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## EVALUATION OF VOLUMETRIC PARAMETERS OF THE VENTRICULAR ASSIST DEVICE USING BIOIMPEDANCE METHOD

Volumetric parameters of operation of the pulsatile ventricular assist device (VAD) are the key clinical indicators for the evaluation of adequacy of the process of mechanical heart assistance and ensuring the patient's safety. The bioimpedance method has been proposed to evaluate blood volume changes of the VAD. The method is based on volume electric conductivity of the blood. A change in VAD volume involves changes in impedance. Periodic changes in VAD volume during its operation result in a pulsatile impedance wave; its amplitude in the subperiod of filling and ejection correlates with the volume of blood in the VAD. The paper presents the way of acquisition of the bioimpedance signal. It also presents the results of experimental studies, that were carried out with the use of the flow test stand, and an approach to analysing the bioimpedance signal to evaluate the stroke volume.

### 1. INTRODUCTION

The natural heart assistance is used in cases of serious heart injury, when its own sufficiency is not enough to sustain the body's vital functions. Assisting with the use of ventricular assist device (VAD) is carried out when the patient is waiting for transplantation or to regenerate the cardiac muscle [1]. Currently, the most commonly used VAD is the extracorporeal pneumatically controlled pulsatile prosthesis. The VAD contains a space filled with blood (blood chamber), volume of which changes periodically due to the movement of the flexible membrane. In order to monitor the performance of heart prosthesis, fundamental meaning has got the knowledge of hemodynamic parameters such as pressures in the VAD and stroke volume, which is commonly used as a clinical indicator of blood pumping effectiveness [2].

As a part of the Program "Polish Artificial Heart", bioimpedance method, next to acoustic method of measuring degree of filling of the blood chamber [3] and ultrasonic measurement of blood flow in the aortic connector, was accepted as one of the applicable ways of estimating the hemodynamic parameters of the VAD. Impedance methods in biomedical applications have been used for many decades. These methods are used in many areas of research related to the natural tissues, for both measurement *in vitro* and *in vivo*, allowing noninvasive acquisition of signals from the surface of patient's body [4]. Bioimpedance measurements are widely used in the evaluation of the body segments volume, particularly in the circulatory system. Impedance cardiography is being used increasingly for noninvasive determination of cardiac stroke volume, and impedance plethysmography is used for the diagnosis of limbs blood vessels. Bioimpedance methods also allow to determining the fluids content in the body. Impedance measurement is used for example to evaluate the total amount of fluids in the thorax [5].

The bioimpedance methods are based on passive electrical properties of biological tissues. Tissues have characteristics of anisotropic conductor consisting of resistive and reactive components [6]. The measurement is usually made by passing a sinusoidal current of constant amplitude through the test object. The measured voltage contains information about the test impedance. Diagnostic information is obtained by measuring the impedance value and its changes over time. To evaluate the volumetric parameters of operation of the pulsatile heart prosthesis, we decided to use the bioimpedance method. The physical basis for the application of the bioimpedance method is the phenomenon of volume electric conductivity of blood in the VAD. Changes in the volume of the VAD and changes in blood conductivity, associated with spatial orientation of erythrocytes, result in a pulsatile impedance wave. Bioimpedance

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signal from the end of the filling phase to the end of the ejection, reflecting changes in the blood volume in VAD, provides opportunities to determine the stroke volume for each operation cycle.

## 2. BIOIMPEDANCE METHOD

### 2.1. PHYSICAL BASIS

From the point view of electrical properties, blood may be considered as a suspension of cells (erythrocytes and leukocytes) in the plasma. Plasma and cytoplasm of the erythrocytes are characterized by resistance properties. The cell membrane of the erythrocytes with dielectric properties along with cytoplasm and plasma make capacitive structures [6]. We can assume, that in range of application current frequency (10÷100 kHz), practically used in bioimpedance measurements, cells do not conduct current, while a plasma is a conductor. The spatial orientation of cells, especially erythrocytes affects the resistivity of blood. Therefore, impedance measured during pulsatile blood flow depends on volume changes and changes in resistivity of the blood that results from the flow [7].

