

DESIGN OF ADVANCED ELECTRONIC BIOMEDICAL SYSTEMS

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ABSTRACT

In this paper we present a review of some of our projects in the field of biomedical electronics, developed at Electronic Devices Laboratory of Polytechnic University of Bari, Italy, within a research program, with the support of national university medical centre. In particular 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. Then we have also examined a low-cost, electronic medical system, designed for the non-invasive continuous real-time monitoring of breathing functions. 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 designed systems are characterized by originality and plainness of use, as they planned with a very high level of automation.

KEYWORDS: Bioelectronics, Electronic Medical Devices, Health Care Management Systems, Heart and Lung Auscultation System, Electrocardiogram and Respiratory Monitoring, Cardioholter, Prototyping and Testing.

I. INTRODUCTION

In this paper we present a review of some of our projects in biomedical electronics [1-8].

Firstly we describe 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 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, the system sends a warning message to persons able to arrange for his/her rescue, providing also the patient's coordinates. All this occurs automatically without any intervention by the user. The system might be useful also to sportsmen.

Moreover we illustrate a microcontroller-based digital electronic system, oriented to the monitoring of the respiratory cycle and the relevant ventilator setting. The system allows the effective auscultation, the accurate processing and the detailed visualization (temporal and frequency graphs) of any lung sound. Then, it is suitable for the continuous real-time monitoring of breathing functions, resulting also very useful to diagnose respiratory pathologies.

At last we present a system for ECG transmission by Bluetooth and a digital cardioholter with multiple leads.

All designed systems, prototyped and tested at the Electronic Devices Laboratory (Electrical and Electronic Department) of Polytechnic University of Bari, Italy, are characterized by originality, by plainness of use, as they planned with a very high level of automation (so called "intelligent" devices).

In Section 2 we describe the main feature of our system to carry out a complete cardio-respiratory control on remote patients in real time, while in Section 3 we illustrate the electronic system oriented to the monitoring of the respiratory cycle. Section 4 illustrates a system for ECG transmission by Bluetooth and a digital cardiolter with multiple leads. The conclusions are reported in Section 5.

II. HEART AND LUNG AUSCULTATION SYSTEM

The designed system [1] [2] is a medical electronic informational platform for diagnostic use, which permits the doctor to carry out a complete cardio-respiratory control on remote patients in real time.

In fact, as if the doctor is present personally near the patient, the system allows him to receive the following data in real time:

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 band 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 SpO₂ 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 data base 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 database.

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 and requires a 320 Kb/s minimum band or a UMTS Mobile telephone.

The system has an user friendly software interface very easy to be used, because it 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 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's 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.

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 identified by 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.

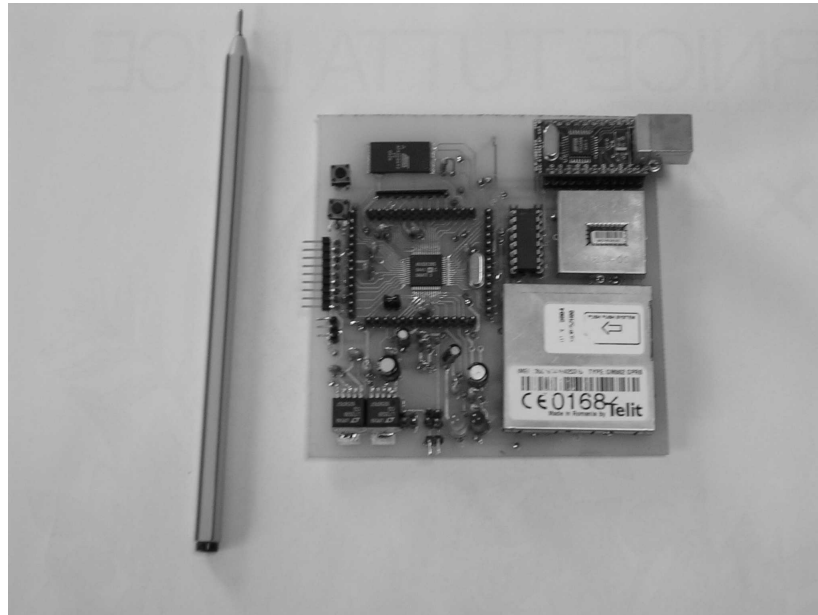


Figure 1. A picture of the Portable Unit.

