A SENSORIZED PLATFORM TO MONITOR AND REGULATE VAD FUNCTIONALITIES

Wearable and Implantable Devices to Improve VAD Performances and Extend its Field of Application

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Abstract: A novel system to control Ventricular Assist Device (VAD) is under study in the frame of the project SEN-SORART (FP7-ICT-248763, funded by the European Commission). The SensorART platform will be open, interoperable, extendable and VAD-independent and it will incorporate different hardware and software components in order to improve both the quality of the patients' treatment and the workflow of the specialists. In the frame of this project a set of implantable sensors will be identified, developed and/or adapted for long term implant, in order to gather all the necessary information to control the VAD functionalities by a wearable hardware unit. Wearable sensors will be studied to assist the decision algorithms by gathering physiological parameters using non invasive approach. Purpose of this paper is to give a brief description of the system under study and describe the preliminary activity performed during the developing of the implantable and wearable sensors. In particular, the evaluation and calibration of a novel catheter pressure sensor is reported and the results of the feasibility of a tonometry wearable system is described.

1 INTRODUCTION

Heart failure (HF) is the most increasing cause of death in Western Countries. For that reason, together with the difficulty of having a sufficient number of donor organs, it is recognized that the device-based therapeutic approaches will assume an increasingly important role in treating the growing number of patients with advanced heart failure, not only as bridge to transplant, but also as destination therapy. In this scenario the project SENSORART (FP7-ICT-248763, funded by the European Commission) leads to the development of a complete system composed by hardware and software devices able to control the Ventricular Assist Device. Scope of this paper is to describe the performed activity in the study of the sensor module.

2 MATERIALS AND METHODS

2.1 System Overview

The proposed platform will be able to vary the functional parameter of the VAD to support patients with chronic heart failure. It will also provide information to healthcare professionals, allowing patients to be treated at home without renouncing to accessing high medical expertise. The main research and development key modules of the integrated platform will be: Sensor Module, Signal Acquisition Module, Hardware Controller and Remote Control Framework. Figure 1 depicts the described platform in principle.

Most VAD controllers derive now all their information by the pump's power consumption, using this information predominantly as monitoring (to detect suction, low flow conditions, pump stoppage) and to trigger alarms. The SensorART platform would take advantage also from physiological signals acquired by a mix of implantable and wearable sensors. All the implantable and wearable sensors will wirelessly communicate with a wearable device. This unit
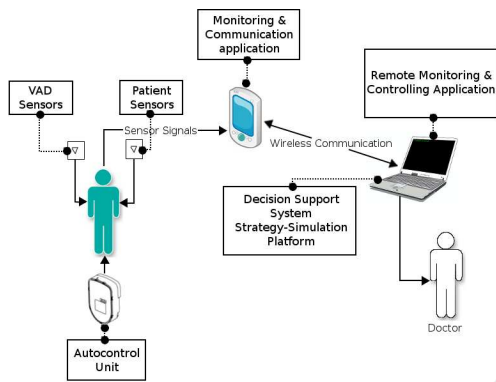
Figure 1: SensorART platform.

will allow to auto-adjust the blood flow provided by the VAD to the patient's heart according to signals coming from physical and physiological sensors, by means of a wireless link to the VAD actuators. Moreover, this unit will monitor the energy consumption, as well as the VAD functionality, thus generating the appropriate crucial and vital alert messages. Real-time adjustable thresholds and control parameters will be a peculiar feature of the proposed platform. The auto-regulation control algorithm will be fully adjustable to the patient's condition and will incorporate context-aware techniques in order to meet the patient's needs according to his/her status. Physiological sensors are usually invasive, with a complex package, and not reliable in long term implants. Within the SensorART project, wearable approach will be exploited together with the implantable ones in order to minimize risk of failures. This paper will describe the actual stage of the project regarding the development of implantable (see 2.2) and wearable sensors (see 2.3).

2.2 Implantable Sensors

Main physiological sensors described in literature as suitable for LVADs monitoring are: oxygen saturation sensor (Nakamura et al., 2000), pressure sensor (Bullister et al., 2001), flow rate sensor (Waters et al., 1999), and acceleration (Maeda et al., 1988) sensors. The first stage of the development of the implantable devices consists in a screening of the cited parameters during tests on laboratory mock-up and in-vivo, in implantable or wearable version. After these trials, the long term implant issue will be faced and a proper package will be studied. Thanks to the collaboration with clinical experts it has been possible to determine a set of variables to be monitored by implantable sensors in order to monitor the residual heart functionalities, the VAD function and the patient's reaction to

