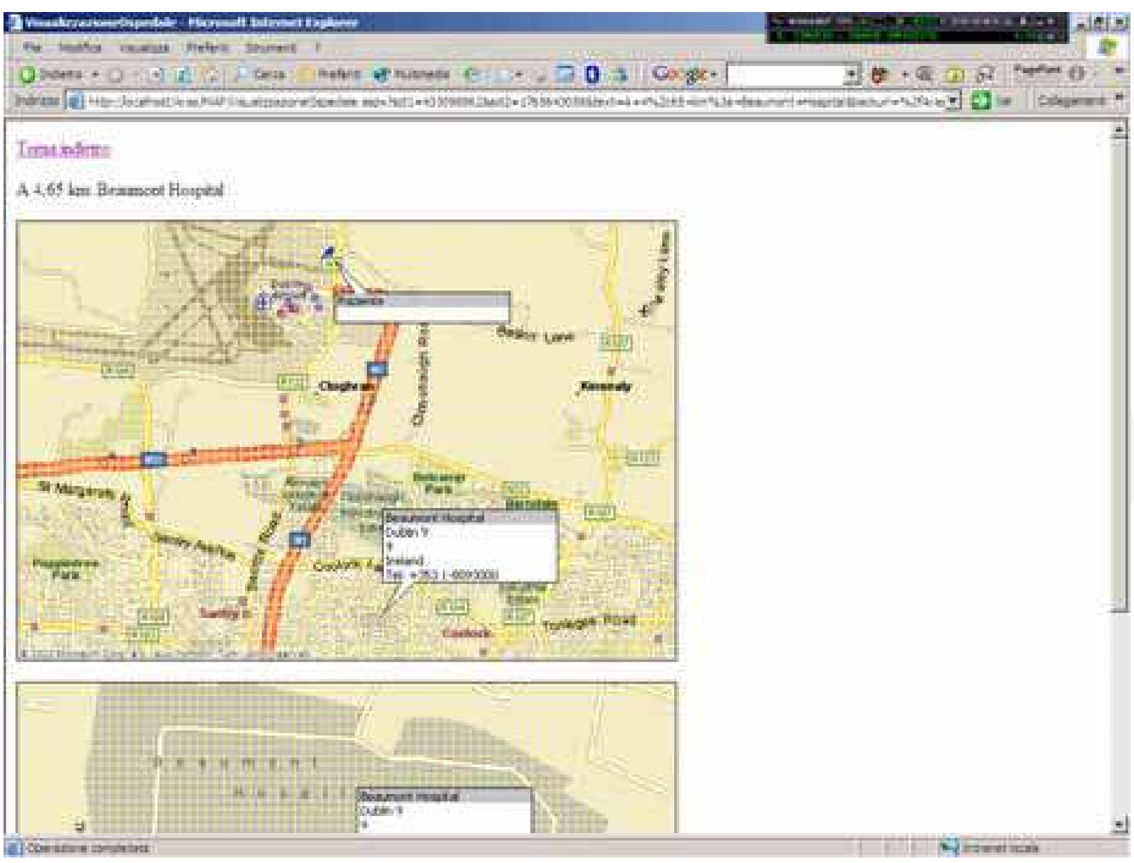

Fig. 2. GPS mapping with address and telephone number of nearest hospital.

Fig. 3 shows a picture of an electrocardiogram transmitted by Bluetooth and plotted on a Personal Computer by the proper developed management software.

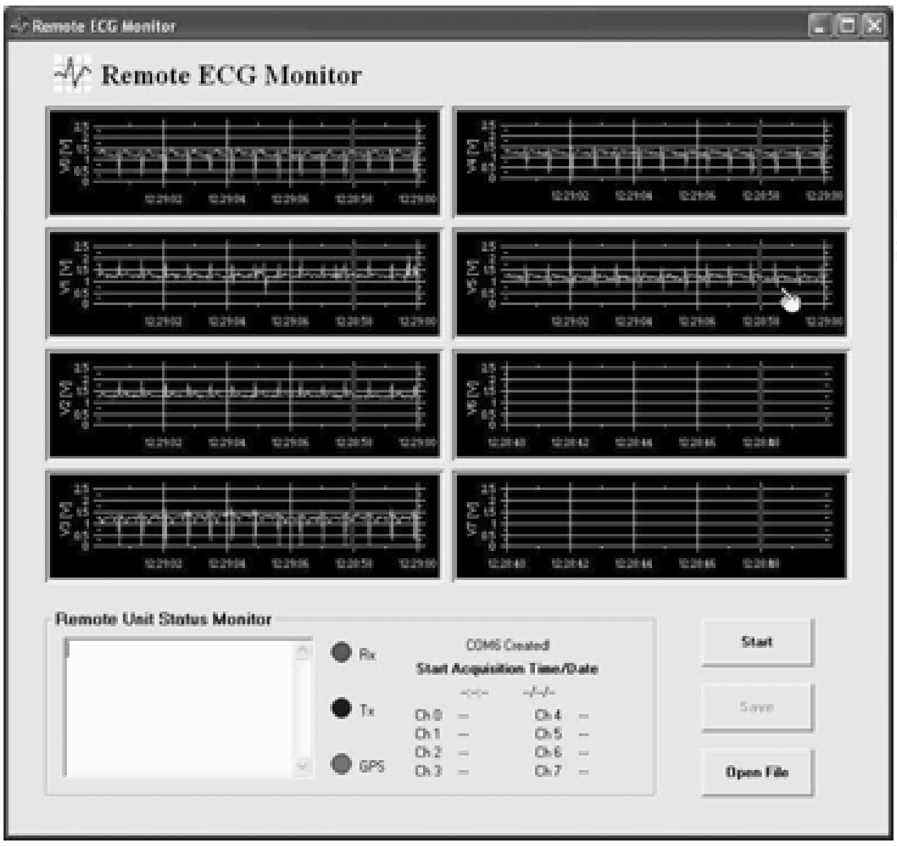

Fig. 3. Example of acquisition by Bluetooth of an electrocardiogram.

The system, in its version for diagnostic use, has been used in a routine clinical context in order to evaluate the feasibility and accuracy of the ACP carried out via Internet compared with the traditional auscultation (T).
At the Cardiac Decompensation Unit of Bari Polyclinic 21 patients (16 males, 5 females, in stable clinical conditions) have been examined. Each patient has been examined by two experienced heart specialists (Obs1 and Obs2) in two successive phases (I-ACP and T-ACP). The I-ACP check-up has been carried out by the instrumentation which the system is equipped with. The audio signal of high quality obtained from the cardio-pulmonary auscultation has been transmitted on internet through a standard ADSL connection from a patient position to a remote doctor position. The observer was able to listen and simultaneously record an audio file (WAV Format) of the ACP. A trained nurse placed the membrane on two auscultations spots under the visual guide of the doctor by means of a properly positioned webcam. The T-ACP check-up has been carried out with a traditional sound phonendoscope. The listened reports were recorded in a data file with preclassified reports. The obtained data have been analysed in terms of uniformity and examined with fisher's exact test ($p < 0,05$) and the kappa-test (where applicable).
In Tab. 1 the data of the ACP carried out both via internet and in a traditional way have been shown for the observer 1 and for the observer 2 (intra-observer analysis).
Moreover, the data registered by the two observers according to the two different ways of check-up (intra-observer analysis) have been compared.

Cardio pulmunary auscultation
Acoustic vs web
Intra-observer / inter-observer analysis

	Obs 1	Obs 2	Web	Acoustic
Total	217/231 (93.9%)	214/231 (92.6%)	224/231 (97,0%)	219/231 (94.8%)
Cardiac	81/84 (96.4%)	79/84 (94.0%)	79/84 (94,0%)	83/84 (98,8%)
Pulmonary	60/63 (95.2%)	59/63 (93.7%)	59/63 (93.7%)	62/63 (98.4%)
Cronology of systolic murmurs	19/21 (90.5%) k=0.82	18/21 (85.7%)	17/21 (81.0%)	19/21 (90.5%) k=0.82
Inspiratory crepitations	20/21 (95,2%) k=0.64	19/21 (90.5%)	20/21 (95.2%)	21/21 (100%) k=0.47

Table 1. Data of the ACP carried out both via internet and in a traditional way.