The basis of bioimpedance method is the easiest to show on the model of cylinder, which during the pulsatile blood flow changes only in diameter.  $Z_0$  impedance measured between the bases of the cylinder is shown by the following equation:

$$Z_0 = \rho \frac{l}{S} \quad (1)$$

where:  $\rho$  – the resistivity of blood,  $l$  – height of the cylinder,  $S$  – cross-sectional area .

Resistivity of non-flowing blood with concentration of electrolytes and proteins in the normal physiological range depends on the hematocrit (HCT) - the number of erythrocytes in relation to the volume of whole blood, and is expressed by equation:

$$\rho = \frac{\rho_p}{0,93 - 1,2 \cdot HCT} \quad (2)$$

where:  $\rho_p=0,63$  - plasma resistivity [8].

Impedance change caused by volume change  $\Delta V$  in result of blood flow is given by Nyboer model, which is the basis of bioimpedance method:

$$\Delta Z = \frac{\Delta V}{\rho \cdot (l/Z_0)^2} \quad (3)$$

This simple model does not take into account many factors that characterize changes of the blood impedance in VAD. Blood chamber with complicated shape, depending on the position of the membrane, changes its volume during VAD operation. Assuming that the electrodes are in a fixed positions, only the cross-section area of conductor is changed. Impedance increases with the decrease of blood volume in the VAD. The phenomenon of volume conductivity is dominant, but we should also take into account the variability of blood resistivity caused by spatial reorganization of erythrocytes, especially during the period of filling and ejection of the blood.

### 2.2. MEASURING INSTRUMENTATION

Bioimpedance measurements require good electrical contact between the measuring system and the test medium. Because of insulating properties of material used to made a chamber, metal rings of inlet and outlet valves were used as measuring electrodes. This way the direct electrical contact with the blood was obtained, which allowed to make impedance measurements using the constant current two-electrodes

method. There is no voltage drop at the contact between electrode and blood, so the rings can also act as receiving electrodes.

The analog part of bioimpedance measuring channel consists of application current source and the circuit to receive input signal. The sinusoidal current source with high amplitude stability ( $100 \mu A_{RMS}$ , fluctuations  $<1\%$ ), frequency of 40 kHz, and a wide range of load impedance  $Z_x$  (up to  $1500 \Omega$ ) was obtained by using PI controller in a feedback of the output current amplitude stabilizing circuit (Figure 1).

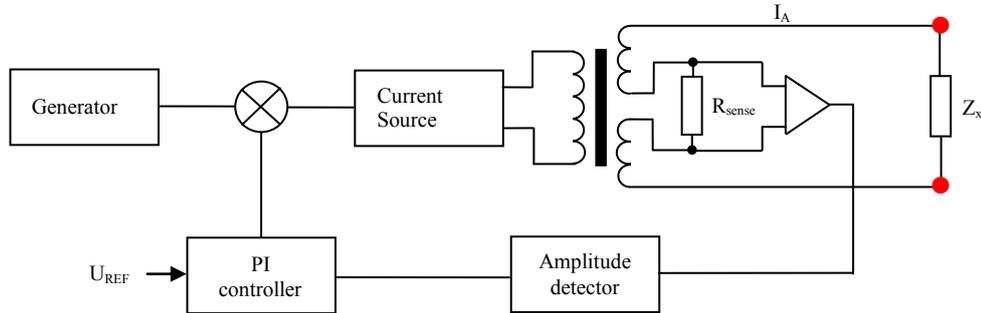


Fig. 1. Block diagram of the application current source.

The analog input circuit of bioimpedance channel (Figure 2) consists of amplifier, input filter, demodulator designed as full wave rectifier, and the analog to digital converter. Due to the relatively large variable component of demodulated signal against the constant component, and the use of 16-bit A/D converter, it was possible to resign the classical solutions of analog AC coupling.

The measuring module also allows the simultaneous recording of signals from the pressure sensors and from external ultrasonic volume flow meter Transonic TS206. This way we enriched the possibility of variable impedance component analysis with respect to other physically related signals. In experimental studies, the signal from flow meter was a source of information about the changes of the VAD volume, while pressures in the blood chamber and in the outlet connector were used to detect characteristic points of bioimpedance signal corresponding to the beginning and the end of ejection phase.

