artificial heart, ventricular assist device (VAD), pulse oximeter

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MEASUREMENTS OF BLOOD SATURATION INSIDE A VENTRICULAR ASSIST DEVICE[2]

Information about the level how well arterial blood is saturated with oxygen, i.e. the overall patient saturation, in particular a patient with a ventricular assist device (VAD) inoculated, is very important for efficient and dependable course of blood circulation support. The paper presents the method for measurement of blood saturation with oxygen that is carried out with use of a commercially available pulse oximetric sensor upon necessary modifications and installed directly on a outflow connector of the VAD. Operability of the presented solution has been verified by experiments on a flow control test bench with use of animal blood. The final validation of the measuring circuit was carried out during experiments with an animal. The completed experiments demonstrated that both the blood saturation with oxygen as well as artificial pulse rate can be measured with accuracy. Unfortunately, similar measurements for venous blood proved infeasible.

1. INTRODUCTION

The need to supply each cell of a living organism with oxygen is the indispensable condition to maintain its vital processes. This function is carried out initially by the respiratory system and the blood circulation system of a human body [3]. Most if oxygen is conveyed from lungs to cells by oxidized hemoglobin, whilst a small part of oxygen dissolves in blood plasma. According to the gradient of oxygen pressure, released oxygen molecules diffuse to cells, while carbon dioxide diffuses towards the opposite direction. Arterial blood is saturated with oxygen and is conveyed from lungs to cells via the blood circulation vessels, whilst venous blood is deoxygenated and carries carbon dioxide from cells to lungs. It is obvious that monitoring of correct saturation of blood with oxygen is crucial to maintain vital processes of humans. The attention should be also paid to the fact that both the respiratory and the circulatory systems are responsible for correct oxidization of blood.

The basic parameters of oximetry measurements include: saturation of hemoglobin with oxygen SpO_2, referred also to as oxygen blood saturation, as well as partial pressure of oxygen pO_2. Saturation measurements make it possible to detect insufficient supply of organism with oxygen (hypoxemia) whilst abnormally high partial pressure of oxygen is the symptom of toxic oxygen surplus, which is extremely important for various medical procedures, e.g. an oxygen therapy [3]. The relationship between the oxygen saturation and the oxygen partial pressure is expressed by the dissociation curve of oxyhemoglobin. [2, 3, 4].

Saturation measurements are really important for clinical treatment [7]. In practice, saturation can be measured by means of invasive methods that consists in taking samples of arterial blood to determine the saturation level at a laboratory. Otherwise, saturation is measured during monitoring of the overall oxygen managements within a brain hemisphere when a catheter is introduced directly into a neck artery [3].

It is also possible to determine the oxygen blood saturation by means of non-invasive photometric methods that are currently commonly used by clinical practitioners [2, 3, 7]. A photometric sensor usually measures the absorption of transmitted light by body parts that can be easily passed throughout by the radiation emitted from the light source, e.g. a finger or an auricle leaf.

Monitoring of blood saturation in patients being subjected to various medical treatment and in cases of life hazard is nowadays a standard medical procedure. In particular, monitoring of oxygen blood saturation in patients with a ventricular assist device (VAD) is the matter of crucial importance due to

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failure of the patient natural heart. The efficiency of enforced assistance to the patient's heart is decisive for sufficient supplying of oxygen to all cells and tissues of the organism. In the foregoing context the idea of direct measurement of blood saturation that is discharged from the outflow connector of the VAD seems to be really tempting since the measurement results can be used as control parameters for automated operation of the VAD [5, 6, 9, 11].

The possibility to measure oxygen saturation was checked on a test bench made up of commercially available components upon their appropriate modification and adjustments. The studies were carried out within the frameworks of the Long Range Project 'The Polish Artificial Heart'. The outcome from the investigations in that field shall be outlined in the further part of the paper.

2. FUNDAMENTALS FOR MEASUREMENTS OF BLOOD SATURATION WITH USE OF PHOTOMETRIC METHODS

This section briefly reports key facts related to design and operation principle of modern pulse oximeters. Detailed information related to these issues can be found in [2, 3, 4, 7].