the treatment. These parameters are: left atrial pressure, aortic blood flow rate, aortic pressure, blood pressure and flow in the VAD cannula, pulmonary artery or right ventricular pressure. A previous work of the authors (Valdastri et al., 2008) describes a wireless implantable platform for in vivo monitoring. A similar approach has been used to integrate an innovative pressure sensor made by STMicroelectronics, that is still in evaluation phase (P30PCB). After the necessary characterization phase, this sensor will be encapsulated in a custom made catheter to perform the first session of tests. An electronic front-end has been developed in order to acquire the signal derived by the sensor inserted in a controlled pressure chamber. The output of the sensor needs a differential reading that is performed by an instrumentation amplifier (AD623N). The pre-amplified signal is then low pass filtered by an RC filter (band pass at 20 Hz) and amplified by a non inverting amplifier, realized with a CMOS operational amplifier (LMC6482).

Figure 2 shows the system realized for the calibration using a reference sensor (MPX5050 GP by Freescale semiconductor). The acquisition circuit,
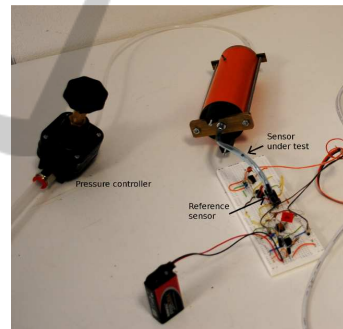

Figure 2: Calibration system for the pressure system.

based on a wireless microcontroller (CC2430 by Texas Instruments) can communicate wirelessly (zigbee ready) or by USB connection to a PC. A graphical interface, acquires and stores data with a sampling rate of 25 Hz by both test and reference sensors. The pressure in the chamber has been varied step by step in the range from 8 kPa to 35 kPa. The range has been chosen taking into account the final field of application, that is the radial artery pressure measurement. The measures have been performed on both growing and decreasing pressures, to evaluate the hysteresis of the signal. Tests have been performed on 3 sensors to assure the reproducibility. Three complete cycles have been acquired for each sensor with pressure set as following: 8 kPa, 16 kPa, 24 kPa, 32 kPa and 35 kPa. The calibration curves have been approximated by polynomial fitting by using Matlab software. Also the stability of each sample has been tested, by means

of long acquisition (30 min) at stable pressure (8 kPa,
24 kPa and 35 kPa).

2.3 Wearable Monitoring Devices

One of the most relevant physiological signals to be
monitored is arterial blood pressure. This can be mon-
itored by either implantable or wearable sensors. In
particular, radial tonometry (Chemla et al., 2008), has
been explored to derive the central arterial pressure
by means of non-invasive technique. An example of
such type of device is the BPro by HealthSTATS[1]. In
the frame of the project a wearable system with wire-
less communication will be developed. In order to
monitor the central pressure 24/7 and pulse by pulse,
the system will be designed to assure the stability of
the signal in case of patient's arm movements. Wear-
ability, ease of use and ergonomics will be carefully
considered. An ad hoc support has been produced by
fast prototyping with a 3D printer (Invision SI2 by
Inition), to investigate this technique. Figure 3 shows
the support and its placement on the wrist for the pre-
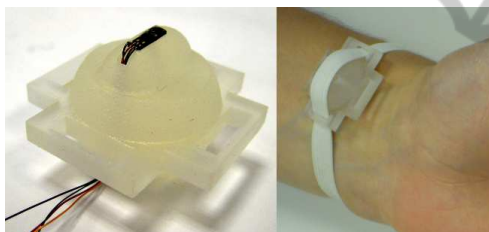liminar tests.

Figure 3: P30PCB STM pressure sensor and the support for
the tonometry device (left), placement of the system on the
radial artery (right).

The support is designed in order to assure the arte-
rial applanation, while reducing the discomfort. Ap-
propriate slots allow to use an elastic ribbon to fix
the support on the wrist. It is possible to regulate
the applied force on the skin by the protrusion with
the inserted sensor simply by varying the tension of
the elastic band. The pressure sensor is the STM
P30PCB described in 2.2. An additional sensing sys-
tem, that will be developed, regards impedance car-
diography (ICG). Also in this case either implanted
or wearable strategy can be pursued. ICG can moni-
tor the fluid content of the trunk, thus acting as heart
failure detector (Bour and Kellett, 2008), or hemody-
namics variables such as: stroke volume (SV), stroke
index (SI), thoracic fluid content (TFC), systemic vas-
cular resistance (SVR), systemic vascular resistance
index (SVRI), acceleration index (ACI), velocity in-

[1]www.healthstats.com/en/bpro.html

dex (VI), pre-ejection period (PEP), left ventricular
ejection time (LVET) and systolic time ratio (STR).