The intra-observer concordance of I-Vs IACP (number of concordant reports, (%)) for the observer 1 and the observer 2 have been respectively:

- 217/231 (93.9%) and 214/231 (92.6%) (ns) for the total reports,
- 81/84 (96.4%) and 79/84 (94.0%) (ns) for the cardiac reports,
- 60/63 (95.2%) and 59/63 (93.7%) (ns) for the pulmonary reports.

The intra-observer concordance of observer 1 has been 19/21 (90.5%, kappa = 0,82) for the chronology of the systolic murmurs and 20/21 (95.2%, kappa = 0,64) for teleinspiratory crepitations.

The inter-observer concordances for I-Vs T-ACP have been respectively:

- 224/231(97.0%) versus 219/231(94.8%) (ns) for the total reports,
- 79/84(94.0%) versus 83/84 (98.8%)(ns) for the cardiac reports,
- 59/63(93.7%) versus 62/63(98.4%) (ns) for the pulmonary reports.

The detailed analysis of each specific typology of report has been carried out.

The cardiac and pulmonary auscultation, evaluated in our series of cases through concordance analysis, has shown a high concordance of pulmonary and cardiac listener reports both for the traditional approach and for the telemedicine one via Internet.

The intra-observer and inter-observer concordances have not been significantly different for the two observers in the two operational contexts, showing that the cardiopulmonary auscultation with our system is an innovative diagnostic method able to improve the present procedures of telemonitoring.

3. Multichannel system for electronic auscultation of the pulmonary sounds

In this paragraph we describe a low-cost, electronic medical device for the non-invasive continuous real-time monitoring of breathing functions, designed by us within a research program on the remote and non-invasive monitoring of the health, which has been developed at the Electronic Devices Laboratory of the first Faculty of Engineering at Bari Polytechnic, with the support of national university medical centres (Marani et al., 2010).

The system diagnoses respiratory pathologies by the electronic three dimensional (3-D) auscultation of lung sounds (Sovijärvi et al., 2000) (Earis et al., 2000), performing a correlation between lung sounds and diseases.
A block diagram of the designed device is shown in Fig. 4.

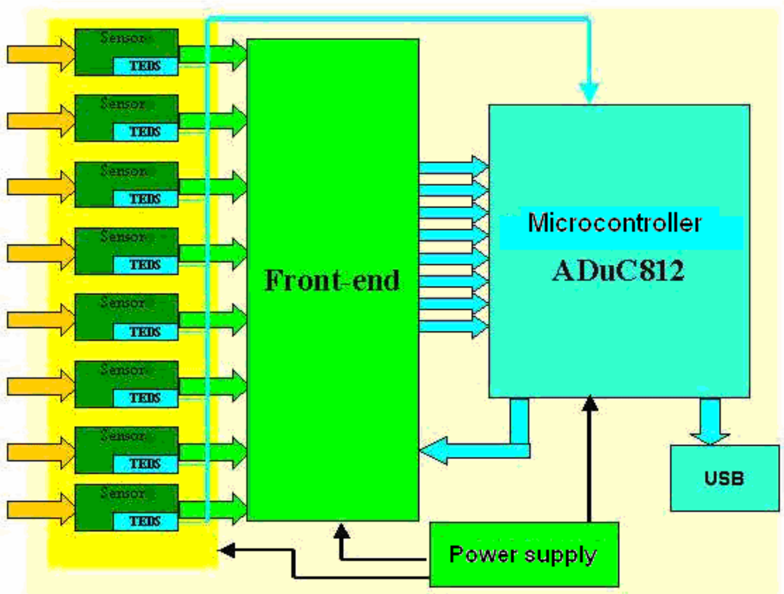

Fig. 4. Block diagram of the designed device.

The signals, coming from analog sensors, are suitably processed by the front-end and sampled at 1 KHz frequency and, then, converted into digital format with 12-bit resolution, therefore guaranteeing high noise immunity.
The Front-End processes the signal to adapt the voltage values coming from the sensors to the input dynamic range (between 0 V and 2.5 V) of the Analog-Digital Converter (ADC) included into the microcontroller.
Sensors can be unipolar (i.e. output voltages can be only positive or negative) or bipolar, where both positive and negative voltages are present. In both cases, the output signal amplitude can be greater than 2.5 V, if each sensor includes an integrated amplifier.
The Front-End must diminish or amplifier the signal coming from each sensors, depending on its level and the input dynamic range of the ADC. If the signal is bipolar, a level shift is required to obtain a new signal greater than zero.
Since the signal processing depends on the sensor features, several shift-voltage values, each time determined by the microcontroller, have to be simultaneously produced (Kirianaki, 2002).
Moreover, the gain of the amplifier has to be dynamically changed.
We have used only two programmable integrated circuits, controlled by a low-cost and high reliability (with particular reference to thermal drift phenomena) microcontroller, by implementing a device self-configuration procedure of the device to avoid any further maintenance work (such as calibration, front-end setting) by the user.
Microcontroller is required to program the Front-end functions, depending on sensor type, recognized by means of the implemented plug and play. The *Three Wire Serial Interface* Connections protocol has been used to establish a dialog between the Front-End and the microcontroller.

We have used the ADuC812 Microcontroller, produced and distributed by *Analog Devices*, a low-cost device, which is very suitable to the design specifications.
A block diagram of the ADuC812 is shown in Fig. 5.

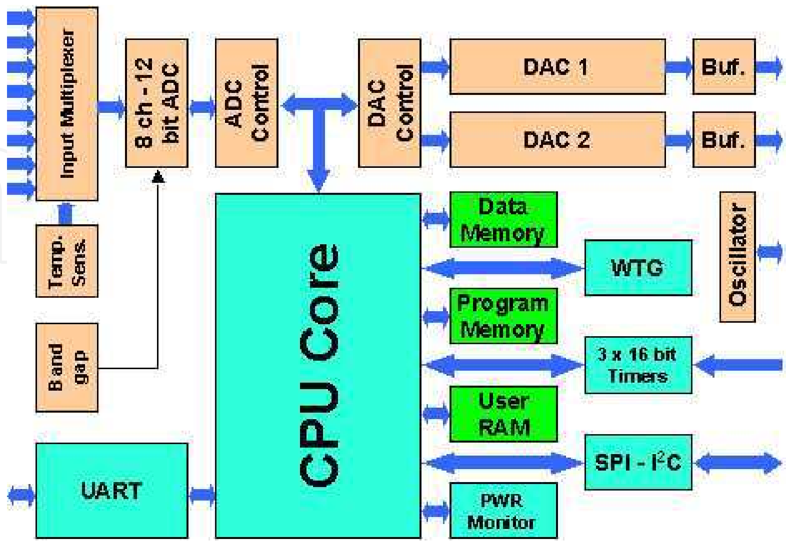

Fig. 5. Block diagram of the ADuC812 Microcontroller.

The Microcontroller allows the data acquisition from 8 multiplexed channels, at a sample frequency up to 200 KHz, and can address up to 16 MB of external data memory. The core is a 8052 compatible CPU, asynchronous output peripherals (UART) and synchronous serial SPI and I^{2}C.
The Sensor Plug and Play has been realized through implementation of IEEE standard P1451.4, with *1-wire system* Communication Protocol.
Each sensor includes a transducer electronic data-sheet (TEDS), which stores the most significant informations relevant to the sensor type (manufacturer, offset, output range, etc).
Based on the stored data, microcontroller identifies the sensor and sets the Front-End device to suitably process the signal and perform the Analog-Digital conversion in very accurate manner. Each TEDS is a serial type Electrically-Erasable-Programmable Read Only Memory (EEPROM), connected to the microcontroller by only two wires.
The realized prototype is shown Fig. 6.