The pulse oximetric technique combines the ideas of spectrophotometry and plethysmography, where body parts with high density of capillary blood vessels are illuminated by means of a light source with further measurements of either reflected or transmitted light. Nowadays, the technique with transmitted light is commonly used due to convenience and reliability of measurements [2, 3]. Photometric sensors are attained to poorly transparent tissues of a human organism. However, there is so called 'transmission window' with the wavelength from 600 to 1200 nm, i.e. for the radiation at the border of visible light and near infrared [2, 3]. Light radiation with the wavelength falling to that range passes through tissues and enables to record a pulsating waveform of heart beating that is referred to as a plethysmographic wave. Oxygen blood saturation can be determined from the recorded waveform owing to the two following rules:

- spectrometric effect – the rate of red light absorption is different for oxyhemoglobin that is reach with oxygen and deoxyhemoglobin with scarce amount of it;
- plethysmographic principle: the length of optical path and therefore the rate of light absorption varies in pace with blood pressure in the circulatory systems.

The recorded plethysmographic wave oscillates in time in line with blood pulsation in irradiated blood vessels. To achieve a dependable estimation of the amounts for the two components of hemoglobin, i.e. oxyhemoglobin and deoxyhemoglobin, two sources of light are used with different wavelengths, usually one with the length that corresponds to red light (ca. 660 nm) and the second one with the length of near infrared (ca. 905 nm). Upon determination of the variable component (that depends on the momentary pressure value) and the constant component (that depends on damping due to other matters that obstructs the path of the passing light) for the both wavelength of the red and infrared lights as well as under provision that light absorption characteristic curve is known for both the hemoglobin saturated with oxygen (oxyhemoglobin) and deoxidized (deoxyhemoglobin) one can find out the level of oxygen blood saturation defined in percents of the lost hemoglobin. Such a parameter hat can be found out in a non-invasive method is referred to as the functional saturation. The functional saturation refers to the ration of oxidized hemoglobin to the total hemoglobin that is capable to adsorb oxygen.

The value of functional saturation may sometimes differ from the value of saturation determined by invasive methods, where so called fractional saturation is determined from blood samples with regard to all hemoglobin fractions. The fractional saturation is defined as the ration of oxyhemoglobin to the total amount of hemoglobin that is capable to adsorb oxygen and the dysfunctional hemoglobin (dyshemoglobin).

It must be noted that the characteristic curve for light absorption by oxyhemoglobin and deoxyhemoglobin is usually determined for the physiological saturation range from 70 % to 100 %. The saturation level of arterial blood below that range is considered as a serious life hazard for patients and is not frequent for the clinical practice.

The principle of blood saturation measurement with use of a photometric sensor is shown in the schematic diagram in figure 1a, whilst figure 1b presents the timing for the recorded plethysmographic wave.

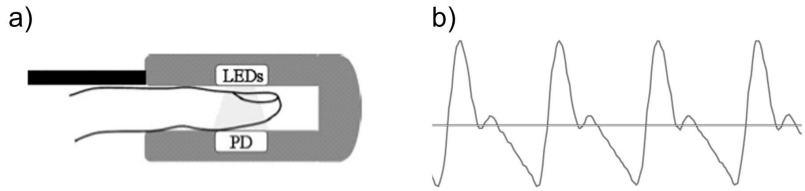

Fig. 1. Design and operation principle of a photometric sensor (a) and the timing for the plethysmographic wave (b).