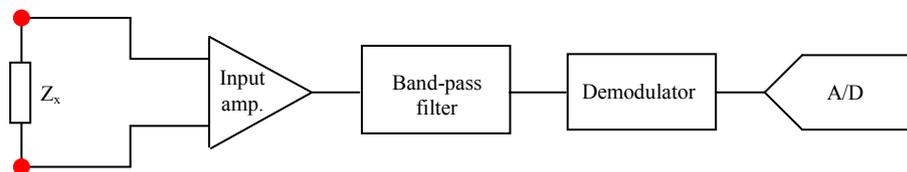


Fig. 2. Block diagram of the input circuit of bioimpedance channel.

### 3. THE EXPERIMENTS

In order to verify the nature of processes occurring during the blood flow through the VAD, and to determine the impact of volume changes on bioimpedance signal, series of experiments were made on the flow test stand with the use of animal blood. Appropriate conditions for experiments were provided in the laboratory of Foundation of Cardiac Surgery Development in Zabrze. The experimental flow test stand - see Figure 3.

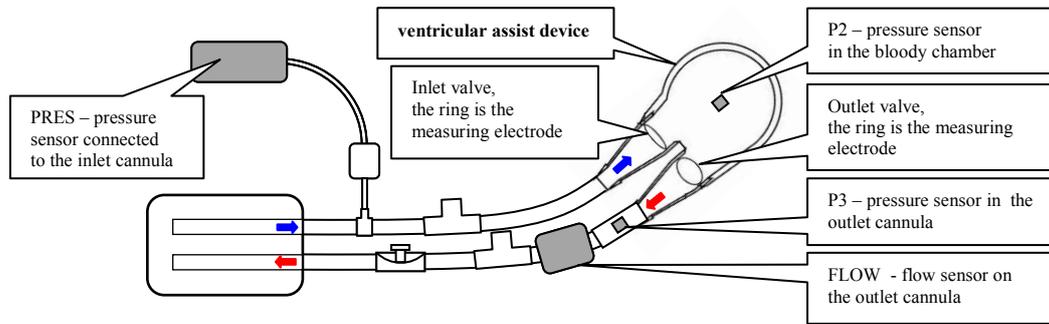


Fig. 3. The general idea of the experimental flow test stand.

An animal blood with determined hematocrit (HCT) was used in experiment. During the experiment, HCT was changed within the range of values occurring physiologically. For each obtained HCT there were made simultaneous signals recordings: pressure in the blood chamber (P2) and in the outlet connector (P3), blood flow in the outlet connector (FLOW) and bioimpedance signal in the blood chamber (REO). Records were made for three different, visually controlled, levels of filling the blood chamber. Single cycles of recordings which were made for HCT=53 and heart rate HR=40 are shown in Figure 4. The vertical lines indicate the phase of blood ejection from the VAD. The beginning and the end of ejection is respectively corresponding to the opening and closing the aortic valve. The second waveform shows that amplitude of REO signal depends on the VAD volume changes. Changes of the amplitude of REO signal during ascending phase, which are limited by two extreme plateau points on pressure waveforms, correlate with stroke volume of the VAD.

As shown in Figure 4, the waveforms 1 and 3 with full ejection are characterized by the occurrence of oscillations at the end of ejection phase. This is unfavorable from the view of bioimpedance signal analysis. Large oscillations in the final phase of ejection cause inability to indicate the increase of impedance corresponding to the total change of VAD volume.

