WEARABLE HEALTH-CARE SYSTEM: NEW FRONTIER ON E-TEXTILE

R. Paradiso

*Milior S:p.A.and Smartex s.r.l. Prato, Italy

ritap@milior.com

ABSTRACT
A comfortable health monitoring system named WEALTHY is presented. The system is based on a wearable interface implemented by integrating fabric sensors, advanced signal processing techniques and modern telecommunication systems, on a textile platform. Conducting and piezoresistive materials in form of fiber and yarn are integrated in a garment and used as sensors, connectors and electrode elements. Simultaneous recording of vital signs allows extrapolation of more complex parameters and inter-signal elaboration that contribute to produce alert messages and synoptic patient table. Purpose of this publication is to evaluate the performance of the textile platform and the possibility of the simultaneous acquisition of several biomedical signals.

Keywords—Fabric sensors, fabric electrodes, physiological signs,

INTRODUCTION
A new concept in health care, aimed at providing continuous remote monitoring of patient vital signs, is now emerging. This paradigm shift is both socially driven-the rising cost of assistance, the need to improve early illness detection and medical intervention- and technologically driven. In particular, the advances in sensor technology, as well as in communication technology and treatment of data, constitute the basis on which this new generation of health care systems can consolidate. These systems are designed to be minimally invasive for health status monitoring, based on flexible and smart technologies conformable to the human body, they can help to improve the autonomy and the quality of life of patients. Wearable system are also cost-effective in providing around-the-clock assistance, for example in rehabilitation from cardiac disease or for the monitoring of professional workers subject to considerable physical and psychological stress and/or environmental and professional health risks. Finally, by providing direct feedback to the users, they improve their awareness and potentially allow better control of their own condition.
A remote health monitoring can be accepted and used only if the monitoring devices is based on truly wearable sensing interfaces, easy to use and easy to customise; the new interfaces must guarantee to users a continuous remote control, in a “natural” environment without interfering with daily activity. The less interfering device has to be based on textile, functionalised materials in fiber and yarn form can be integrated and used as basic elements to fabricate woven or knitted fabrics possessing distributed sensors and functions.
This work is focused on a system named Wealthy, that aims to set up a comfortable health monitoring tool, based on a on a sensing textile platform. The system is designed to be minimally invasive, comfortable and wearable, to this aim conductive and piezoresistive materials in form of fiber and yarn are used to realize clothes where knitted fabric sensors and electrodes are

distributed and connected to an electronic portable unit, the acquired signals can then be transmitted to a remote monitoring system.
The simultaneous recording of vital signs allows parameters extrapolation and inter-signal elaboration [1][2] that contribute to produce alert messages and personalized synoptic tables of user's health.

WEALTHY SYSTEM

Strain fabric sensors based on piezoresistive yarns, and fabric electrodes realized with metal based yarns, enable the realization of wearable and wireless instrumented garments capable of recording physiological signals and to be used by the patient during everyday activity. Breathing pattern, electrocardiogram, electromiogram, activity sensors, temperature, can be listed as physiological variables to be monitored through the proposed system. A miniaturized short-range wireless system is integrated in the sensitive garment and used to transfer the signals to WEALTHY box/PCs, PDA and mobile phones. An "intelligent" system for the alert functions, able to create an "intelligent environment" by delivering the appropriate information for the target professional is the complementary function implemented. The system is addressed for the monitoring of patients suffering with heart diseases during and after their rehabilitation.

WEALTHY FUNCTIONS

WEALTHY system is developed as the integration of several functional modules. The main functions of portable modules are shown in Fig. 1, namely: sensing, pre-processing, , processing and transmission.