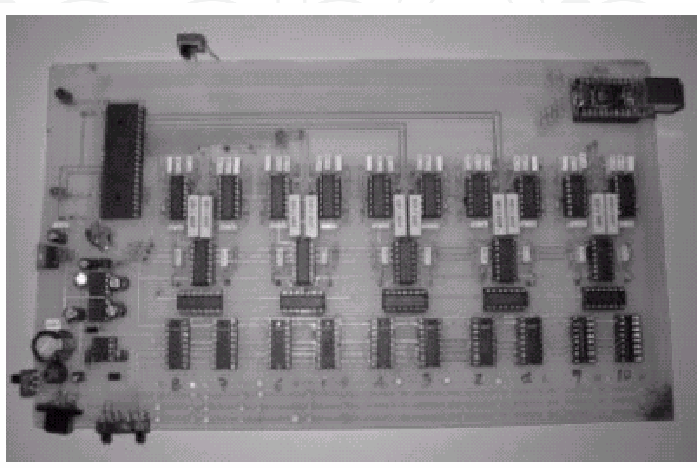

Fig. 6. The prototype: a double-sided printed circuit board.

The device, characterized by compactness and small-size, performs self-configuration, data-acquisition and conversion, data transfer to a Personal Computer and post-processing (such as ventilator setting). All the data can be processed in real time, but an external memory support can be used to realize a data-bank accessible from any PC.
Fig. 7 shows the graph of a signal both while recording it (real time) and after saving it.

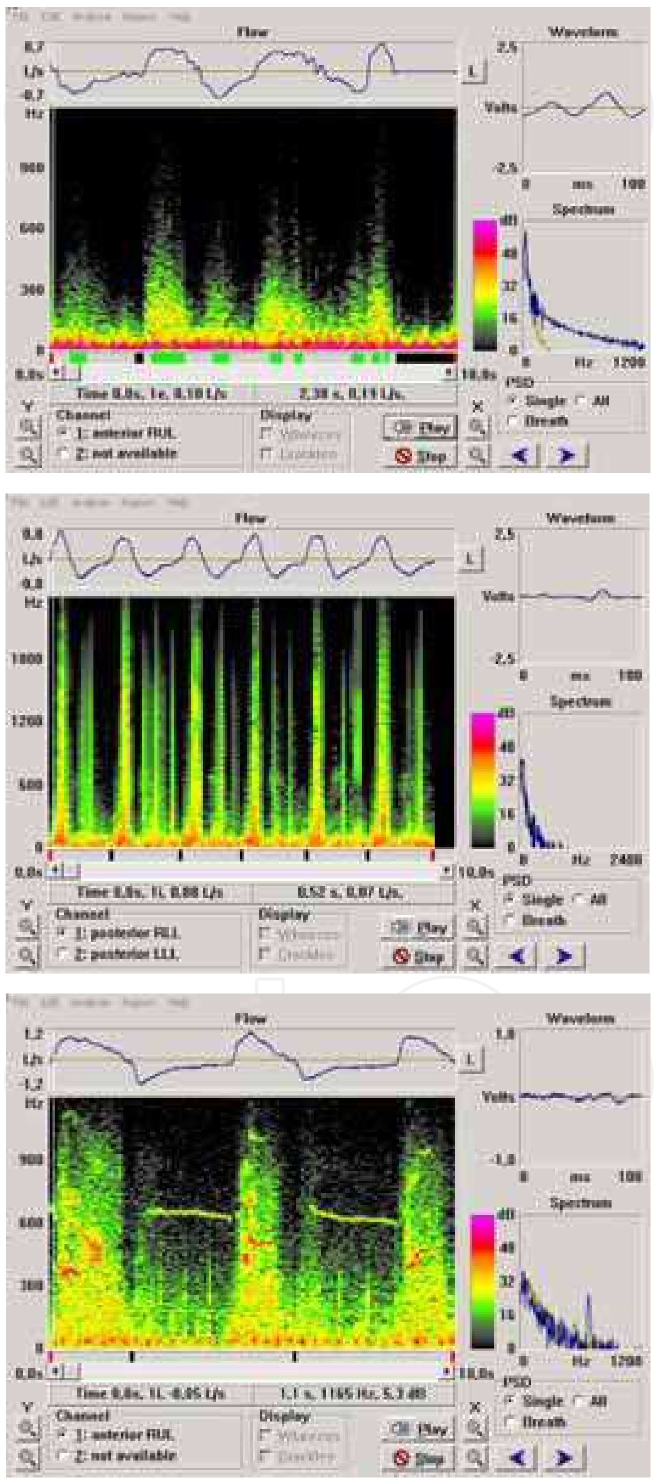

Fig. 7. Graphs of some lung sounds (respectively *Normal*, *Crackle*, *Wheeze*).

A research (Grasso et al., 2000) has pointed out the effectiveness of the frequency analysis of lung sounds for the diagnosis of pathologies.
The experiment illustrated below shows that computerized tomography (CT) results perfectly match those of a simple frequency analysis of previously recorded lung sounds.
Some studies (Vena et al., 2002) have been carried out on the frequency analysis of lung sounds and researchers have set the threshold for the detection of pulmonary pathologies at 500 Hz (see Fig. 8).

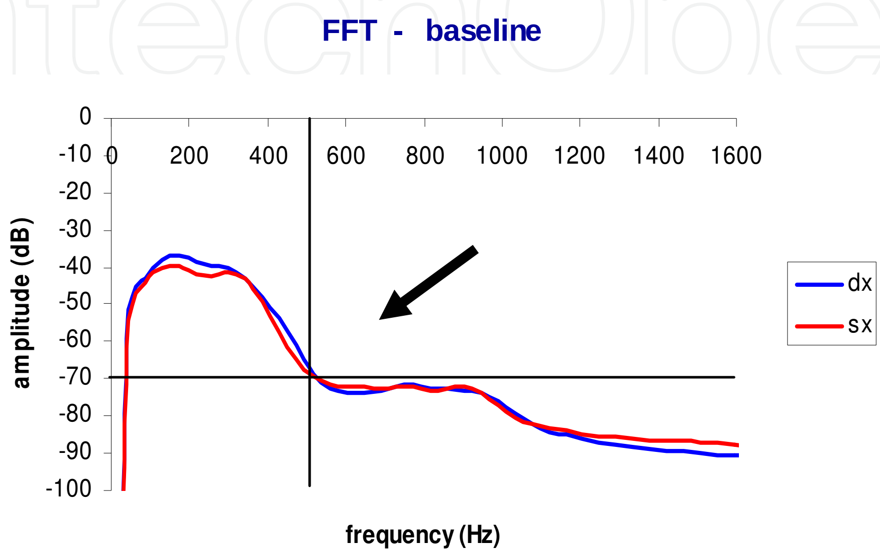

Fig. 8. FFT – spectrum of a lung sound in a patient with no pulmonary pathologies.

Spectrum components over that threshold (500 Hz) may be indicative of pulmonary disease.
It is widely known that in patients treated with mechanical ventilation a gradual PEEP increase (PEEP = positive end-expiratory pressure) results in a progressive re-expanding of alveoli which were previously collapsed due to a pathology.
The obtained experimental results, reported in Fig. 9, show that a gradual PEEP increase – from 5 to 20 – has effected a gradual reduction in lung damage, thereby leading to improvement in the patient's respiratory health.
The CT results, shown in the first column, perfectly match those of the frequency analysis on the right.
Moreover, there are also research projects about pulmonary acoustic imaging for the diagnosis of respiratory diseases. In fact, the respiratory sounds contain mechanical and clinical pulmonary information. Many efforts have been devoted during the past decades to analysing, processing and visualising them (Kompis et al., 2001).
We can now evaluate deterministic interpolating functions to generate surface respiratory acoustic thoracic images (Charleston-Villalobos et al., 2004) (Marani et al., 2010).
Moreover the following options are available:

- temporal graph of a breathing sound
- frequency graph of a breathing sound
- spectrogram of a breathing sound
- temporal graph of the airflow
- measurement of both airflow and inspiratory/expiratory volume.