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.

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 coordinates using the GPS unit and the Management Software provides in real time a map indicating the position of the patient.

Fig. 2 shows a picture of an electrocardiogram transmitted by Bluetooth and plotted on a Personal Computer by the developed management software.

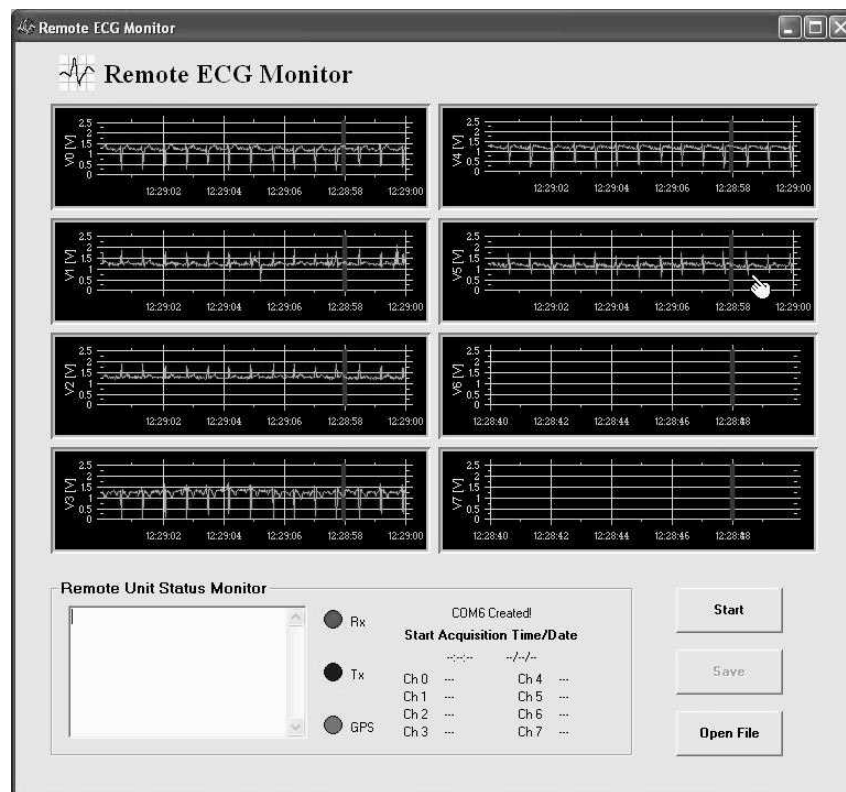


Figure 2. Example of acquisition by Bluetooth of an electrocardiogram.

III. SYSTEM FOR AUSCULTATION OF THE PULMONARY SOUNDS

Methods adopted for the respiratory cycle monitoring can be distinguished into two types: static methods and dynamic methods. Static methods require ventilation interruption from 30 to 60 seconds, being very dangerous for the patients.

One of the most important dynamic method is the Stress Index [9], which is based on the acquisition and following analysis of airway pressure values in constant flow ventilation condition (volume controlled). From the acquired curve we can derive a pulmonary stress index, which represents the extreme hypothesis of induced increase of lungs volume.

A progressive decrease of the slope of the curve designates the alveolar involvement, while a progressive increase of the slope designates over-ventilation.

Therefore, the required parameters for monitoring the respiratory mechanics in the stress index method are flow, pressure and lungs volume.

The device acquires, in non-invasive manner, low-frequency signals ($f_{\max} = 200$ Hz) from a pneumotacograph (flowmeter) and pressure sensors connected to patient's airway by plastic cannula.

The design specifications are high miniaturization level, noise immunity, low costs and chance for future expansions in terms of number of required sensors, implementation of Plug and Play sensors to simplify their use, configuration, easy and fast connection to any Personal Computer.

A block diagram of the designed system [3] [4] is shown in Fig. 3.

