

A real-time non-invasive system monitoring haemodynamic parameters in critical conditions by peripheral blood pressure wave analysis

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Abstract- A non-invasive measurement platform for peripheral blood pressure monitoring and integrated diagnosis based on a piezo film pulse sensor and suitable processing algorithms running on a laptop PC has been developed. Different parameters (such as cardiac output and systolic pressure variation) for integrated haemodynamic management in critical conditions are determined by using mathematical and/or physiopathological models. Moreover, once connected to classical patient monitors, the system computes further parameters used for haemodynamic assessment of critical patients. Experimental results of the clinical in-vivo validation in operating theatres and in intensive care units are reported.

I. Introduction

In the management of critically ill patients, continuous recording and analysis of physiological signals, as well as on-line interactive acquisition and processing, allows information about both patient status and therapy effects can be gathered in real time [1]. In particular, arterial pressure waveform drew considerable attention for assessment of cardiovascular systems for critical patients [2]–[3]. Direct blood pressure monitoring through an arterial catheter is presently considered as the most accurate method using commercially available devices (Picco plus[®], LiDCO[™]plus, Vigileo[™]). However, being invasive, this methodology can be not applied in ambulatory study and, moreover, it presents various disadvantages, such as patient discomfort, need for skilled professional (for catheter insertion), and possibility of complications. In last years, some non-invasive commercial systems arose, such as Tensys[®] medical TL-150, Biopac NIBP100A, Medwave Vasotrac[®] APM205A, and FINAPRES Finometer[®]. Nonetheless, they are dedicated proprietary systems not useful for experimenting innovative techniques, such as new sensors, as well as new algorithms. As a matter of fact, currently, research is more and more focused on non-invasive pressure monitoring from peripheral artery (radial artery) and on consequent synthesis of systemic circulation characteristics [4]–[5]–[6].

In this paper, a non-invasive measurement platform for peripheral blood pressure monitoring is proposed with the aim of constituting a sound basis for experimenting innovative haemodynamic real-time analysis. After a description of the platform prototype, a suitable clinical measurement layout, for gathering information about haemodynamic condition by Pulse Wave Analysis (PWA), is presented. Finally, in-vivo results of the validation of the proposed prototype on patients during cardiac and vascular surgery are discussed.

II. Measurement system prototype

A measurement platform for haemodynamic assessment in clinical environment has to be designed by considering the following features [7]:

- simultaneous acquisition and visualization up to five waveforms,
- computation and visualization in real time of additional derived parameters,
- user-friendly interface and display of a graphic trend,
- on-demand capability of storing waveforms for further off-line analysis,
- set up of all measurements and set values.

The system has to be connected to innovative non-invasive sensors [8], as well as to acquire signals from analog output of classical medical devices. Finally, it has to provide a sound basis for developing

new algorithms of digital signal processing in order to enhance current techniques of haemodynamic assessment.

In the design, connections have to be carried out according to electrical safety practice, because connecting an industrial PC to medical devices can cause a loss of protection for patients, operators and the surrounding area. Therefore, the system has been developed according to safety rules imposed by IEC 60601 standards family for electrical medical systems.

In the following, details on the system's *hardware* and *software* development are given.

Hardware

The platform is based on:

- a piezo film pulse sensor EMFi (SDT1-028K of Measurement Specialties .for measuring the tonometric pressure on the right radial artery, selected because (a) it is very sensitive to low-level mechanical movements, (b) it has an electrostatic shield located on both sides of the element (to minimize 50/60 Hz AC line interference), (c) it is responsive to low-frequency movements in the 0.7 - 12 Hz range of interest, and (d) the foil size is suitable to the applicaton (2.54 cm long);
- a custom interface for analog signal conditioning (Fig. 1), in order to amplify the pressure signal and filter only the bandwidth containing the pressure information [0 – 25 Hz]. The sampling frequency is 200 Hz, thus the filter acts as antialiasing too.
- an acquisition board (PCMCIA ADCard AI-16E-4 (National Instrument™, Austin, Texas);
- a battery-powered notebook PC for safety reasons; furthermore, a dual-core T2300 at 1,66 GHz, with 1 Gbyte of RAM, and 100 Gbyte HD was selected in order to allow suitable digital signal processing algorithms to be experimented.

The sensor does not provide absolute values, thus a calibration for the pressure waveform is needed. With this aim, an automatic cuff-device for domestic use is applied at the opposite radial artery of the wrist. The sensor is calibrated at the beginning of each load level in order to provide systolic and diastolic blood pressure values.

Electrical safety tests according to the above mentioned IEC standards were performed by using the electrical safety tester for medical devices BIOTEK INC 601 SXL.