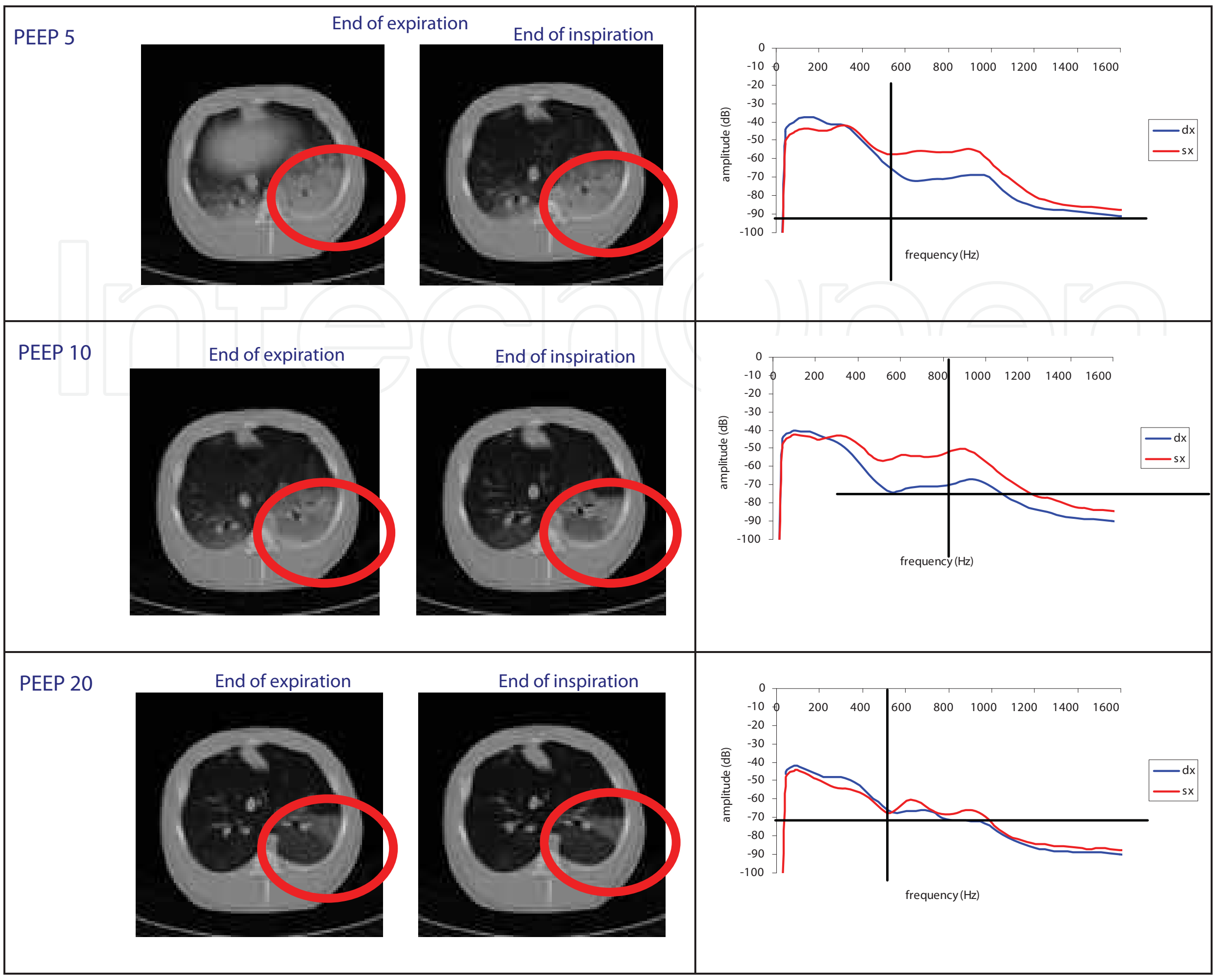

Fig. 9. Correlation between CT results and spectrum analysis of lung sounds.

4. A system for continuous monitoring of breathing and kinetic activity

In physical activity monitoring often only one parameter at a time is detected (Welkowitz et al., 1976) since otherwise patient movement capabilities would be compromised. This is unsatisfactory since correlation among parameters is necessary to reject parameters alteration due to everyday life, but also it is necessary to detect correlated parameter alteration due to medical causes. Let's think about how everyday activities could modify heart rhythm, breathing rate and body temperature.

Moreover the employed sensors have to be very light, non-invasive and absolutely compatible with the ordinary day activities.

In this paragraph we present a new system for acquiring simultaneously some health parameters which are strongly correlated: breathing rate and kinetic activity.

The system is based on a couple of sensors, which are very light, absolutely non- invasive, and compatible with everyday life.

For breathing sensing we use the already known method, the plethysmography (Konno et al., 1967) involving a belt to sense the thorax dilatation, but, in order to eliminate the practical inconveniences due to the presence of metal coils on the thorax, we apply a new kind of dilatation sensor on the belt based on a conductive rubber, which is new in breathing detection, quite cheap and sensitive.

Breathing rate observation is quite useless when no information is available on patient activity that could cause breathing rate change. Therefore we present also a kinetic activity sensor based on commercial accelerometer.
Signals from these sensors are amplified, filtered and elaborated and feed to the ADC of a micro-controller.
Experimental results, as we will illustrate later, have shown a clear correlation between these signals. The evaluation of correlation between breathing rate and kinetic activity requires a complex mathematical procedure, which is currently under development. Actually we can assert that the breathing and kinetic activity monitoring allows in particular to better understand the origin of tachypnea events whether they come from physical activities or not. Furthermore, in patients with lung and heart diseases, it is very useful for the doctor to understand when tachypnea begins during physical activities, and how long it persists after the subject stops.

4.a Breathing monitoring

In past years two main methods for breathing monitoring have been developed (Webster, 1998) (Moore et al., 2004) (Tarassenko et al., 2002). In the first method, the air flow is sensed while in the second one the breast dilatation is sensed.
Air flow monitoring is accurate but is very uncomfortable, since it requires tubing or placing sensors both in mouth and in nose (Lay-Ekuakille et al., 2010) (Wei et al., 2010). This would rule out 24 hours logging. For our project we are so forced toward the breast dilatation monitoring, which may be quite less accurate and very sensitive to arms movements but is much more comfortable.
For breast dilatation monitoring, piezoelectric strain gauge sensors are quite problematic (Bonato, 2003) since the charge generated at typical breathing frequencies (0.25 Hz) can be difficultly amplified. Moreover the temperature effect and the ageing on these sensors may produce a drift of the direct component of the signal. This problem could be solve by the introduction of a low-frequency filter, having a cut-off frequency less than breathing one.
Accelerometers are not suitable, because the tiny breathing acceleration available (about 0.02 *g*) is much smaller than the gravity acceleration *g* and body movement acceleration.
Breast dilatation monitoring is well accomplished using a breast elastic belt (Kim et al., 2006) so sensing the belt stress makes sense breathing possible.
Aside from several stress sensors we have designed a new, very interesting conductive rubber sensor, being it also quite cheap and easy tailored. Conductive rubbers are made by mixing carbon or iron powder in the chemical reactants used to produce rubbers. They have been applied as flexible conductors and as pressure sensors, but we did not found application as dilatation sensors. Indeed conductivity of these rubbers are sensitive to stress, but among the large kinds of conductive rubbers available, not all are suited for this application.

4.a.1 The conductive rubber selection

We look for conductive rubber satisfying these specifications:

- high sensitivity to the stress
- rubber should stand the stress applied to the breast belt, about 10 N
- moderate resistivity, between 0.1 Ω•m and 10 Ω•m.

This value range of resistivity depends on measurement problems, as the sensor is supplied at constant current. In fact, for low values of resistivity, either we would have a low voltage to the sensor and therefore an amplifier would be necessary, or higher currents would be required with consequent higher battery consumption not suited for an apparatus to wear for 24 hours. On the other hand, for high values of resistivity, we could have some reliability problems regards to the rubber contacts (Fig. 10), which would have an higher area.

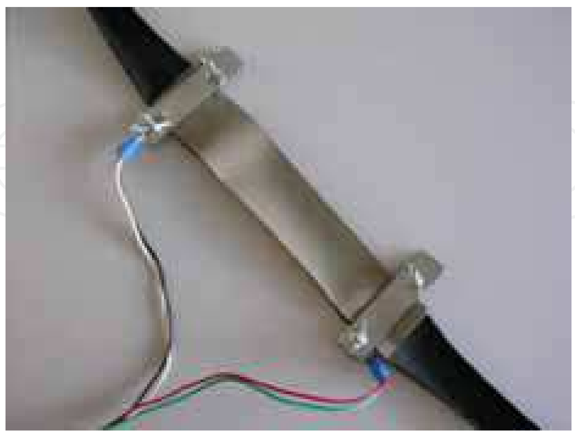

Fig. 10. Rubber contacts.