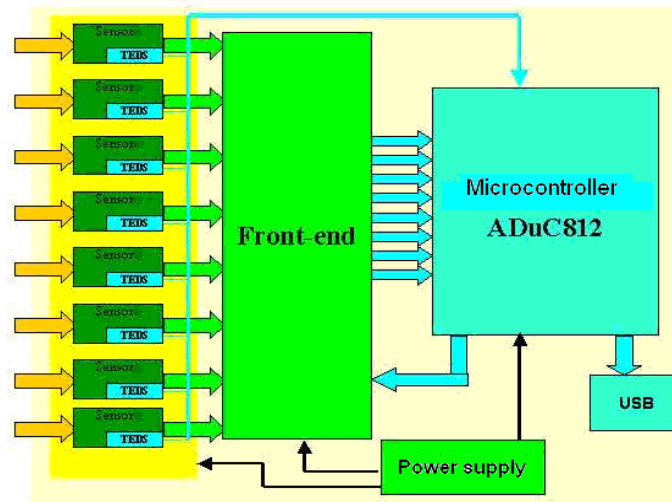


Figure 3. Block diagram of the designed system.

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 amplify 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 [10]. 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 [11] [12].

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. 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 I²C.

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. 4.

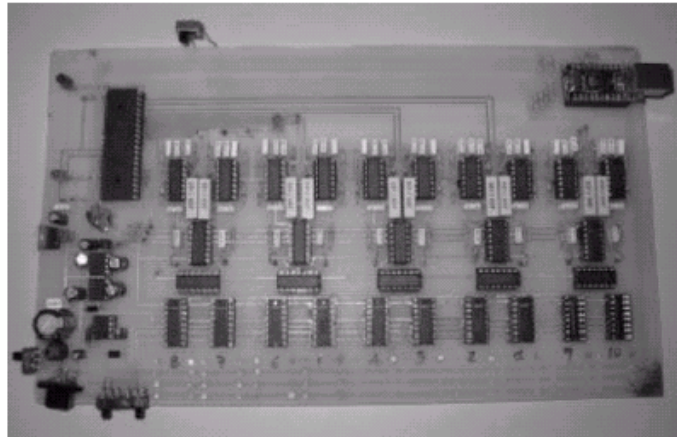


Figure 4. The prototype: a double-sided printed circuit board.

The device is characterized by compactness and small-size and performs the following operations: 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.

Some researches have pointed out the effectiveness of the frequency analysis of lung sounds for the diagnosis of pathologies.

A number of validation experiments show that computerized tomography (CT) results perfectly match those of a simple frequency analysis of previously recorded lung sounds.

Many studies [3-4] 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.

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 shows 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 perfectly match those of the frequency analysis.

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.

We can now evaluate deterministic interpolating functions to generate surface respiratory acoustic thoracic images [13].

IV. 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 centers. 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) 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. 5 shows the prototyped electrocardiograph recorder/storage unit.

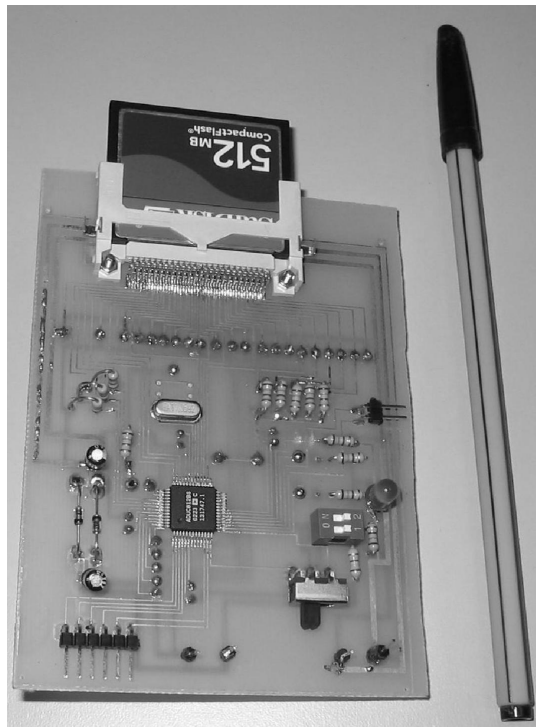


Figure 5. Picture of the prototyped new electrocardiograph receiving unit.

The small dimensions are remarkable even if a further reduction is possible.

The management software to data-download has been properly developed by us, being it custom for this application. It receives the data from the electrocardiograph and allows to store/plot them.