The under study wearable system performs a tho-
racic bioimpedance measurement by means of four
electrodes placed on the thorax at the diaphragm level.
The development is in an early stage and in vivo tests
are scheduled to evaluate innovative approaches.

3 RESULTS AND DISCUSSION

3.1 Characterization of the Pressure Sensor

Tests have been performed on 3 samples of the
P30PCB by using the system described in 2.2, in or-
der to calibrate and evaluate the pressure sensor. The
figures 4 and 5 show the results of the tests in term of
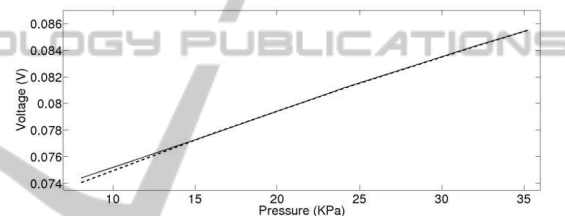hysteresis and reproducibility.

Figure 4: Typical hysteresis plot (dotted line for decreasing
pressure, full line for increasing pressure).

The average hysteresis has been evaluated by cal-
culating the maximum difference, in term of percent-
age of the full scale of the test, between the curves rel-
ative to growing and decreasing pressure. The mean
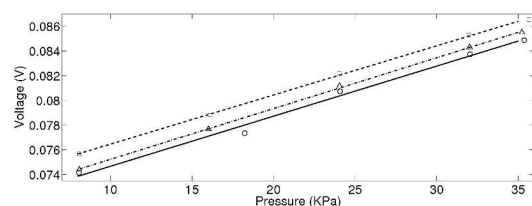among all tests of so calculated hysteresis is 0.33%.

Figure 5: Experimental values (triangles, circles and
squares) and fitting lines for the three tested pressure sen-
sors.

The table 1 collects the slope, the zero value and
the coefficient of determination (R^2) for each calibra-
tion curve, calculated by linear polynomial fitting us-
ing Matlab software.

The coefficient of determination is very close to
one, so the sensors can be considered linear. The
differences in the zero values among the calibration

Table 1: Coefficients for the calibration curve of the three sensors.

	Slope	Zero value	R^2
S1	0,0004	0,0706	0,9987
S2	0,0004	0,0725	0,9989
S3	0,0004	0,0711	0,9874

curves of the samples make necessary the calibration of each implantable device. This is not a problem for the field of application of the SensoART platform.

As example of the stability test, figure 6 represents a typical sensor output at 24 kPa for 30 minutes. All the sensors showed a high stability.
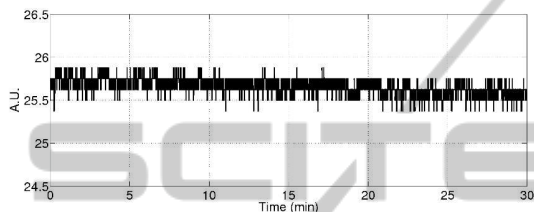

Figure 6: Typical sensor output at 24 kPa.

3.2 Tonometry

Some preliminary acquisitions have been performed with the wireless tonometry device described in 2.3, placed as in figure 3. The gathered signal depicts the pressure wave of the radial artery of the wrist, as depicted in figure 7.

3.3 Conclusions

SensorART project aims to develop a disrupting system that will change substantially the application of VAD in heart failure treatment. The activity presented in this paper is a preliminary step towards this challenging result. The evaluation of the P30PCB sensor as candidate for the pressure implantable catheter and the tonometry system gave positive results. The linear calibration curve and the reproducibility of this sensor, together with its small dimensions allow to integrate it in a catheter to start the evaluation in laboratory mock-up and in-vivo test. Next steps will be the design and production of a custom catheter and the study for the package for a long term implant. The preliminary tonometric signal, acquired by the prototype system, demonstrated the feasibility of this approach. Next development of this system will lead to the improvement of the reliability during movement and to make easier the wearing process.
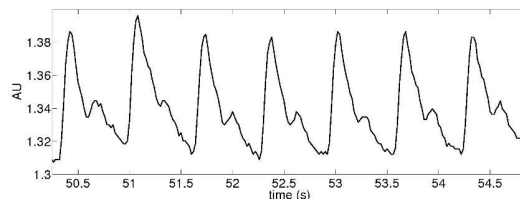

Figure 7: Pressure signal of the radial artery gathered by the tonometry device.

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