We have used a sample of conductive rubber, from Xilor, whose resistivity was only $7 \cdot 10^{-5}$ $\Omega \cdot m$, constituted by an aggregate of small conductive spheroids, about 20 μm wide, as shown in Fig. 11, in which it is clear the structure composed of microspheres of rubber.

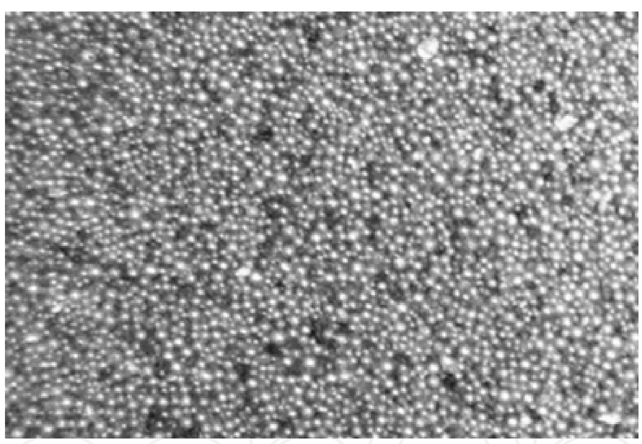

Fig. 11. Microscopic view of the used conductive rubber on a broken side (visual field is 2 mm x 1.5 mm).

This figure has been taken by an optical microscope of our Electronic Devices Laboratory. The resistivity is controlled by the contact surface area between spheroids. This area varies according to the mechanical stress, so that resistivity is very sensitive to the mechanical stress. This material did not satisfied our initial request, because it is not so strong and has a low resistivity, but the sensibility was so high that we have selected this material to develop our prototype.

We took a sample of Xilor rubber 120 mm long, 20 mm large and 0.3 mm thick that was fit in the breast belt, at the place of a piece of belt. Since the sample is not capable to stand all the belt stress, it is not feasible a full belt built only with this kind of conductive rubber. To solve this problem we have added an ordinary non conductive rubber in a mechanical parallel to this sample of Xilor rubber. We are also looking for conductive rubbers having both the

sensitivity and the mechanical strength, but our actual solution with two rubbers is very satisfactory since it splits the mechanical and the electrical problem leaving us more degrees of freedom in the rubbers choice, requiring just a small amount of the more expensive conductive rubber.
Moreover, in this way we can reduce another ageing problem, due to the time variation of the rubber sensibility. Since the sensor is not expansive, we foresee a disposable use of the sensor to overcome the rubber ageing.
Two couples of small iron plates were tightened to each end of the rubber sandwich to ensure electrical connections, as shown in Fig. 10.

4.a.2 Electronic interface and experimental results

The resistance of conductive rubber, about 1 Ω, was measured with the four wires method, two wires to inject a constant current, two wires to sense the voltage. We have not used the well known Wheatstone bridge method because the sensor resistance drift, due to the ageing, could require a continuous bridge balancing and, above all, because the resistance variation is not small.
Since breathing rate ranges from 0.1 Hz to 3 Hz and chest movement signal is impulsive with frequency in the frequency range [0.4 Hz, 3 Hz] our front end amplifier was connected to the sensor through a first-order filter with a low cut off frequency at 0.4 Hz, in order to eliminate the low frequency noise of sensor, and the upper cut off frequency at 3 Hz. Moreover we have considered the low cut off frequency at 0.4 Hz because our prototype is particularly dedicated to sportsmen. Therefore we have considered the 3-Hz breathing rate, corresponding to 180 breaths per minute, to simulate also the transient breathlessness condition due to, for an example, a race. Furthermore it is possible to change the element values of the first-order filter to have a low cut off frequency at 0.1 Hz.
The amplified signal is sent to a peak detector (tuned for breathing rate frequencies), whose output pulses are sent to a peak shaper to have standard length pulses.
This output is already a good signal for breathing rate measurement, but, since we preferred to measure a voltage than a frequency, we feed the pulses in a frequency/voltage converter. A voltage signal for breathing rate measurement allows us to use the ADC of a microcontroller.
In order to have a breath by breath conversion, without contiguous period averaging, we have used the circuit shown in Fig. 12, whose key elements are an exponential-pulse generator and a Sample & Hold (S&H).
For each pulses coming from the previous circuit the exponential pulse generator is triggered, then the tail of this pulses is sampled just before the generator is re-triggered. The synchronization between the S&H and the generator is controlled by a negative edge triggered pulse generator which sends delayed pulses to the exponential generator. Since the exponential pulse is sampled before the reset, the voltage held to the output of the S&H is one to one function of the time length of the last breathing act, that is, in our case, a non linear map from [0 Hz, ∞ Hz] to [0 V, 2.5 V], as shown in Fig. 13.
As benefit no average between consecutive pulses is done and the output staircase waveform is useful for a slow ADC sampling. Since this signal is available only at the end of the breath, this is unsuited for triggering warning in case of breathing stop. Whether this warning would be needed, the output of the pulse shaper (or the output of exponential generator) would be used.

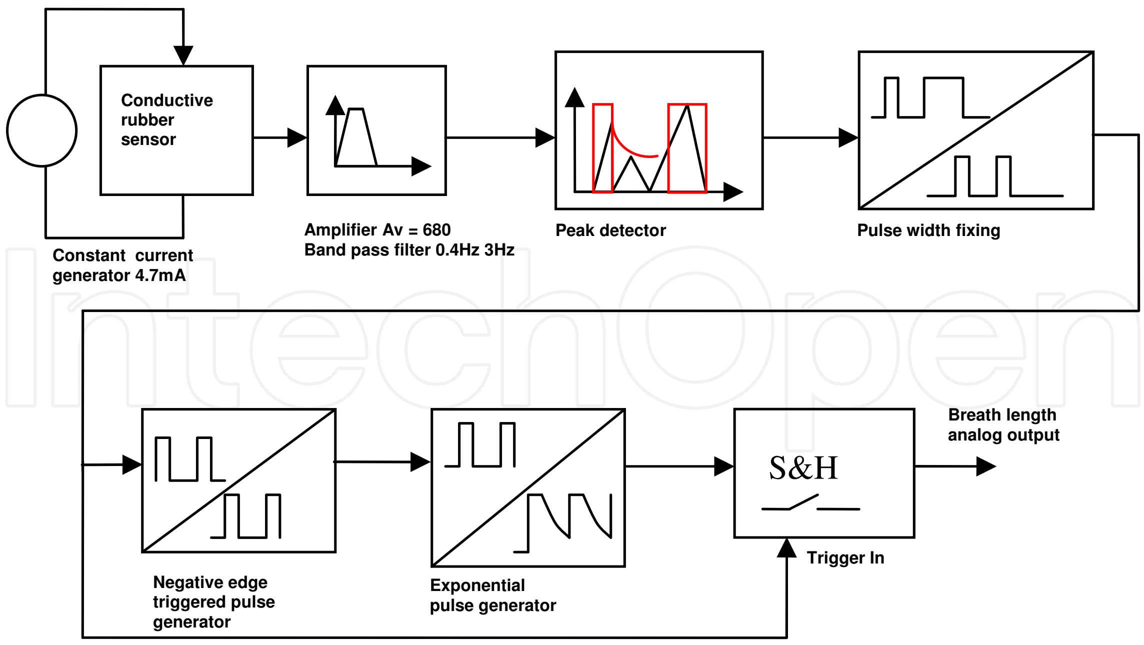

Fig. 12. Circuit used to have a frequency-voltage conversion.