In Fig. 6 a draft of an acquisition example is shown.

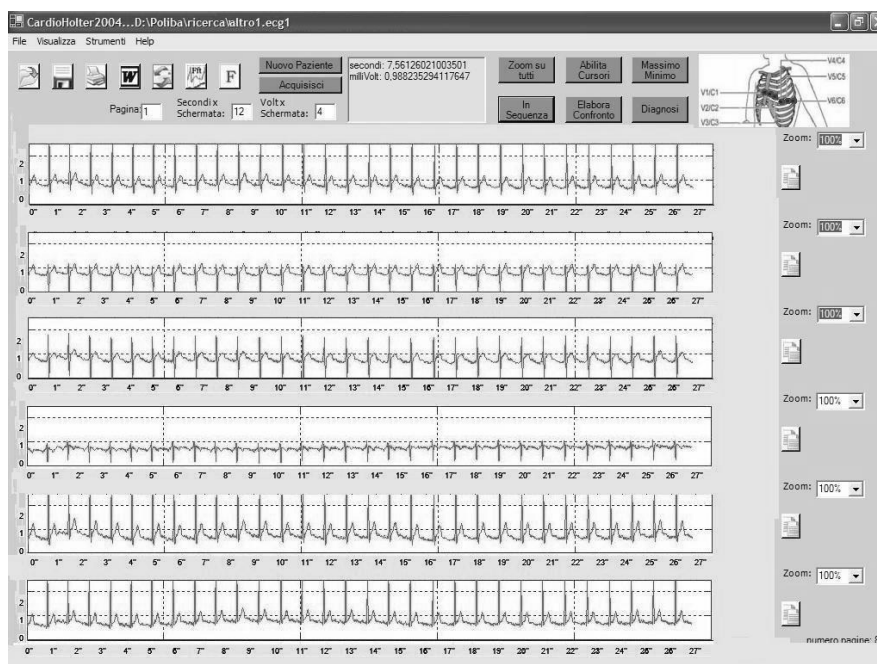


Figure 6. An acquisition example of ECG.

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. 7 shows the relative prototype, realized at our Electronic Devices Laboratory.

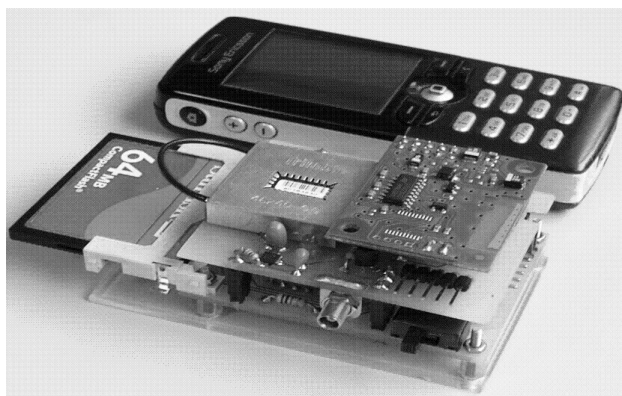


Figure 7. System for ECG transmission by Bluetooth.

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.

V. CONCLUSIONS AND FUTURE DEVELOPMENTS

In this paper we have presented a review of some of our projects in biomedical electronic field, developed at the Electronic Device Laboratory of Polytechnic University 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. Our system appears to be very innovative because, at the best of our knowledge, the only wearable medical device actually offered by the market and oriented to the a remote health monitoring is the electrocardiograph. Moreover, there are not “intelligent” devices, able to activate the rescue fully automatically.

We have also proposed a low-cost, electronic medical system, designed for the non-invasive continuous real-time monitoring of breathing functions. The innovative proposed solutions allow a high miniaturization level, automatization and simplicity of use, since we have employed last-generation programmable integrated circuits. The architecture is general and versatile and allows several signal processing in biological applications.

Actually we are developing the firmware and the post-processing software to optimize the device performance.

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. In particular, the device is made up of a proprietary software which allows the download of the recorded tracing and afterwards the processing of the same tracing thanks to the implementation of digital filters with “easy to use” interface. The small dimensions are remarkable even if it is in development a study to obtain a further reduction.

All proposed systems have been prototyped and tested.

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