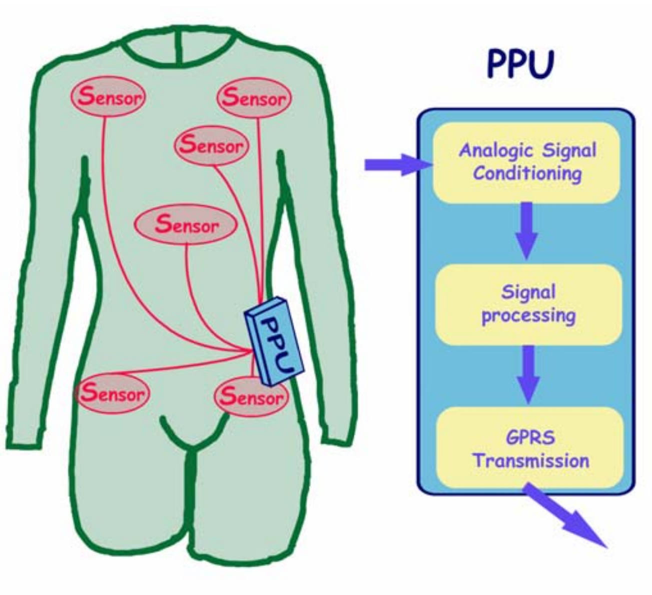

Figure 1: WEALTHY function overall

The garment interface is connected with the portable WEALTHY device where the local processing as well as the communication with the network is performed. A knitted fabric platform containing insulated conductive tracks connected with sensors and electrodes has been implemented to make the cloth. Most signals are transmitted unprocessed to the Monitoring System, described in Figure where they can be analyzed offline. In order to reduce the needed data capacity of the wireless link to the Central Monitoring System, some sensors signals are processed by the portable patient unit (PPU) to extract essential parameters. Local preprocessing of signals has to be decided in a trade-off between the gain in term of wireless link occupancy and the increase of needed local processing power.

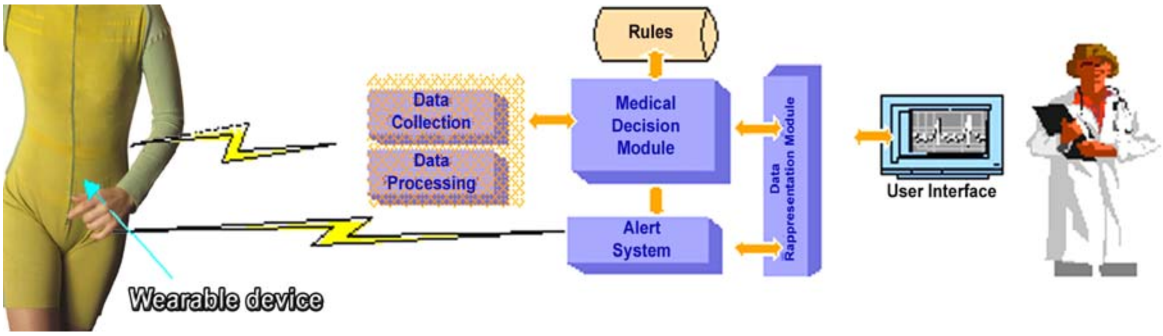

Figure 2:Wealthy Monitoring System

ECG signals are sampled on the PPU at 250Hz, a local processing is applied in order to extract parameters with a higher sampling rate, so that ECG parameters, such as heart rate (HR) value and QRS duration can be computed with a significant number of samples.
In order to decrease the amount of data transmitted by GPRS, the ECG signal is decimated to obtain a sampling rate of 100Hz.
Off-line processing, depending on the application, is carried out at the monitoring center. A preliminary list includes:

- Tachogram
- Level of the T wave with respect R wave
- T wave area
- Spectral analysis of RR signal

Respiration and movement activity come from piezoresistive sensors, sampled at 16Hz. Signals from these sensors are transmitted without local processing.
The PPU is designed to have a simple user interface, a few LEDs and a buzzer for user warning purpose and a button to let him manually trigger an alarm. The PPU electronics is built on an "Europe" form factor board (160mm x 100mm) and packaged in a metallic enclosure. It contains the necessary functions to condition physiological signals, such as filtering, digital analysis and to perform specific higher level processing like HR extraction, run the application, as well as communicate over GPRS with a monitoring center. All the circuits, sensors and communication module are powered by a 1100mAh/3.6V lithium battery. The battery autonomy ranges between a few hours and eight hours, depending on the level of use of the GPRS link. It can be recharged using a dedicated front panel connector.
The final aim is to recognize those parameters that define an event. Several statistical tools based on a multifunctional analysis, may be used for this purpose. In order to offer full mobility to the patient or the user, the acquired signals are transmitted wirelessly from the PPU to the remote Monitoring System. The communication is based on TCP/IP that is the standard protocol for GPRS communication. For GPRS bandwidth limitation reason, the monitoring centre shall select

the ECG lead to be transmitted (one at the time). All signals are sent in quasi real-time to the remote Monitoring Centre.

The WEALTHY Central Monitoring System is a s/w module interpreting physical sensor data received from the PPU and representing them in simple, graphical forms. It will be used by the proper staff in order to judge the automatically generated alerts and forward only the critical alerts to the doctors and the patients.