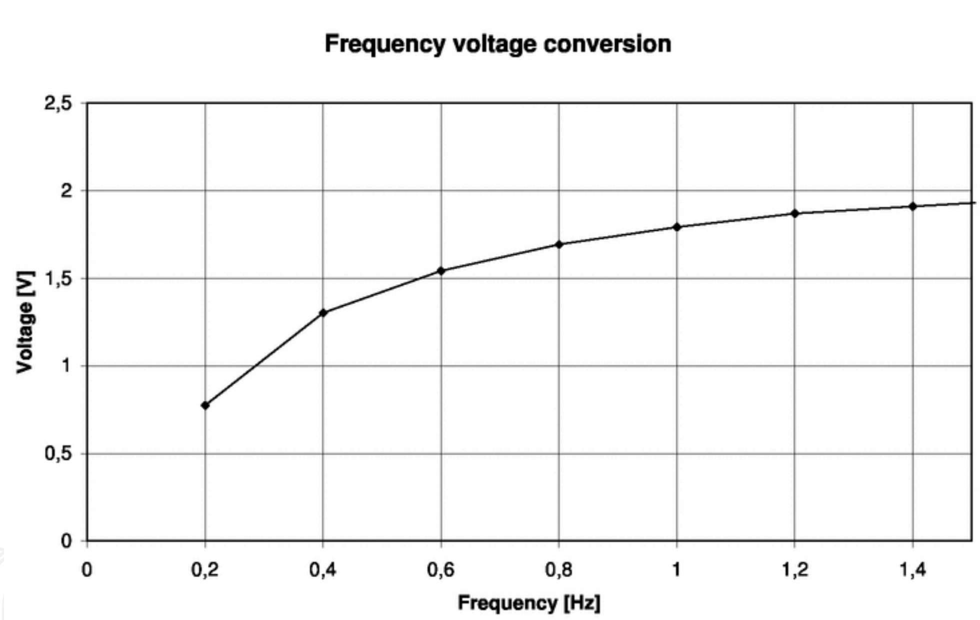

Fig. 13. Frequency voltage conversion diagram.

Using exponential generator, the map between the frequency and the voltage is nonlinear. This is not so bad, since nonlinearity could be corrected on the remote computer display and the exponential allows to map any time length to a finite voltage. Furthermore, since the output voltage is fed to an ADC, and because of the nonlinearity, the best resolution would be given at the most common breathing rate, while the uncommon rates would have lower resolution.

Of course, noise and time delay would cut off the far ends of the [0 Hz, ∞ Hz] range from the map, but the remaining interval is still wide: the system has been tested on the wide interval [0.05 Hz, 6 Hz].

Figs. 14 and Fig. 15 show the signal obtained with the described electronic set-up.

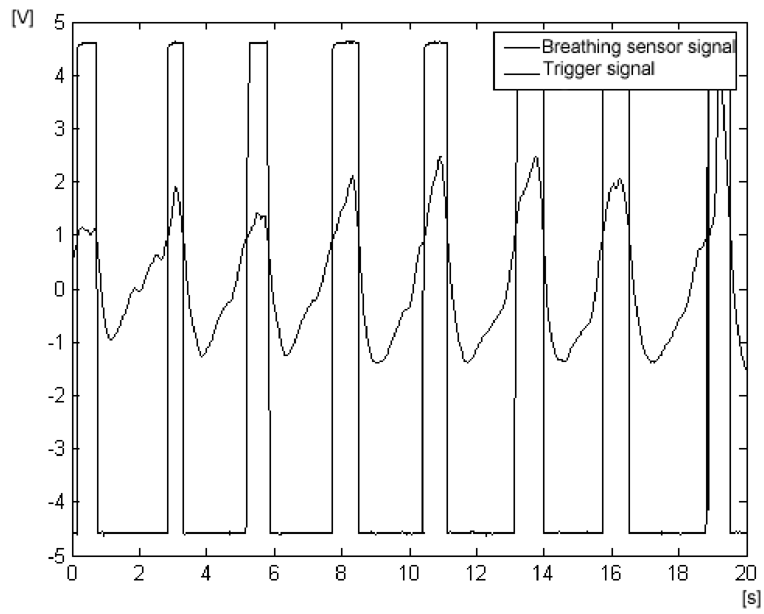

Fig. 14. Breathing act identification: the square pulses are from peak detector while the wavy signal is the amplified sensor signal.

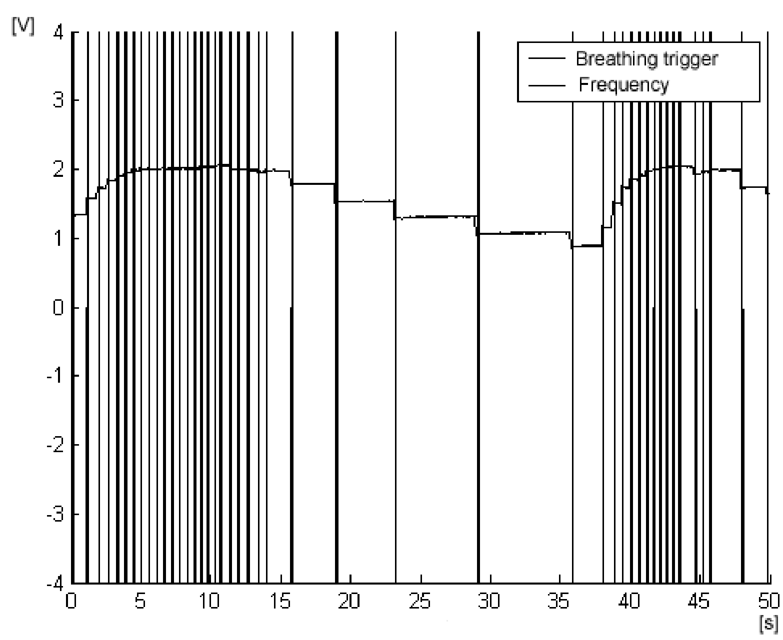

Fig. 15. Frequency measurement: the vertical pulses are trigger pulses from the pulse width fixing block, while the wavy line is the voltage converted frequency at the circuit output.

As shown in Fig. 14, the signal is clear and noiseless; it is also shown the signal from the peak detector which is well behaved.
The system has been successfully test on a wide breathing rates interval (see Fig. 15), but still the ageing problem remains.
In order to allow a test on a wider frequency range, Fig. 15 has been obtained using an electronic pulse generator whose signal was feed to the frequency voltage converter.

4.b Kinetic activity sensor monitoring

The physical activity is important also to understand the medical meaning of heart and breath dynamics. For example, let's think how the meaning of an high heart rate could be different whether the subject is running or standing.

Physical activity monitoring is also very useful to understand objectively the lifestyle of a patient to evaluate his daily energetic expenses.

4.b.1 Sensor

We have observed that root mean square (r.m.s.) values of acceleration (passed through a high pass filter) on the body surface is fully correlated with walking speed. Experimental data collected in previous experiences with other accelerometer, show that vertical acceleration on the shoulder of a running patient peaks from -1 *g* to 2 *g*, while power spectrum spans up to 20 Hz (Fig. 16). Peaks comes from each impact of feet on ground.

This signal includes a contribute coming from the gravity that is $g(\cos\theta)$ where θ is the angle between the sense direction of the accelerometer and the gravity. The variable θ is not constant at all when the accelerometer is fixed on the clothes of a patient but varies widely when a subject bows or stands up. Fortunately the power spectrum of θ is concentrated at frequency below 1 Hz, much lower than the frequencies of the acceleration of a walking or running patient. In conclusion it is necessary and also enough to use a high pass filter to cut off the gravity.

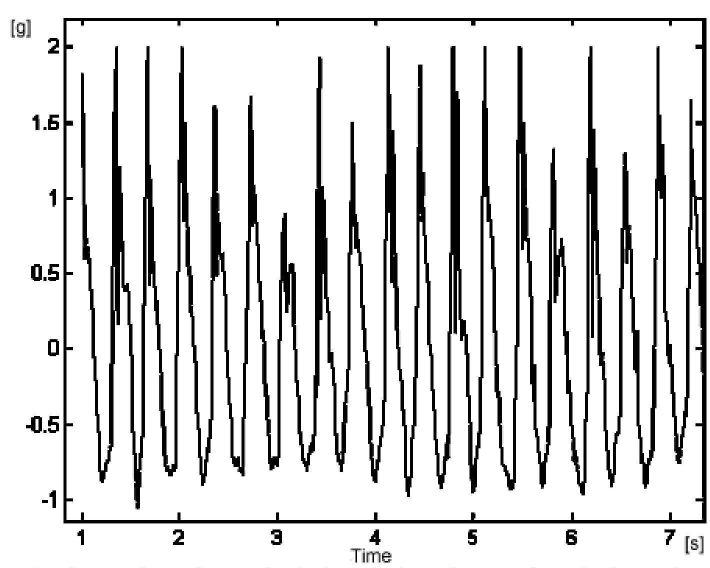

Fig. 16. Acceleration signal detected on a running man. The acceleration is measured in g = 9.81 m/s².