3. DESIGN OF THE CIRCUIT FOR OXYGEN SATURATION MEASUREMENTS

3.1. MEASURING CIRCUIT

Nowadays various manufacturers offer integrated automatic modules of pulse oximeters that are able to directly convert signals received from photometric sensors into a digital form. The digital package comprises information about the level of saturation, heart rate, quality of the plethysmographic wave and status parameters [10]. Modern high resolution measuring circuits provide automatic adjustment of the conversion scale for the measured constant and variable components within a very wide range. A very accurate mechanism for control of radiation intensity in sensors as well as application of light-emitting element of high luminance may enable to use such measuring module that is able to shine through the blood passing a outflow connector of VAD with considerably large diameter, although it is much more difficult than is case of a finger or so, where the amount of passing blood is much less. It is why a miniature BCI OEM (Original Equipment Manufacturer) module of the WW 3711 type from Smiths Medical [10] was chosen for measurement of oxygen saturation across such a peculiar object as an outflow connector of a VAD. The module is supported with an OEM application designed for communication with the module and for visualization of received signals directly on the computer display.The completed initial tests revealed that the plethysmographic wave that is available at the module output in the digital form after conditioning and filtration is deprived of much essential information related to operation of the module, in particular the information about adaptive control when luminance of light source is automatically adjusted to the ambient conditions of the saturation measurements. Therefore the decision was made to enhance the embedded measuring circuit of the module with a node that would be responsible for conversion of the original plethysmographic wave obtained directly from the analog part of the module applied. Thus, it was necessary to transform the acquired wave to the form that is suitable for direct sampling with use of an analog-digital (A/D) converter. It enabled to independently measure two components of the plethysmographic wave, the one obtained for red light and the other one for infrared radiation. The diagram of the measuring circuit is shown in figure 2a and figure 2b presents the arranged measuring equipment.

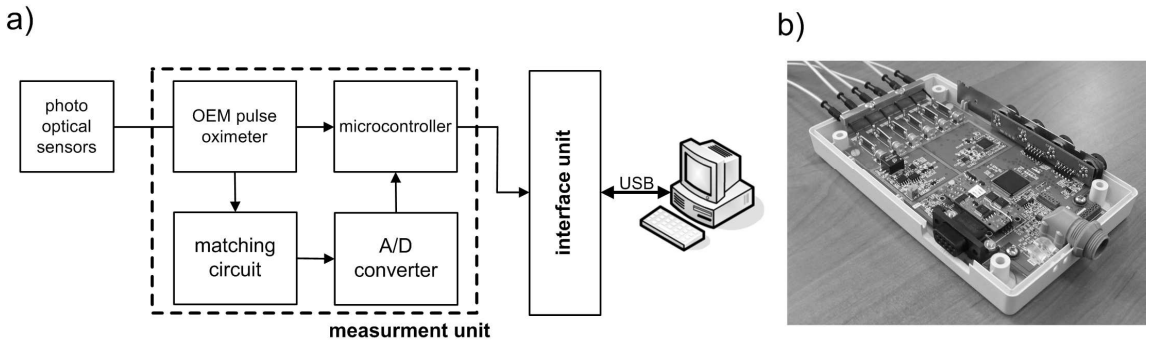

Fig. 2. The measuring circuit diagram (a) and arrangement of the measuring equipment (b).

3.2. DESIGN OF THE MEASURMENT SPOUT

The photometric sensor of a pulse oximeter to be installed directly on the measurement spout (equivalent of outflow connector of VAD) comprises optical components dismantled from an original finger-attained sensor. Light-emitting diodes (LEDs) for the wavelength of 660 nm and 905 nm, integrated on a common ceramic substrate as well as the detecting photodiode (PD) were encapsulated in factory-made plastic housings with the dimensions of 4.2 x 5.6 x 1.6 mm (Fig. 3a).

The measuring spout was made by injection moulding of the same biocompatible polyurethane that is also used for production of the VAD. Side walls of the spout were provided with dedicated sockets to install photo optical components of the sensor. To minimize absorption of the light wave the walls of sockets for photo optical components were thinned to the thickness of 0.3 mm. The rearranged spout was additionally provided with an extra socket to enable installation of a pressure gauge. The issues related to pressure measurement in a VAD are detailed in [8]. The inner diameter of the measurement spout was 14 mm, which is also the length of the path that the light has to shine through. The measurement spout (with no photo optical parts installed) is depicted in figure 3b. In addition, side walls of sockets provided in the spout for photo optical parts were blacked. The important thing is to sink sockets for photo optical parts in such a way that they accurately face one another.