The user will be able to watch the health status of all patients connected to the Central Monitoring System (through the WEALTHY garments). The definition of the monitoring profiles will provide an easy to use monitoring of the patients' health status in real time and with different fully customisable views.

Simultaneously, the user will be able to review the generated alerts and using past medical data will determine the true and false alerts and correspondingly contact doctors through direct phone calls and online alerts. This Central Control module is not necessary in order for the Monitoring System to work. It is an optional module ensuring the minimal generation of false alerts to the doctors and will be necessary for large scale hospitals dealing with hundreds of patients.

The Central Monitoring System performs the following tasks:

- Coordinates and controls the data flow between the different actors.
- Collects and stores the data transmitted by the sensors integrated in the WEALTHY garment through the Portable Patient Unit (PPU).
- Continuously monitors vital health parameters of the patients.
- Generates alerts to inform doctors for critical health situations.
- Gives access to the central database to doctors and other health professionals.
- Presents to the qualified users the health situation of the patients using different user-friendly interfaces.

All the Monitoring System modules are able to run on a single computer without the need of dedicated high-end servers.

The WEALTHY platform will give the possibility to monitor and assist patients through a remote medical advice service. The use of intelligent systems provide to physicians the data to timely detect and manage health risks, diagnose early illness or injury, recommend treatment that would prevent further deterioration and, finally, to make confident professional decisions based on objective information all in a reasonably short time.

WEALTHY Interface

Strain fabric sensors based on piezoresistive fabric or yarns, and fabric electrodes made with metal based yarns, enable the realization of wearable and wireless instrumented garments capable of recording physiological signals, to be used during the routinely activity, to be worn instead of a classical garment without discomfort for the user. Respiration, electrocardiogram, electromiogram, activity sensors, temperature, may be listed among the physiological variables that can be monitored through the proposed system.

Piezoresistive fabric sensors have been realized by using lycra® fabric coated with carbon loaded rubber, as well as by weaving a commercial electroconductive yarn (PAC 250 dtx x 1 , by Europa NCT, Poland). These fabrics behave as strain gauge sensors and show piezoresistive properties in response to an external mechanical stimulus. The coated lycra® fabric has been used to detect respiration signal, due to the higher efficiency shown in term of quality of the signal, compared with the other fabric sensor. The Europa yarn has been used for the activity sensors and knitted in the multifunctional fabric. The behavior of a knitted piezorestive sensor is

different when stretched towards warp or weft direction. Preliminary tests have been done to select the more efficient technique of knitting and the direction of stretching. The fabric sensor have been integrated and oriented in a way to maximize the gauge factor according with the response shown during the preliminary tests.
Electrodes have been realized with a yarn where two stainless steel wires are twisted around a viscose textile yarn (Elitè by Lineapiù SpA, Italy). Electrodes were knitted by using tubular intarsia technique to get a double face, using the external –non conductive- part to isolate the electrode from the external environment. The basal yarn (not sensitive) was the same yarn used as core for the conductive electrode yarn. To improve the electrical signal quality in dynamic condition a hydro-gel membrane purchased by ST&D Ltd (Belfast-UK), has been used. The use of the membrane affects also the comfort as electrodes have a rough surface and a prolonged contact with the body can give rise to skin irritations. The contact between conductive fabric and skin can be improved by increasing the adherence of the garment with the use of an higher percentage of elastic component in the yarns. Another approach is the use of conducting rubber or silicon as coating layer for the electrodes; in our future work both the approaches will be investigated.
Connections have been realized by means of tubular intarsia technique. A supplementary layer has been woven by using of vanisé technique. The final connection is a multi layered structure where the conductive surface is sandwiched between two insulated standard textile surfaces. The same conductive yarn is used for the electrodes as well as for the realization of connections, a particular of the textile prototype is shown in Figure 2.