We have chosen the accelerometer ADXL103 (by Analog Devices) whose characteristics are ideal for our application. While the band is much larger than what we need (but this is not a problem), the noise density is low, 10^{-4} $g/\mathrm{Hz}^{1/2}$, useful for good measurements. Its power dissipation is low, it takes 0.7 mA at 5 V, very useful since our system is battery powered. It is also quite cheap (about 9 $).

A particular explanation should be deserved to our interest in the sensitivity range: ±1.7 *g*. This is a bit lower than maximum measurement on a running patient, so this would cause accelerometer signal clipping and would create a progressive saturation of our circuit

output signal. We do not foresee a complete saturation, since this would happen only if the patient runs in a very heavy way.
This is not a real limitation, since a running patients could be statistically marginal and signal partial saturation would be marginal; furthermore for athletic application a new device would be used with larger sensitivity range and different tuning. On the other hand, the cut at ±1.7*g* cuts off the high acceleration peaks, up to several tens of *g*, coming from collisions of accelerometer with the environment. In absence of clipping, high *g* peaks could ruin the 24 hour averages of r.m.s. acceleration.

4.b.2 Electronic interface and experimental results

The signal chain is quite simple and requires a band pass filter to cut off low frequencies at 0.7 Hz (related to gravity) and high frequencies at 20 Hz to clean unforeseen unwanted signal outside the signal band. The upper part of Fig. 17 shows the output signal.

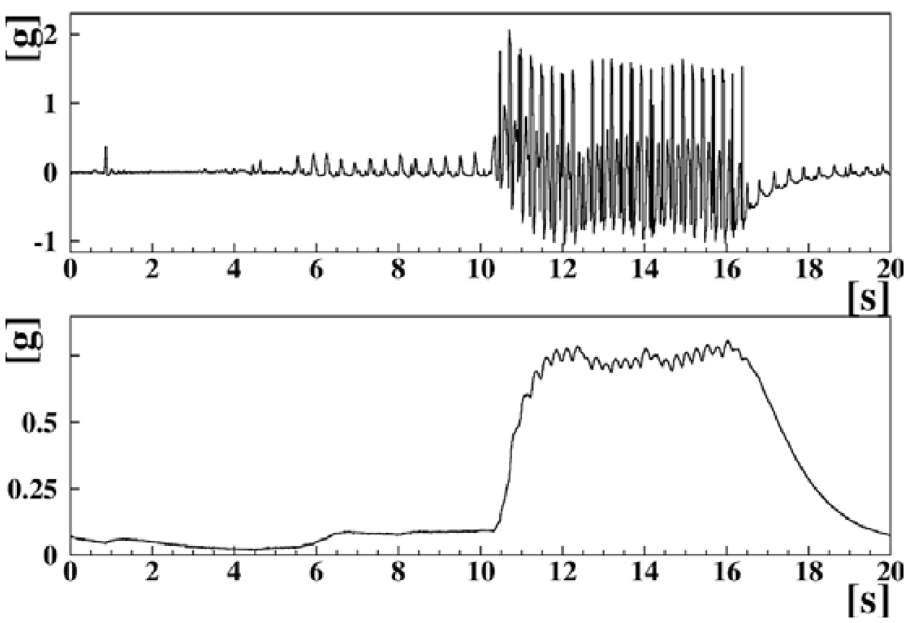

Fig. 17. Upper trace: accelerometer signal. Lower trace: r.m.s. filtered signal.

The filtered signal is passed to a cheap and effective r.m.s. converter, the AD737, whose precision is enough for our purposes. The r.m.s. converter output is filtered to cut off frequencies over 0.1 Hz to kill off the residual ripple observed on running patients. The lower part of Fig. 17 shows this signal.
The signal is clean and spanned voltage range is matched to input span of the ADC of our wearable unit.
Unfortunately the proposed system still presents some ageing problems (Marani et al., 2010).
Indeed the rubber resistivity raised tenfold after few hour of usage, when the rubber was fit in the belt with the dilatation method. While this could be compensated with an automatic gain control at the front end amplifier, it would be better to measure compression effects on rubber conductivity.
A second problem is the sensibility to the arms movements, which could trigger false breathing pulses. This is intrinsic to the belt method, but the effect is not so frequent compared to the breathing rate.

The proposed kinetic sensor, based on commercial accelerometer, has been tested on several subjects, for each patient it was clearly possible to recognized whether the subject was standing, walking or running.
The observed signal is correlated to the physical activity but also to the weight of the subject, and (we suppose) also the way subject walks. For simple qualitative analysis this is not a problem, but, if a quantitative analysis is required, a personal calibration would be performed, or simply a statistical parameterization of calibration on some biological parameter, e.g. weight, height, sex and age.
With this calibration, we hope that this physical activity measurement would allow a good quantitative estimator of the energetic expenses to what concern walking and running, and we hope that, using also other biological parameters to evaluate basic metabolism, it could be possible to estimate the daily energetic expenses.
This would be very interesting since available method that measure the CO_2, with mouth and nose tubing (Lay-Ekuakille et al., 2010) (Wei et al., 2010)., and the heat production (in a calorimetric box) are not suited for 24 hour measurements.

5. A system for holter applications with ECG transmission by Bluetooth

Today the most used tape-recorder type electrocardiographs for the long term registration provide the acquisition of two or three channels thus allowing the detection of a limited number of pathologies and missing crucial details relevant to the morphology of the heart pulse and the related pathologies, given only by a static ECG executed in the hospital or in medical centres (Carr et al., 2001) (Webster, 2004).
Moreover, the sampling frequency for the analog to digital conversion of the signal, for the best known portable ECG, is typically lower than 200 Hz, thus missing important medical data carried out by the electrocardiograph signal. Finally, the most used medical devices for long term registration (holter) of cardiac activity are generally so uncomfortable especially due to their dimensions.
Within our biomedical engineering researches, we have designed and prototyped a new medical device for holter applications intended to overcome the above mentioned limitations and to advance the state of the art.
In fact the designed device presents the following advantages:
1. data from up to 12 channels;
2. sensors, embedded in a kind elastic band;
3. possibility to place on the thorax many electrodes without reducing the movement potentials;
4. the elastic band mounting a wireless module (Bluetooth) (Senese, 2003) to send the data to the recorder/storage unit;
5. implementation of a diagnostics algorithm and/or to download, in real time, the data by UDP channel.

The system core is a microcontroller-based architecture. It is composed by: multiplexed internal ADC with a 12 bit resolution, 8K bytes Flash/EE program memory; 32 Programmable I/O lines, SPI and Standard UART. Normal, idle and power-down operating modes allow for flexible power management schemes suited to low power applications.
Fig. 18 shows the prototyped electrocardiograph recorder/storage unit.

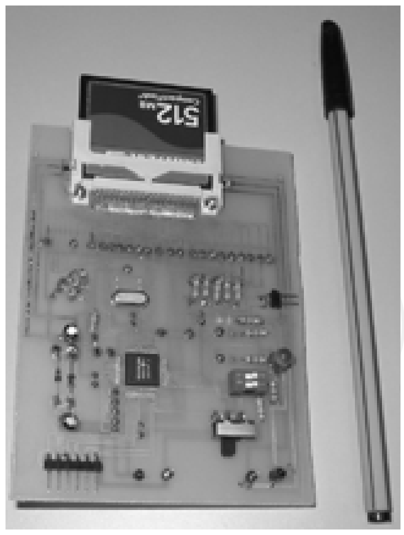

Fig. 18. Picture of the prototyped new electrocardiograph receiving unit.

The small dimensions are remarkable even if a further reduction is possible.
The management software to data-download has been properly developed by the us, being it custom for this application. It receives the data from the electrocardiograph and allows to store/plot them.
In Fig.19 a draft of an acquisition example is shown.