Software

The software, implemented in LabVIEW®, allows parameters for haemodynamic assessment of critical patients to be developed easily. A virtual instrument is used to transfer methodologies of signal processing in the clinical environment in order to test new diagnostic tools. Software design, especially for the user interfaces, considers the standard used in traditional medical devices, in order to allow an easy use by medical staff.

As first stage of development, algorithms for computing the trend of the Cardiac Output (*CO*) by the time derivative of the radial artery pressure (*Pas*), and the Systolic Pressure Variation (*SPV*) from PWA have been implemented [9]-[10]. *CO* and volemia (the amount of blood in the body) are important haemodynamic parameters to be monitored both during surgery and in Intensive Care Unit (ICU) [11]. In the following, the main characteristics of the implemented diagnostic algorithms for (i) *CO*, and (ii) volemia are illustrated.

- (i) At the moment, the most widely used method to estimate *CO* in practical clinical activity is based on termodilution technique [10]-[11]. However, an intermittent bolus injection is needed, and its usefulness for monitoring rapid and unpredictable changes of hemodynamic status of critical ill patients is poor.

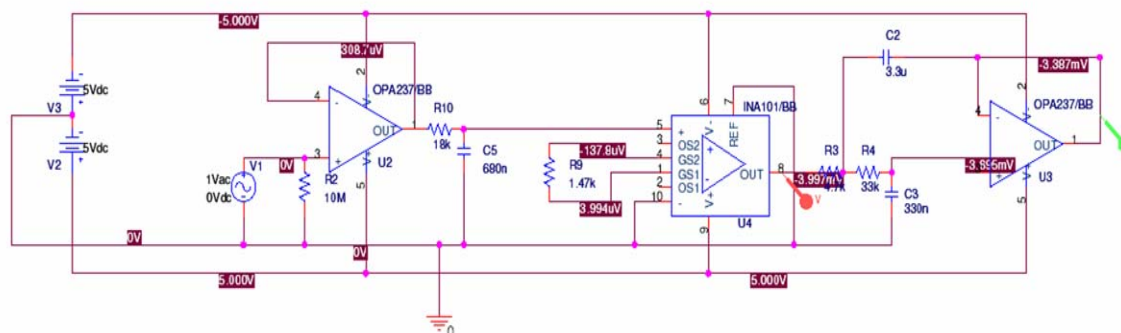


Figure 1. Schematic of the custom interface for analog signal conditioning.

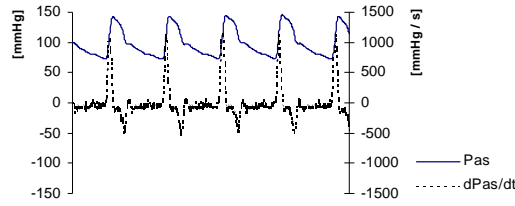


Figure 2. Radial artery pressure (Pas) and its time derivative.

An interesting trend in the state of the art investigates the clinical value of the maximum of peripheral pressure time derivative ($\max\{dPas/dt\}$, Fig. 2), in patients in epidural anaesthesia [12]. In this conditions, the vascular resistance has a low influence on CO . Variations in $\max\{dPas/dt\}$ are essentially due to contractile factors, thus it turns to be a valid efficiency indicator of the entire cardio-circulatory system. This surgery is nowadays performed more and more on elderly patients requiring surveillance greater than the one obtained by combining standard and innovative monitors.

- (ii) Different studies have proposed $SPVs$ for assessing left ventricular preload during intermittent positive pressure ventilation ($IPPV$) [13]-[15]. During mechanical ventilation (Fig. 3), systolic $SPVs$ and the parameters derived from its maximum (SP_{max}) and minimum (SP_{min}) values, as well as during apnoea (SP_{apnea}), were demonstrated to be fairly sensitive to volemia, by using mathematical models of cardiovascular system in animal studies and on humans [9],[13]-[16].

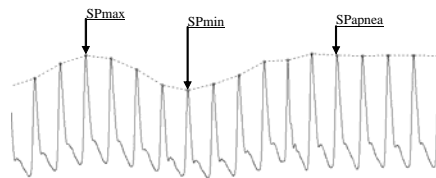


Figure 3. Variation of systolic blood pressure during mechanical ventilation

III. In-vivo results

The prototyped system was validated in comparison to a reference system by an in-vivo measurement campaign on 29 patients during cardiac and vascular surgery. As a reference, the monitoring system for invasive measurements Hewlett Packard 1175A – Merlin was used (Fig. 4a). Arterial pressure (Pas) was acquired invasively by using 20 G needle inserted into left radial artery, while Central Venous Pressure (CVP), Pulmonary Pressure (Pap), and reference for CO by using a Swan Ganz catheter.