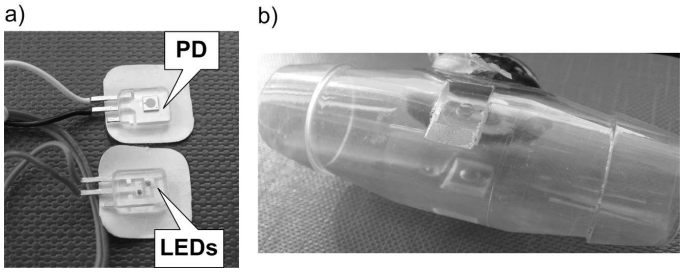

Fig. 3. Photo optical components of the photometric sensor (a) and design details of the measurement spout (b).

4. RESULTS OF EXPERIMENTS

In vitro experiments with use of animal blood were carried out on a simple flow control test bench with its arrangement depicted in figure 4. The measurement data was visualized by means of the OEM measuring circuit along with the dedicated application software designed for the pulse oximeter module from BCI as well as with an own-developed measuring module provided with a software application not only meant to visualize results of measurements but also to record initial, analog components of the plethysmographic wave for both red and infrared light. For reference measurements the i-SAT Portable Handheld was applied [1].

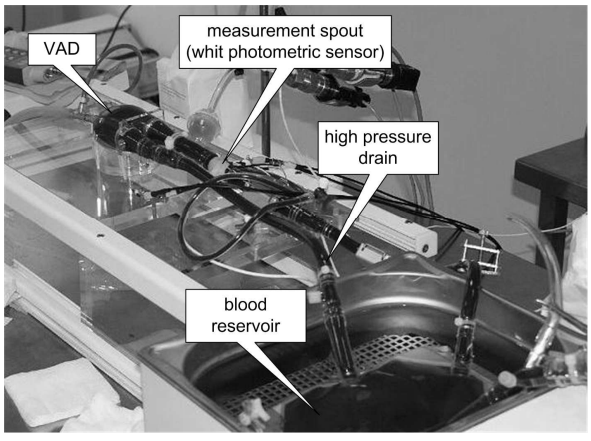

Fig. 4. Layout of the flow control test bench dedicated for saturation measurement of animal blood.

Suitability of the proposed solution for direct measurement of arterial blood saturation with oxygen was verified with use of heparin pig blood. In the first experiment the saturation indication measured directly across the measurement spout and the reference measurements were 80% for the both cases with the measuring error less than ±2 %, which is in line with technical parameters of the applied pulse oximeter module [10]. For that case the measurements of pulse rate corresponded to the artificial heart rate (AHR) of the VAD. The subsequent experiment was also performed with use of arterial blood. The initial saturation was 94 % and dropped to 86 % at the experiment end due to natural deoxidization of blood. It was also the case when indications of the pulse oximeter indications matched the results of reference measurements. The waveforms for plethysmographic pulsations recorded for the first case are shown in figure 5.

Fig. 5. Plethysmographic waveforms recorded for measurements on arterial blood.

The subsequent series of experiments was intended to verify whether the suggested method can be applied to measurements on venous blood. The experiments were carried out with use of the same flow control test bench (Fig. 4) on heparinized pig venous blood. The initial experiments performed on venous blood with saturation at the level of 19 % (measured by the reference method) demonstrated that the suggested method is useless for determination of so low saturation level. The reason for the failure lies undoubtedly in the fact that for such low non-physiological values of saturation the characteristic curve that establishes the relationship between absorption factor determined for light shining through the blood and the percentage value of saturation was unavailable. The physiological saturation of venous blood normally forced to lungs ranges from 40 ÷ 70 %.