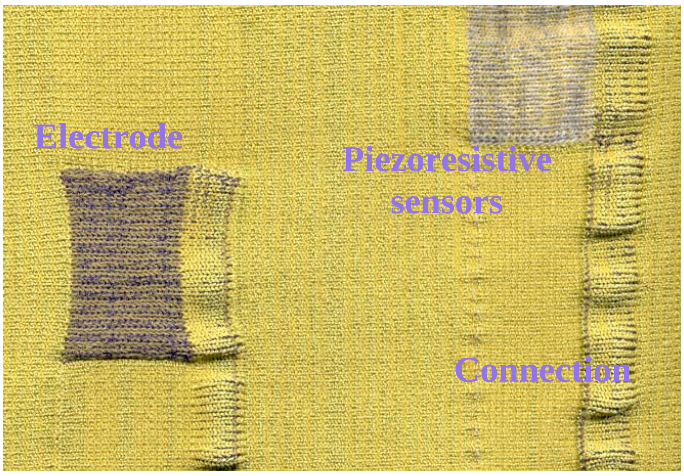

Figure 3: Particular of WEALTHY interface

Knitting fabric has been made with a flat-knitting machine (Vesta Vx 12 – Steiger, Switzerland). A draft position of sensors was implemented on the knitted fabric, and then by means of the use of models was possible to cut the fabric in a way to get the sensors in the desired configuration. The garment was finally sewed, which means that the final position of sensors and connections was achieved in the manufacturing phase.
The prototype model [3] is shown in Figure 4 where the electrodes position is highlighted, in the picture the Einthoven and Wilson derivations (E, W), V2 and V5 as Precordial leads (P) and the Reference electrodes (R) are shown, respectively, while two Breathing sensors (B) are positioned

one on the thorax and the other on the abdomen; in Figure 4 is shown the position of 6 movement sensors.

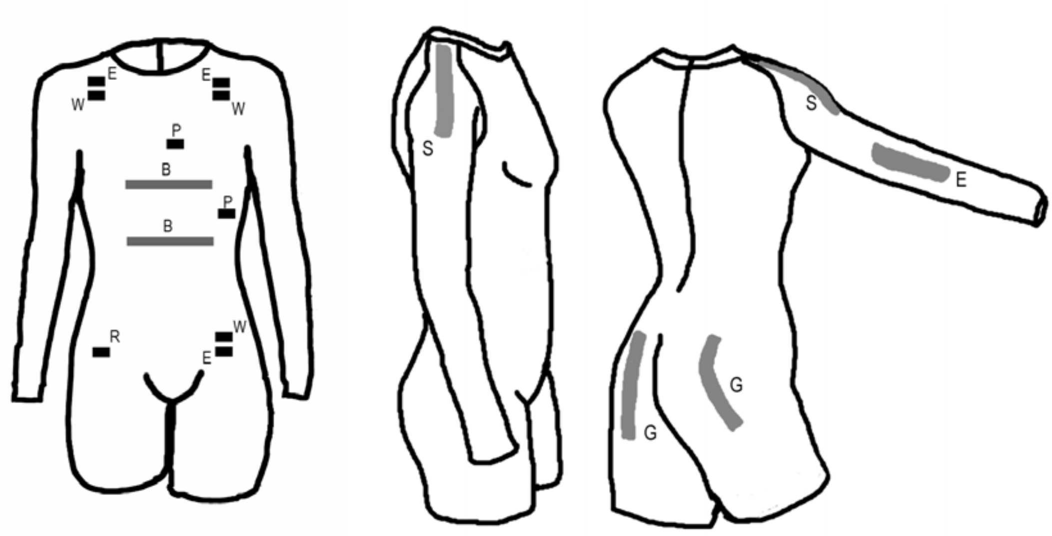

Figure 4 Prototype model: on the left: E Einthoven, W Wilson, R Referee, P Precordial leads, B Breathing sensors; on the right: Movement sensors

Stainless steel threads have been selected for the realization of fabric electrodes for a series of reasons: first of all they are compatible with industrial textile processes, they are inert and stable in the presence of O2, finally the cost of steel is very competitive compared with pure silver, or pure gold.
Naturally the fineness and flexibility of metal components have been chosen to get a final conductive yarn suitable for knitting, weaving and more in general for textile processing, which means that the metal threads used are washable, flexible and biocompatible. The same approach has been used for all the sensorial yarns and fabric developed in the project. It is also possible to work with silver coated threads that are occasionally employed for special fashion effects or for antibacterial purposes in textile world. Preliminary tests done with fabric containing polyester yarns coated with silver have shown that the use of stainless steel threads is more convenient: in fact during the experiments it has been observed that the conductivity of the silver electrode was lower than stainless steel ones, when samples with the same dimension were compared. This is probably due to the small amount of metal components localized only in the coating layer of the threads. It is important to underline that the fabric cannot be realized only with metal yarns otherwise this region of the garment will be too rigid and not conformable, the amount of metal in the fabric is a compromise between the demand to increase the conductivity and the necessity to improve the touch sensation (the hand) of the cloth. Moreover the quality of silver adhesion was very poor, after several tests large metal coating regions looked removed; the electrodes need to be used with gel or conductive past and finally the electrodes have to be chlorinated.
Conductive and piezoresistive yarns are resistant to repeated washing in aqueous solutions, the physiological signals detected after washing have shown that the performances of the fabric sensors are not affected by the process.
An alternative strategy to measure respiratory activity is the use of the impedance pneumography. In this case four electrodes are placed in thoracic position. The two external ones

are used to inject an high frequency current (50 kHz) and the other ones allow to capture the voltage variation caused by thoracic impedance change. The output signal is modulated by changes in the body impedance accompanying the respiratory cycle. In Figure 4 is shown the position of the electrodes for the impedance pneumography.