These parameters were acquired during several different anaesthesiological (before and during anaesthesia, in the weaning phase, and so on) and surgical (pre post arterial clamp, beating heart surgery, and so on) phases, influencing haemodynamic status by the prototyped and the reference systems simultaneously (Fig. 4a). A suitable brace for blocking the arm, the wrist, the thumb, and the piezo film sensor has been realized in order to place the piezo-film pulse sensor correctly (Fig. 4b).

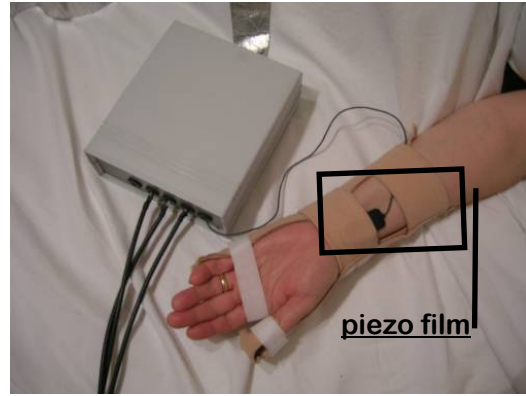
In Fig. 5, the developed virtual instrument of the prototyped system is shown. In particular, the results of an in-vivo comparison test for a 77-years old-male patient in ICU, 4 days after a substitution surgery of the ascendant aorta, are illustrated. A typical result for the channels (i) CH1, the non-invasive radial artery pressure signal, (ii) CH2, the reference invasive radial artery pressure signal, and (iii) CH3, the ECG signal, is reported. (Channel CH4 is left available for other parameters to be acquired). Comparison between CH1 (prototype sensor) and CH2 (reference transducer) waveforms highlights the effectiveness of the proposed sensor.

IV. Conclusions

A platform for experimenting innovative hardware and software non-invasive techniques of cardiovascular assessment has been prototyped. The system is based on a notebook PC operating in a



(a)



(b)

Figure 4. In-vivo validation experimental setup: (a) the proposed system (left) connected to a traditional patient monitor, and (b) the brace to properly acquire pulse wave by using piezo film sensor.

software environment developed in LabVIEW®. It is equipped by a non invasive piezo film sensor for monitoring peripheral blood pressure.

The system allows data to be acquired (also from invasive state-of-the-art instruments), on-line processed, displayed, stored, and retrieved. In-vivo measurements aimed at demonstrating the effectiveness of the proposed system by comparison with traditional systems showed satisfying results. Moreover, from the measured peripheral blood pressure waveform [5],[16]–[20] algorithms can be implemented in the proposed prototype in order to estimate other haemodynamic parameters, such as arterial compliance, peripheral resistance, aortic impedance, stroke volume, stiffness, cardiac output, and so on.

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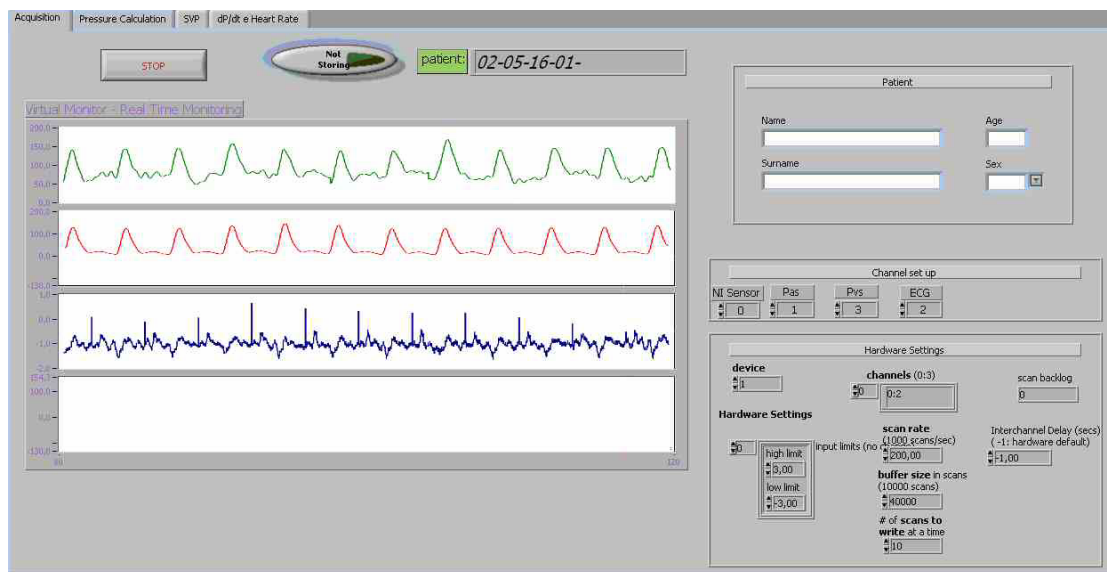


Figure 5. The developed virtual instrument of the prototyped system.

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