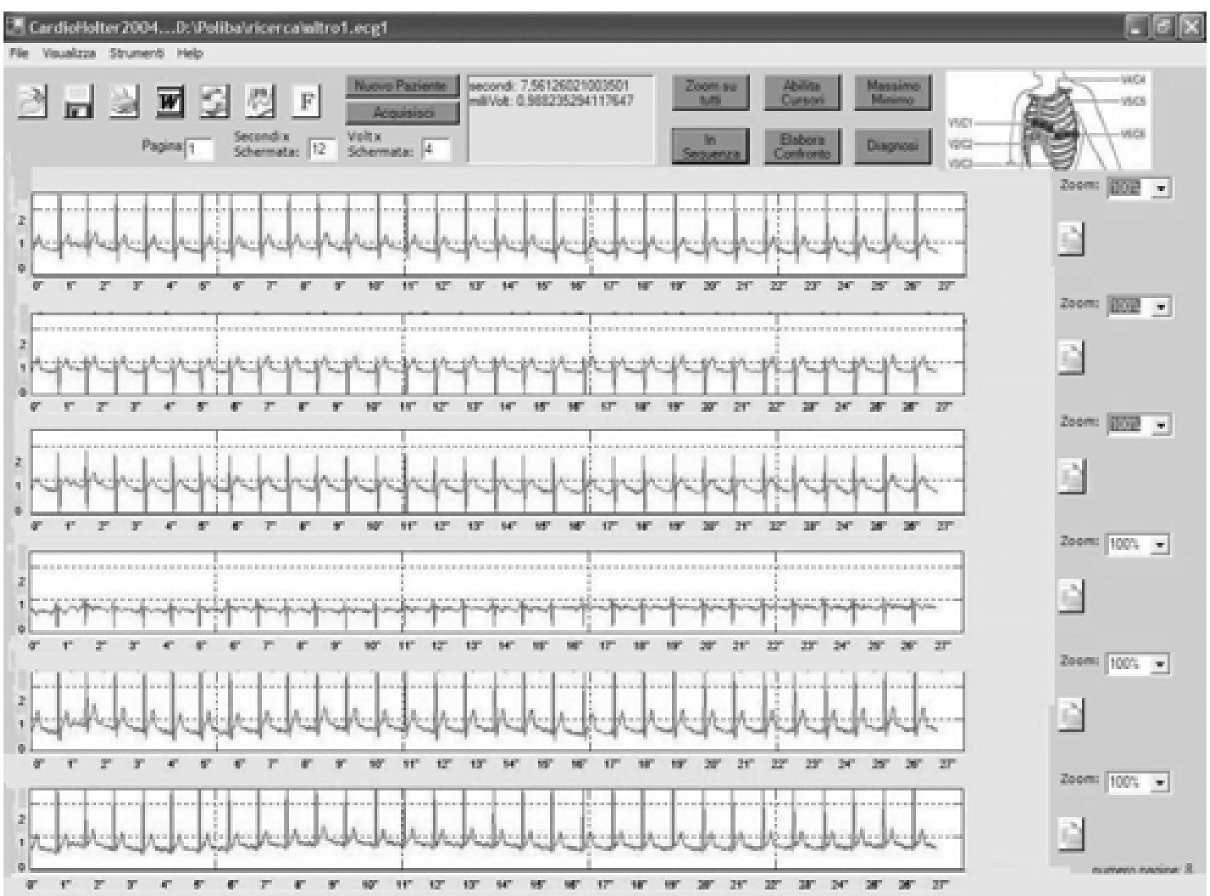

Fig. 19. An acquisition example of ECG.

The management software allows to view/plot one or more channels, to make a real-time automatic analysis of the incoming signal and to perform digital filtering. In fact the software performs the Fourier Transform of the incoming signal, useful to make a real time filtering if needed to improve the quality of the ECG. A wavelet filtering is also available. The operator has to evaluate only the frequencies to suppress, after seeing the Fourier Transform of the signal, and the software performs the signal filtering.
As regards the wireless module to send the data to the recorder/storage unit, Fig. 20 shows the relative prototype, realized at our Electronic Device Laboratory.

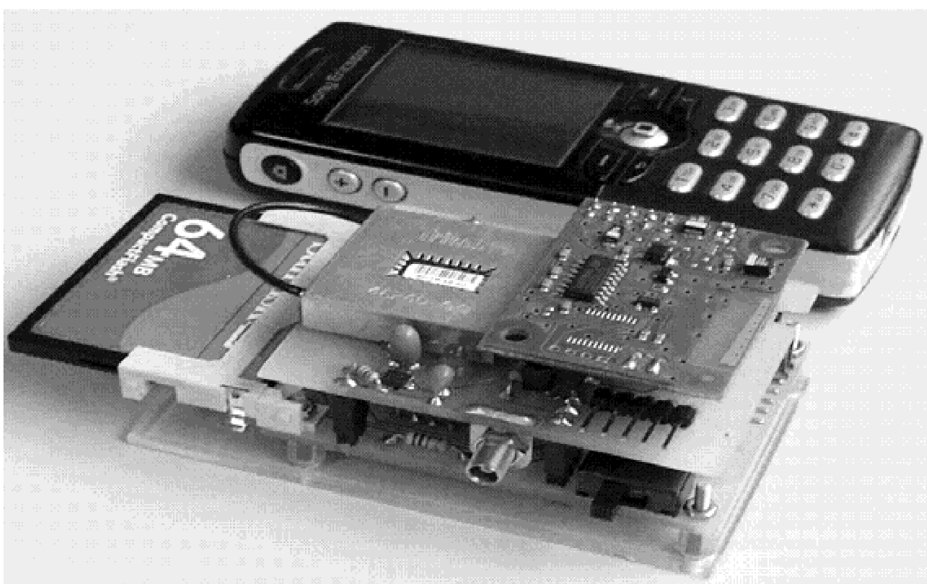

Fig. 20. System for ECG transmission by Bluetooth.

It is also equipped with GPS module for the patient location in real time.
It proves particularly useful indefinite places such as nursing homes and rest homes for elderly people.
However by using a mobile phone the system also allows transmission within a long range by GPRS/GSM.
The microcontroller permits to implement a diagnostics algorithm and/or to download, in real time, the data by UDP channel.
The tracing can be also stored on flash cards legible with any PC equipped with a reader of flash memories.

6. Conclusions

In this chapter we have presented a review of our principal projects in biomedical electronic field, developed at the Electronic Device Laboratory of the first Faculty of Engineering of Polytechnic of Bari, Italy, within a research program, with the support of national university medical centre.

Firstly we have proposed a medical electronic-computerized platform for diagnostic use, which allows the doctor to carry out a complete cardio-respiratory control on remote patients in real time. The system has been patented and has been designed to be employed also to real-time rescue in case of emergency without the necessity for data to be constantly monitored by a medical centre, leaving patients free to move.

We have also proposed a low-cost, electronic medical device, designed for the non-invasive continuous real-time monitoring of breathing functions.

Moreover we have presented a new system for acquiring simultaneously the breathing rate and the kinetic activity.

At last a new system for cardioholter applications, characterized by the possibility to send ECG by Bluetooth to 6 or 12 leads, has been described.

All proposed systems have been prototyped and tested.

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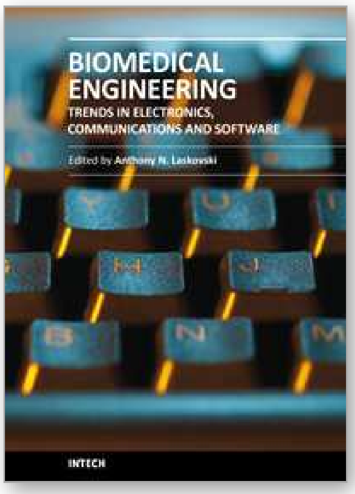

Biomedical Engineering, Trends in Electronics, Communications and Software
Edited by Mr Anthony Laskovski

ISBN 978-953-307-475-7
Hard cover, 736 pages
Publisher InTech
Published online 08, January, 2011
Published in print edition January, 2011

Rapid technological developments in the last century have brought the field of biomedical engineering into a totally new realm. Breakthroughs in materials science, imaging, electronics and, more recently, the information age have improved our understanding of the human body. As a result, the field of biomedical engineering is thriving, with innovations that aim to improve the quality and reduce the cost of medical care. This book is the first in a series of three that will present recent trends in biomedical engineering, with a particular focus on applications in electronics and communications. More specifically: wireless monitoring, sensors, medical imaging and the management of medical information are covered, among other subjects.

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