The next experiment also employed venous blood, but the test bench was additionally provided with an oxygenerator with the aim to increase of oxygen blood saturation to a physiological level. The blood saturation after the oxidization treatment, measured by means of the reference instrument, achieved 76 %. Unfortunately, for that case the saturation measurements with use of the presented solution were incorrect and unsteady. Only measurements of pulse rate coincided with the AHR already set up for the VAD. The recorded plethysmographic waveforms were substantially distorted by noises (Fig. 6a). The analysis of unprocessed, original signals from the photometric sensor for both red and infrared light, made it possible to find out that the pulse oximeter module is able to correctly compute the pulse rate but accurate determination of the venous blood saturation proved infeasible due to low dynamic variations of the recorded waveforms. One can allege that the variations of signal absorption across a very rigid spout with a specific diameter caused by variable concentration of blood cells during a forcing phase is insufficient for correct reproduction of the heart beating waveforms, in particular the rising edge rates (differentials). The light absorption components caused by variations of the optical parts associated with blood vessel expansion is no existent in that case.

The foregoing hypothesis was proved by measurement results achieved with use of a flexible spout with no alterations to flow resistance of the circuit. The signal strength and quality as well as rising edge rates of waveforms substantially with no changes of flow resistance that led to steady detection of the pulse rate as well as unbiased results for the oxygen saturation measurements, which correlated to the referenced values (Fig. 6b)

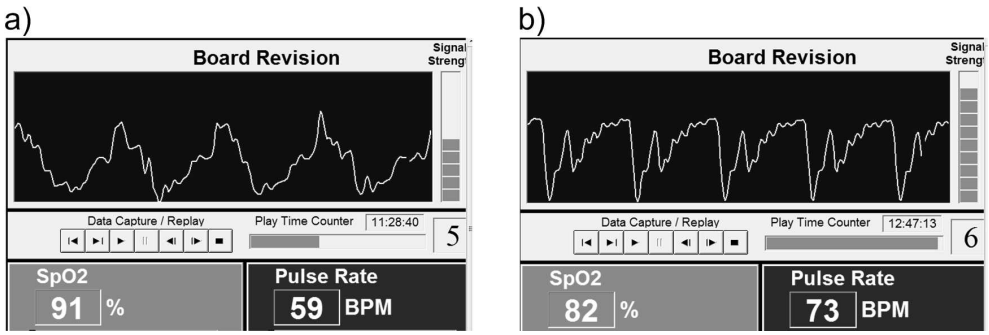

Fig. 6. The plethysmographic waveforms recorded from measurement on venous blood with a rigid spout (a) and a spout with improved elasticity (b).

The final verification of the suggested method for measurement of oxygen saturation was carried out on an animal (a pig with a weight of ca. 100 kg). The sensor for saturation measurements was placed between the outflow connector of the VAD and a cannula inserted into the pulmonary artery. The inflow connector of the VAD was connected to the right heart atrium with another cannula. The experiment assumed measurements of oxygen saturation for venous blood with the saturation about 58 % determined by means of the reference method. The circuit did not allow achieving the full filling and, consequently, full ejection from the VAD, which resulted in limited flow down the measurement spout. The image recorded for the photoplethysmographic waveforms (PLET) with insignificant amplitude proved to be sufficient for measurements of pulse rate but too low to determine the blood saturation (Fig. 7a).

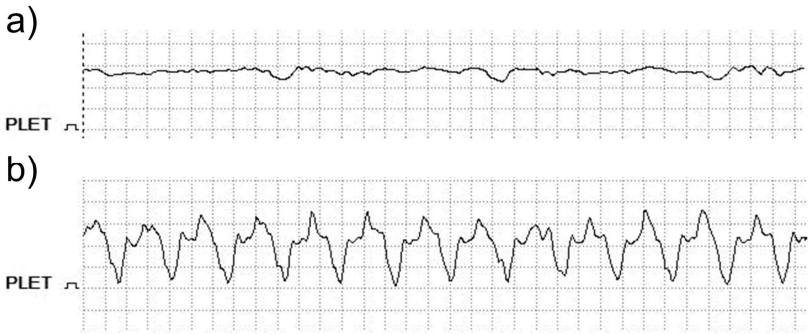

Fig. 7. Plethysmographic waveforms for venous (a) and arterial blood (b) recorded during an experiment on an animal.