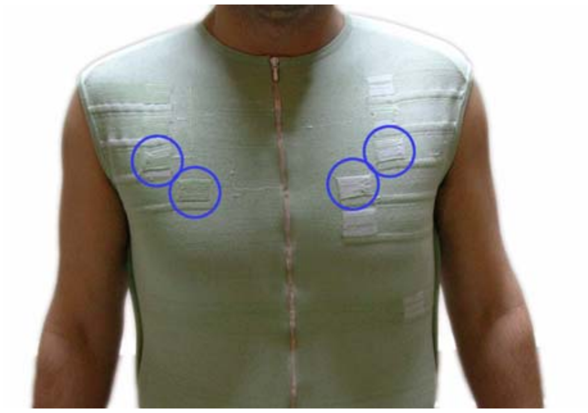

Figure 5*:* Electrodes position for impedance pneumography

RESULTS

WEALTHY system is an innovative device able to provide improved health care to users. The integration of multiple parameters and their continuous transmission to a monitoring clinical center makes the system quite unique and different from currently used medical devices.

In Figure 5 is reported an example of simultaneous acquisition of signals obtained from ECG leads and piezoresistive sensors for movement (left shoulder and elbow) and respiration (abdominal and thoracic).

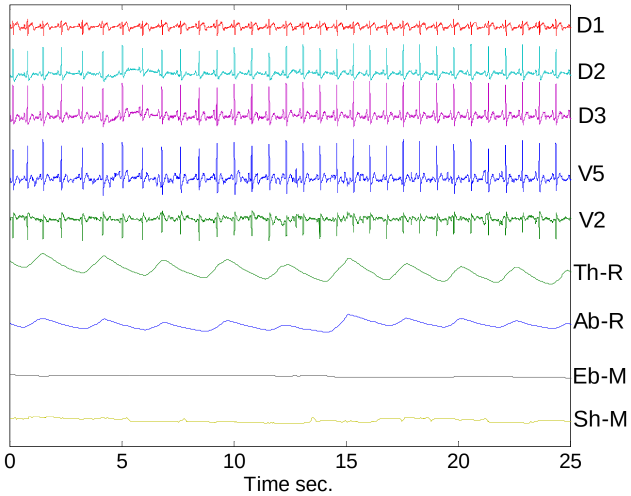

Figure 6: Signals in basal condition, D1, D2, D3 Einthoven leads I, II, III. V2, V5: Standard precordial leads V2 and V5. Th-R, Ab-R: Respiration sensors on thoracic and abdominal position respectively. Sh-M, Eb-M: Movement sensors on the left shoulder and elbow, respectively.

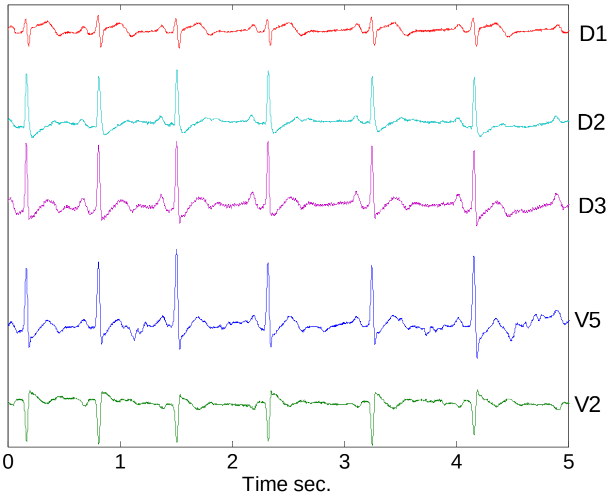

Figure 7: Detail of ECG signal in basal condition

The same signals has been acquired during some movement, for instance during the complete flex-extension of the elbow. In Figure 6 are shown the results of this experiment and in Figure 8 an enlargement of the ECG signals.
Acquiring more ECG leads is possible to select the more meaningful signals. Movement artefacts are present only in some leads, as shown in Figure 9 so the other ones can give sufficient information. A cross-talking between the sensor on the shoulder and the one on the thorax can be noticed analysing the signals. In this case, the signal obtained by the shoulder sensor can help in the revealing of artefacts on the thoracic respiration sensor, due to movement.