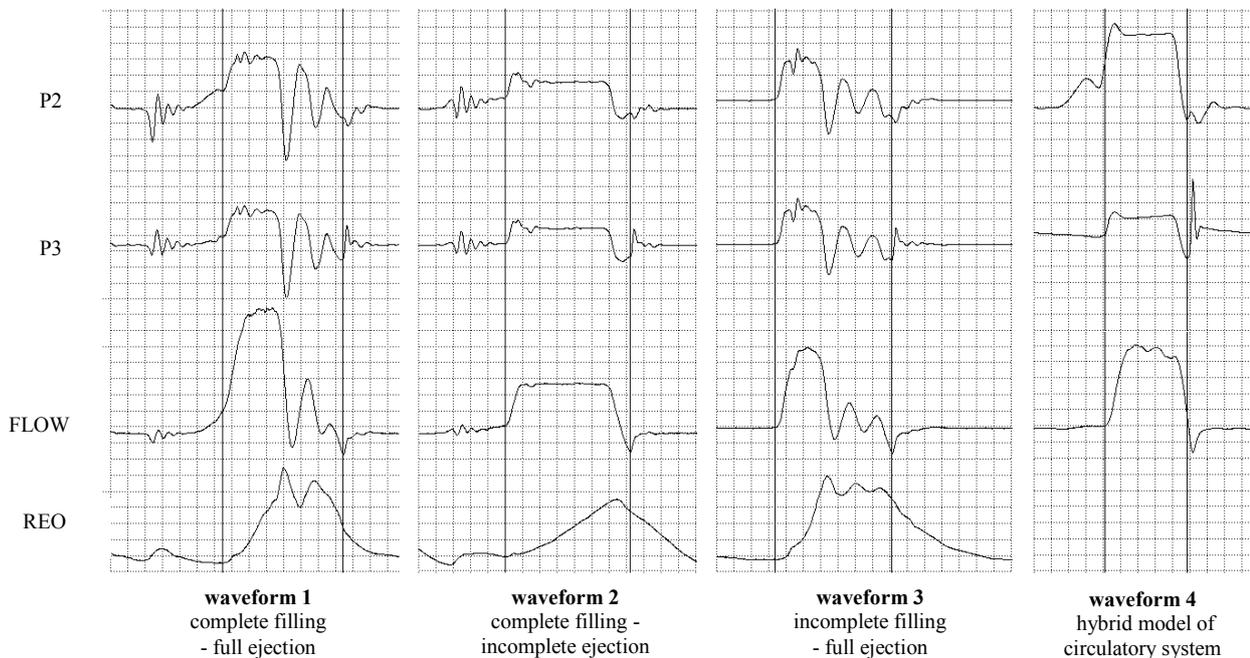


Fig. 4. The signals waveforms in various operating modes of the VAD.

In order to find the source of oscillations in the waveforms, they have been compared with recordings obtained by using a hybrid model of the circulatory system [9]. Complicated structure of the hydraulic part unfortunately prevents the use of blood in the test, and therefore it was impossible to make the impedance measurement. The waveform 4 (Fig. 4) shows simultaneous recorded signals of pressure in

the blood chamber and in the outlet connector as well as the flow in the outlet connector. By using hybrid model, more similar to the natural circulatory system, the effect of wave reflection of blood flow from the VAD has been eliminated. So the reason of harmful oscillations occurrence in the previous experiment was the way of simulation of vascular resistance by a clamp on the outlet cannula. Basing on this observation, it was concluded that we should expect signals without these distortions, when VAD will be implanted to the natural living object.

The VAD is implanted between the heart atrium and the artery at the outlet of ventricle. This creates a parallel channel of blood flow. During bioimpedance measurements, when the current source is connected to the valves rings, natural heart with inflow and outflow cannulas constitute parallel channel of the application current flow. Blood impedance measured in the blood chamber is bypassed by blood impedance in the natural heart and cannulas. Variable component of the impedance caused by the operation of natural heart can affect the shape of bioimpedance signal, especially in the case of asynchronous operation of natural heart and the VAD. An experimental simulation of the impact of inefficient natural ventricle on the bioimpedance signal was performed. For this purpose, the in-vitro circulatory system with two VADs was constructed; one is working as an inefficient heart - it is assisted, the second one is the assisting device (Figure 5).