The final phase of the experiment consisted in connecting the inflow cannula to the left heart atrium, which definitely improved images for the plethysmographic waveforms and enabled oxygen saturation measurements for oxidized blood (Fig. 7b). The pulse rate, displayed on-line on the display, was 76 min^{-1}, which coincided with the AHR of the VAD, whilst saturation indication was 99 %, which was comparable to the results of measurements on the animal tongue carried out with use of a combo cardioscope monitor.

5. CONCLUSIONS

The completed studies have led to development of a circuit suitable for measurements of oxygen blood saturation directly across the outflow connector of a VAD. The measuring circuit arranged for experiments was subjected to practical verification by means of experiments that were carried out on animal blood on a simple flow control test bench and validated by an experiment with a live animal. The achieved results unambiguously demonstrated that the suggested method cane be used for determination of oxygen saturation for arterial blood. However, determination of oxygen saturation for venous blood within the range below 70 % and with the required accuracy (±2 %) proved infeasible due to non-existent calibration curves for such low values of saturation. Measurements for the saturation range from 70 % to 80 % are possible, but the experiments demonstrated that a flexible measurement spout should be made for installation of photometric sensors to achieve improved stability of measurements.

The experiment results achieved for materials and equipment used so far shall need revalidation when coatings are applied to inner surfaces of the VAD in order to minimize the risk of blood coagulation, since such coatings may introduce additional and unacceptable absorption of light radiation with the wavelength of 660 and 905 nm that are used for pulse oximetry measurements.

BIBLIOGRAPHY

[1] ABBOT POINT OF CARE, i-SAT Portable Handheld, http://www.abbottpointofcare.com/Products-and-Services/iSTAT-Handheld.aspx, access: 06.09.2012.
[2] ALEXANDER C.M., TELLER L.E., GROSS J.B., Principles of pulse oximetry: theoretical and practical considerations, Anesth Analg, 1989.
[3] CYSEWSKA-SOBUSIAK A., PAŁKO T., Oximetry, in NAŁĘCZ M., Biomeasurements, Akademicka Oficyna Wydawnicza EXIT, Warszawa, 2001, pp. 685-710 (in Polish).
[4] CYSEWSKA-SOBUSIAK A., Metrological problems of identification of attributes of the living object exposed to noninvasive transillumination, Wydawnictwo Politechniki Poznańskiej, Poznań, 1995 (in Polish).
[5] GAWLIKOWSKI M., PUSTELNY T., KUSTOSZ R., Selected problems of mechanical heart supporting automation, European Physical Journal, 2007, Vol. 154, No. 5, pp. 65-69.
[6] GAWLIKOWSKI M., PUSTELNY T., KUSTOSZ R., The methods of physical parameters measurement regarding the heart supporting automation, European Physical Journal, 2007, Vol. 154, No. 5, pp. 71-76.
[7] JUBRAN A., Pulse oximetry, Critical Care, Vol. 3, Issue 2, http://ccforum.com/content/3/2/R11.
[8] MOCHA J., SOBOTNICKI A., CZERW M., Measurements of blood pressure inside a ventricular assist device, Journal of Medical Informatics and Technologies, 2011, Vol.17, pp. 287-293.
[9] NAKAMURA M., MASUZAWA T., TATSUMI E., TAENAKA Y., OHNO T., NAKAMURA T., ZHANG B., KAKUTA Y., NAKATANI T., TAKANO H., Control of a total artificial heart using mixed venous oxygen saturation, ASAIO Journal, 1999, Vol. 45, Issue 5, pp. 460-465.
[10] SMITH MEDICAL, Digital Micro Power Oximeter Board, http://www.smiths-medicaloem.com/Upload/products/PDF/196001_Digital-Micro-Oximeter.pdf, access: 06.09.2012.
[11] TAKATANI S., NODA H., TAKANO H., AKUTSU T., Optical sensor for hemoglobin content and oxygen saturation, Application to artificial heart research, ASAIO Journal, 1988, Vol. 34, Issue 3, pp. 808-812.