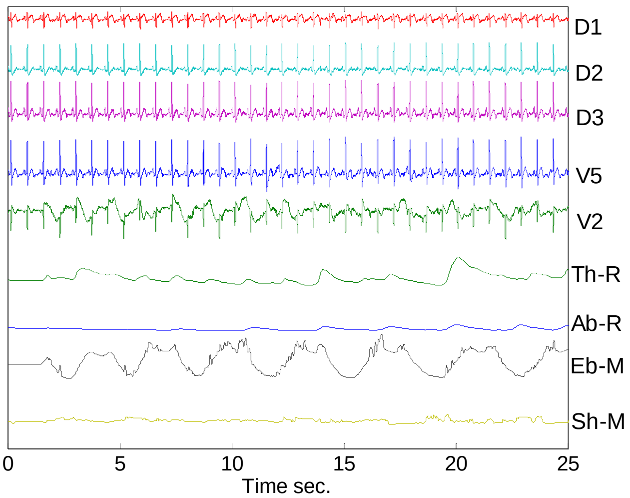

Figure 8 Signals obtained during flex-extension of the left elbow

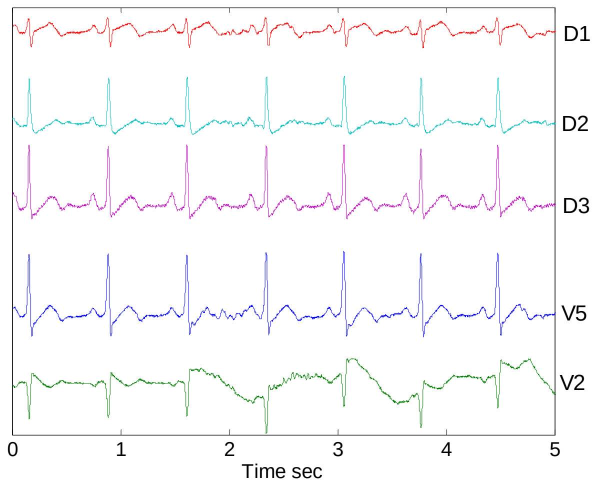

Figure 9 Detail of ECG signals obtained during flex-extension of the left elbow

DISCUSSION

The achieved results show that fabric electrodes endowed in the sensing shirt allow a continuous and simultaneous monitoring of bioelectrical and biomechanical physiological signals in a behaving subject. In a previous work [4] has been shown that the signals recorded by fabric electrodes are comparable to those acquired with gold-standard electrodes commonly employed in research and clinical use. The electrical and mechanical properties of fabric electrodes have not been modified by their integration in the wearable shirt, as the characteristics of electrocadiographic (ECG) and respiratory (RESP*) signals are comparable to those obtained with standard electrodes in similar conditions. The response of the system during an activity phases is observable in Figure 8, Figure 9, where the EGG data indicate that standard Eintoven leads exhibit a remarkable stability and are free from artifacts, when also the background noise appears negligible. In the precordial V2 derivation the signal is less stable and the amount of artifacts related to movement clearly increases (Figure 9). This may be related to the lack of adherence of the garment to the body during exercise. Moreover, the engagement of the pectoral muscles in this type of exercise may be responsible for the higher background noise observed. The signal to noise ratio can be improved by modifying the model of the shirt, a modification of sleeve connection will let to a good performance of the system also during movement.. The quality of the ECG signal allow the computation of heart rate and its variability throughout an experimental cycle.

The ECG can be adequately employed to study non invasively and in behaving conditions more complex functional indexes related to the sympatho-vagal balance, such as Low Frequencies and High Frequencies components derived by spectral analysis of RR interval variability [1], respiratory sinus arrhythmia and area under T wave of the ECG.

In Figure 10 are shown respiration signals detected through piezoresistive sensors, according the following protocol: the baseline conditions were recorded when the subject was lying in supine position (R1) for a period of 10 minutes, followed by a control period of 2 minutes with the subject sitting on a cyclette (R2). This was followed by a period of progressively increasing

physical exercise (cycling with increasing frequency and force) M1, M2, M3, M4, 5 minutes each. Then the subject was stopped cycling and he was monitored during the rest period, still in vertical position on the cyclette, for 2 minutes, as in R2 (R3).
Finally, the subject was asked to stand up and to lie in supine position for other 10 minutes (R4) as in R1. The experimental protocol is summarized in table 1.