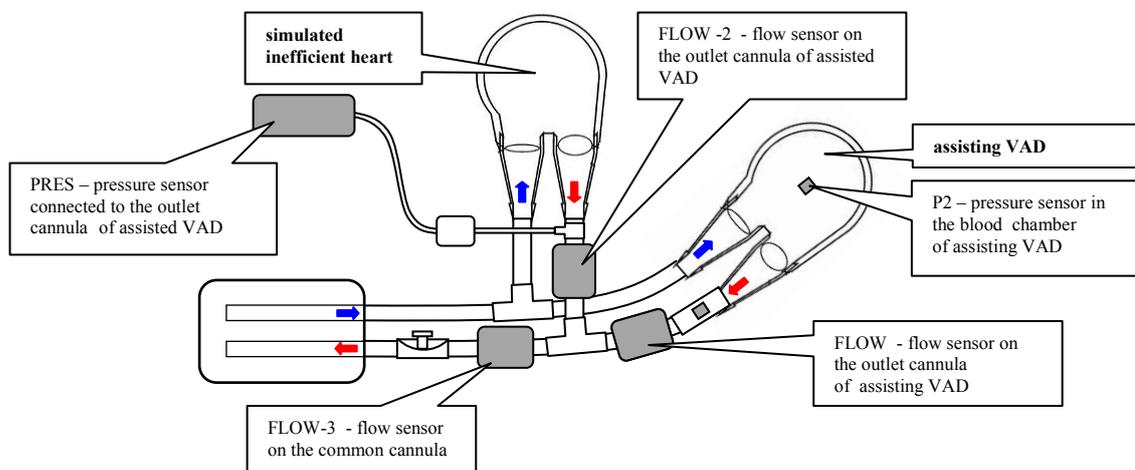


Fig. 5. The signals waveforms in various operating modes of the VAD.

As shown in Figure 6, the blood ejected by assisted VAD in negligible degree impacts the shape of REO signal and its amplitude. Bypassing the impedance of assisting VAD by the blood in assisted device and cannulas does not affect the ascending phase of REO signal. This means that the evaluation of the VAD stroke volume, based on the analysis of ascending phase of REO signal, would not be distorted. However, it was observed that the total measured impedance is changing (decreasing), therefore the calibration in the target system will be necessary.

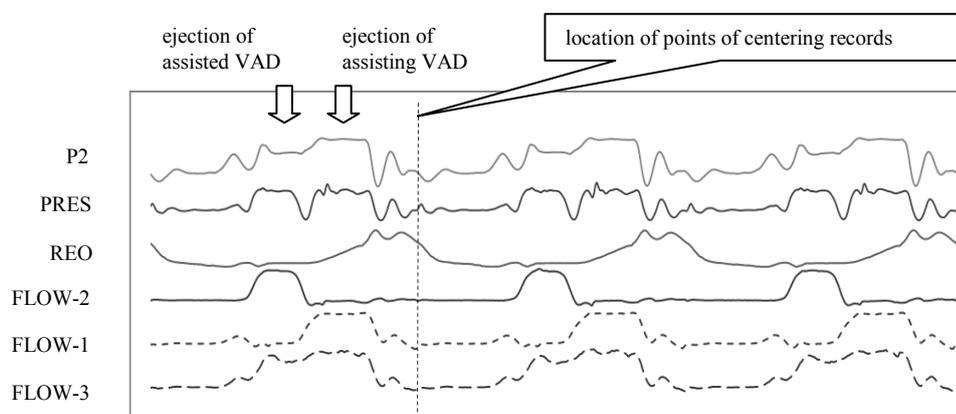


Fig. 6. The recordings obtained during synchronous operation of assisted and assisting VADs.

In order to determine the influence of overlapping ejection phases of assisted and assisting VADs on a shape of REO signal, the experiment with asynchronous operation was performed (Figure 7). Visible interferences in REO signal and suppressing its amplitude will have significant impact on the evaluation of the VAD stroke volume. In addition, precise determining the characteristic points on the REO signal will be difficult in the presence of interferences in pressure signal. These effects may practically prevent evaluation of stroke volume, and certainly affect its accuracy. The results of experiment allow conclusion that reliable evaluation will be possible only if the operation of the natural heart and VAD will be synchronized and the phases of ejection will not occur at the same time.

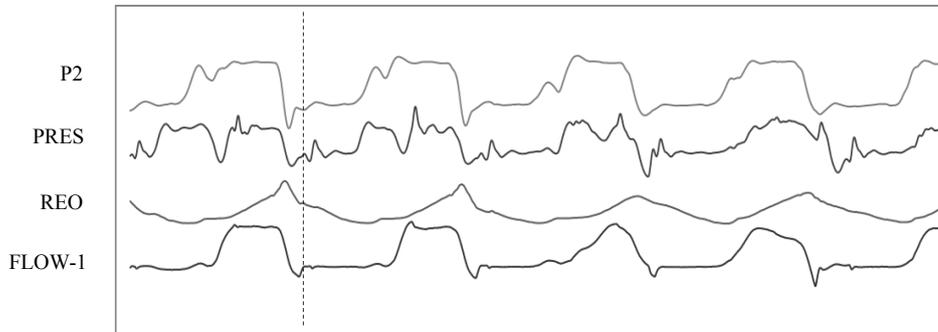


Fig. 7. The recordings obtained during asynchronous mode of both VADs operation.