R1	R2	M1	M2	M3	M4	R3	R4
10 min.	2	5 min.	5 min.	5 min.	5 min.	2	10 min.

Table 1 : experimental paradigm with cyclette

.
Also in this case is evident a remarkable stability and an excellent signal to noise ratio during the experimental session. Moreover the signal time course is adequate to reproduce the thoracic excursions without detectable phase shifts. Thus the respirogram yields accurate information about respiratory rate while the variations of signal amplitude can give only a qualitative estimation of the respiratory depth.

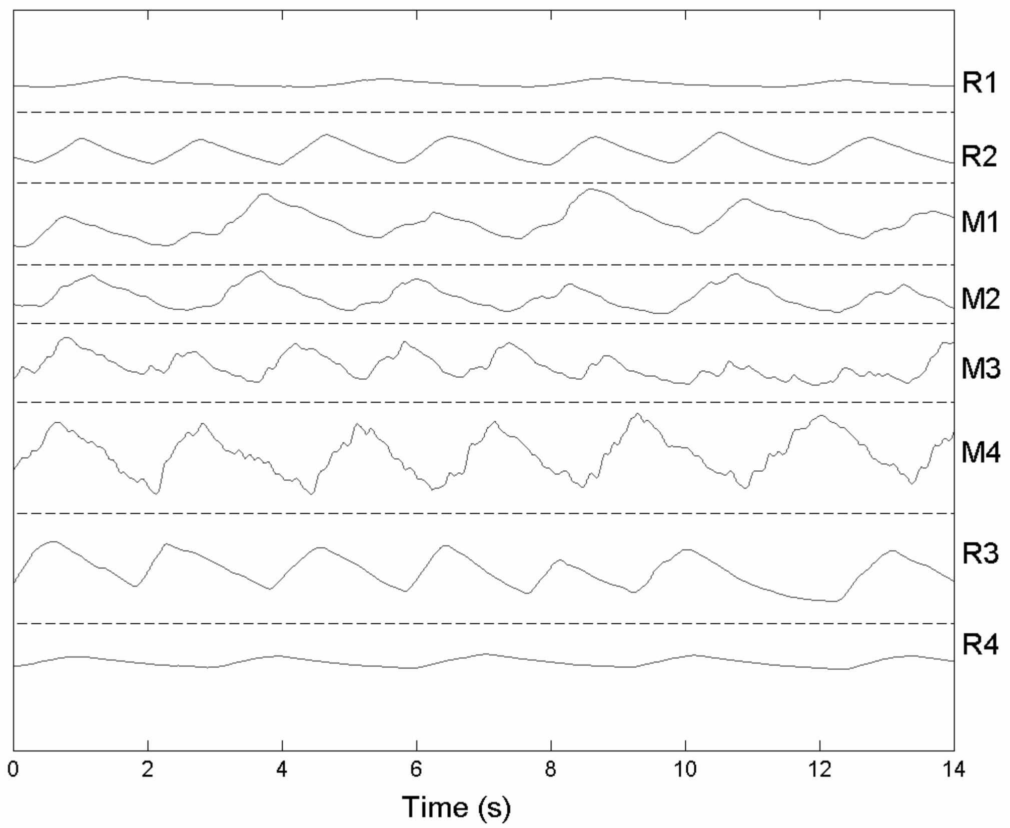

Figure 10: Respiratory activity, reading plethysmography in thoracic position, in each experimental condition

As shown in Figure 6-8 the sensing shirt, makes possible a simultaneous and multi-parametric acquisition of several physiological variables in different behavioral conditions. This possibility represents a significant advantage when it is necessary to monitor the vital asset of workers in extreme environmental conditions as well as sportsmen during high physical performance or military personnel engaged in war sites.

The most innovative character of this system consists in the use of functionalized materials in form of fibers and yarns, which can be knitted or woven into a sensing fabric. Preliminary results [5] show that the basic sensing features on which vital sign recording is based can be implemented using integrated knitted sensors and electrodes. Previous authors works [6][7] have shown that low frequency mechanical signals of cardiopulmonary origin (respirator signals, ballistogram) or generated by body segments relative motion (kinesthesia) could be recorded by textile strain gauges. Finally bioelectric potentials related to cardiac or skeletal muscle activity (ECG, EMC) have been faithfully recorded by metal based fabric electrodes. The integration of these different components with appropriate elastic electrical conductors and properly designed connectors to the wearable electronic unit, leads to a comfortable wearable cloth which has no counterpart in any existing monitoring system. These new integrated knitted systems enable applications extending even beyond the clinical area and open new possible applications in sport, ergonomics and monitoring operators exposed to harsh or risky conditions (fire fighters, soldiers etc.). The possibility of simultaneously recording different physiological signals provides an integrated view of normal and abnormal pattern of activity which could be otherwise impossible to be detected by recording each signal in different time. Finally it must be outlined that the possibility of recording physiological variables in a more “natural” environment may help to identify the influence of the psycho-emotional state of the subject in the performance of a physical activity. This is not easily detectable when recording is done within a protected (medical) environment. A further innovation is the in-context data interpretation. While a simple telemonitoring system would just transmit or record real-time physiological signs, the WEALTHY system will be able to process physiological parameters in context, so that appropriate feedback can be given to the patient.

CONCLUSIONS

The innovative approach of this work is based on the use of standard textile industrial processes to realize the sensing elements. Transduction functions are implemented in the same knitted system, where movements and vital signs are converted into readable signals, which can be acquired and tele-transmitted. In our fabric sensors, electrodes and bus structure are all integrated in textile material, making possible to perform normal daily activity while our clinical status is monitored by a specialist, with a comfortable wearable cloth which has no counterpart in any existing monitoring system[8][9]. WEALTHY system will benefits of the performance of the textile sensing interface to guarantee a continuously remote monitoring of user vital signs, the signals will be acquired and elaborate on body and a set of signals and parameters will be tele transmitted and managed by a remote Control System. The philosophy of this approach is focused on the realization of a friendly , human oriented textile based system, where the choose of sensing material is a compromise between comfort for the users and signal quality for the specialists.

ACKNOWLEDGMENTS

The authors would like to thank the European Commission for funding (IST-2001-37778) and all partners involved in the project, University of Pisa, Italy; Centre Suisse d'Electronique et de Microtechnique, Switzerland; Atkosoft S.A., Greece; Institut National des Sciences Appliquees de Lyon, France; Istituto Scientifico H San Raffaele, Italy; Centre de Recherces du Service de Sante des Armees, France; Messe Frankfurt GmbH, Germany; Centre National de la Recherche Scientifique, France.

REFERENCES

[1] Task Force of the European Society of Cardiology and the North America Society of Pacing and Electrophysiology, (1996) "Heart rate variability standards of measurement, physiological interpretation and clinical us" *Circulation* 93(5): 1043-65

[2] R. Paradiso R., A. Gemignani, E.P Scilingo, D De Rossi. "Knitted Bioclothes for Cardiopulmonary monitoring" 25^{th} Annual International Conference, IEEE-EMB, Engineering in Medicine and Biology Society-Cancun (2003), 3720-3723.

[3] R. Paradiso, "Tessuto in maglia per il monitoraggio di segnali vitali", Italian Patent N. FI2003A000308 (2003).

[4] Enzo Pasquale Scilingo, Angelo Gemignani, Rita Paradiso, Nicola Taccini, Brunello Ghelarducci, Danilo De Rossi, (2004) "Sensing Fabrics for Monitoring Physiological and Biomechanical Variables", Submitted to IEEE Special Issue

[5] M. Pacelli, R. Paradiso, G. Anerdi, S. Ceccarini, M. Ghignoli, F. Lorussi, P. Scilingo, D. De Rossi, A. Gemignani, B. Ghelarducci, "Sensing Threads and Fabrics for Monitoring Body Kinematic and Vital Signs" Fibres and Textiles for the Future, August 16-17, 2001 Tampere , Finland

[6] De Rossi D., Mazzoldi A., Lorussi F., Paradiso R., (2001) "From sensitive fabrics to distributed wearable sensors", *Proc. of SPIE's 8th Annual International Symposium on Smart Structures and Materials*, 4-8 March 2001, Newport Beach, California USA

[7] D. De Rossi, F. Lorussi, A. Mazzoldi, P. Orsini, E.P. Scilingo, Monitoring Body kinematics and gesture through sensing fabrics, 1st Annual International IEEE-EMBS Special Topic Conference on Microtechnologies in Medicine & Biology, October 12-14, 2000, Lyon, FRANCE

[8] M. A. Sackner D. M. Inmann, "Systems and methods for ambulatory monitoring of physiological signs", Patent Application Publication US 2002/0032386.

[9] Park Sungmee , Jayaraman Sundaresan "Full-fashioned garment in fabric having intelligence capability" International Publication number WO 02/100200 A2.