The experimental studies allowed creation of an algorithm determining the position of characteristic points on the REO signal, corresponding to the beginning and the end of the blood ejection from the VAD (Figure 8).

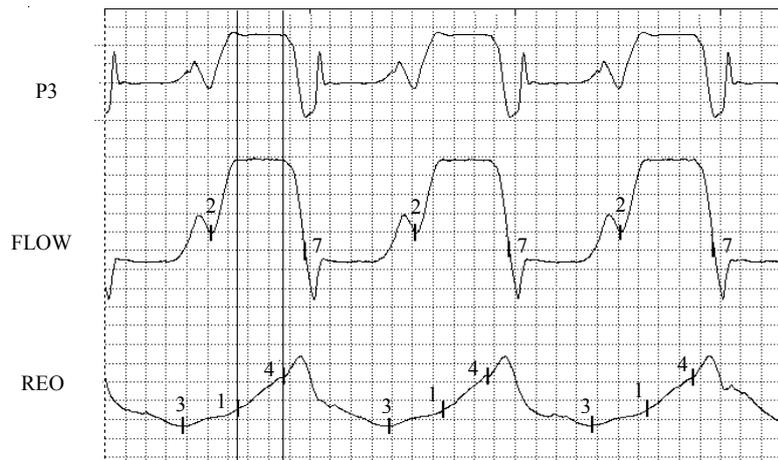


Fig. 8. The method for determination of characteristics points on the bioimpedance signal.

In three consecutive cycles of VAD operation, the characteristic points 1,4,3 on the REO signal, and points 2, 7 on the FLOW signal were determined. Points 1 and 4 on the REO signal correspond to extreme plateau points of the pressure signal P3 in the outlet connector. These points determine the range of blood impedance changes related to the movement of the membrane, and thus the volume changes in the blood chamber. Point 3 is a base impedance  $Z_0$  which depends on the volume of fulfilled chamber and frequency of the VAD operation. Point 2 corresponds to the beginning of ejection phase. Point 7, for the zero value of the FLOW signal, determines the ending moment of the blood ejection from VAD.

When determining the location of characteristic points 1 and 4 on the REO signal, intentionally omitted were the subperiods of the ejection phase which are characterized by large pressure changes. Dynamic pressure changes during opening and closing the valves cause that the blood flow is not laminar and there are some local turbulences. Changes in spatial orientation of erythrocytes in the turbulent flow affect the blood resistivity. Therefore, during subperiods of opening and closing the valves, on the measured bioimpedance signal, and more specifically on the impedance module, affect both volume

changes and changes in electrical parameters of the blood, caused by changing the spatial orientation of erythrocytes. Bioimpedance signal in these subperiods cannot be used to evaluate the VAD volume.

#### 4. CONCLUSIONS

Periodic changes in the volume of the blood chamber during the VAD operation result in a pulsatile impedance wave. The amplitude of the impedance wave at the phases of filling and ejection correlates with the blood volume in the chamber. In subperiods of opening and closing the valves, the measured bioimpedance signal is affected both by volume changes and changes in electrical parameters of the blood, caused by changing the spatial orientation of erythrocytes. The experimental results show that reliable evaluation of the VAD volume is possible only if the operation of the natural heart and VAD are synchronized and the phases of ejection do not occur at the same time.

The developed algorithm allows us to determine the characteristic points of the bioimpedance signal. These points define the range of blood impedance changes related to the volume changes in the VAD, which make possible the calculation of stroke volume for each VAD operation cycle.

Results of experiments confirm the practical usefulness of bioimpedance method to evaluate the stroke volume of VAD. However the final confirmation of the possibility of using this method, needs the experiment on living object, when the VAD will assist the natural heart in the real circulatory system.

#### 5. ACKNOWLEDGEMENT

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