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Acoustic System of Determining the Instantaneous Volume of the Blood Part of the Ventricular Assist Device POLVAD-EXT

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The paper presents the results of investigations concerning the noninvasive method of estimating the actual volume of the blood chamber of the POLVAD-EXT type ventricular assist device (VAD) during its operation. The proposed method is based on the principle of Helmholtz's acoustic resonance. Both the theory, main stages of the development of the measurement method as well as the practical implementation of the proposed method in the physical model of the POLVAD-EXT device are dealt with. The paper contains the results of static measurements by means of the proposed method (conducted at the Department of Optoelectronics, Silesian University of Technology) as well as the dynamic measurements taken at the Foundation of Cardiac Surgery Development (Zabrze, Poland) with the professional model of the human cardiovascular system. The results of these measurements prove that the proposed method allows to estimate the actual blood chamber volume with uncertainties below 10%.

Keywords: acoustic Helmholtz's resonator, blood volume estimation, VAD.

Notations

VAD – ventricular assist device,
CO – cardiac output,
AHR – average heart rate,
SDP – systolic drive pressure,
DDP – diastolic drive pressure,
AGC – automatic gain control.

1. Introduction

Due to the changes in the way of life, the modern society is more vulnerable to civilization diseases – especially cardiovascular ones. The most distressing fact is a fast growth of the number of people suffering from end-stage heart failure who cannot be cured using drugs induced treatment alone. One of the possible treatments of those patients are Ventricular Assist Devices (VAD), basically pumping the blood and releasing the heart from much of its burden – which might lead – in some cases – to a partial or even full recovery of the heart muscle (Young, 2001).

In the case of pneumatic type of such a device (Fig. 1a) the problem of efficient monitoring of pumping the blood, leading to an automation of the heart support process, is still to be solved. Finding a solution of this problem would allow an automatic adjustment of the parameters of the heart support process in terms of actual hemodynamic condition of the patient. The pulsatile-type heart support devices are mostly used in short and medium-term treatments where the heart muscle may be regenerated, making the heart transplant procedure superfluous (Young, 2001; Grady *et al.*, 2004). In that case matching the heart support process to the actual state of the patient can vastly improve the regeneration of the heart muscle, and even allow treatment process in home conditions. In the commonly used VAD solutions, the medical staff modifies manually the heart support parameters considering the actual state of the prosthesis and that of the patient. It is relatively easy in the case of extracorporeal VAD's (connected outside the patients' body with the cardiovascular system) but still requires a constant presence of the personnel.

a)

b)

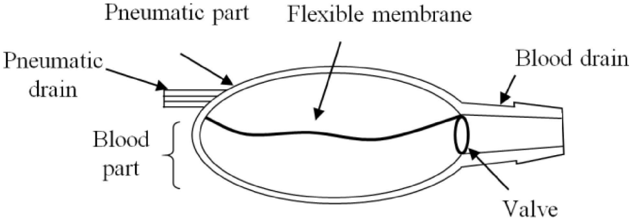

Fig. 1. Religa-Ext – image (FRK, 2014) and diagraph of construction.

The full automation of the heart support process can be accomplished only when the unit controlling the VAD's operation will possess sufficient information about the state of the patient (blood pressure, pulse, blood oxygenation etc.) as well as the heart support process. In the case of VAD very valuable information is provided by the cardiac output (CO) parameter. It informs about the volume of blood being pumped in a course of one minute. One of the solutions to measure this parameter is the application of external flow-rate meters – they require periodic scaling and thus also additional reference measurements.

2. The actual state of the researches in terms of the monitoring of the actual blood volume in the VAD

The construction of the pneumatic VAD devices is relatively simple. They consist of the blood part and the pneumatic part, separated by a flexible membrane (Fig. 1b). The pressure change in the pneumatic part causes the membrane to move, thus induces the blood flow. The direction of the flow of the blood is determined by the orientation of the valves installed in blood drains. This simple construction causes problems in the case of monitoring the VAD's operation – the membrane "wrinkles" in a random way. Thus, simple methods of measuring the distance cannot be used.

The problem of monitoring the volume of the VAD was researched in the past. The most common solutions, incorporated with the construction of the VAD, provided a partial answer to the problem by detecting the full-filling and complete-empty state of the blood chamber of the prosthesis (magnetic and optical methods) (Reichenbach *et al.*, 2001; Franco, Verrier, 2003). They allow a proper full/empty operation – not allowing a fluent alteration of the CO. In other cases indirect measurements utilizing the air flow in the air duct, as well as the blood flow in the blood ducts are used but they require periodic scaling realized by means of other methods (Reichenbach *et al.*, 2001). In the case of blood flow-rate measurements, the most common solutions due to their noninvasiveness, are ultrasound flow-rate meters. Their size hinders their use in implantable solutions.

The last group comprises blood impedance measurements methods. However, their operation depends on the changing properties of blood and requires a constant flow of the current through the blood environment, which makes them only partially noninvasive (Guyton, 1991; Sasaki *et al.*, 1991). There were several approaches to solve the problem in the case of the Polish solution – POLVAD. They were based on measurements of the blood impedance, optical reflection as well as acoustic quasi-white noise phenomena (Darlak *et al.*, 2007), none of which have been applied in the actual prosthesis.

The literature of the problem does not describe solutions of the problem that would allow a constant monitoring of the actual volume of the blood in the VAD, incorporated with the construction of the pulsatile VAD, making the measurements uncertainties of the maximum of 10%. Despite the extensive researches, the problem of a full automation of the heart support process in the case of pulsatile VAD is still actual, which proves that the problem is not a trivial one.

3. Acoustic approach to the volume measurement problem

Researches of the problem were also conducted in the field of acoustics. The previous approaches were based on acoustic quasi-white noise generation in the pneumatic chamber (which acted as an acoustic filter). Fourier's spectrum of the detected filtered signal may be directly associated with the actual volume of the blood chamber. The method operated under the dynamic conditions, but depending on the wrinkling of the membrane the path between the acoustic emitter and the detector, may be disrupted hindering a proper estimation of the volume of the last 30 ml (out of 85 ml in total). This problem and the short durability of the speaker exposed one-sided to rapid pressure changes disqualified the method for further investigations.

The researches proved, however, that the acoustic approach might provide a solution to the problem. Extended researches concerning the modified acoustic method were conducted within the frame of the Polish National Artificial Heart Program. This time, the possible use of Helmholtz's acoustic resonance was investigated.

Helmholtz's acoustic resonator consists of a limited volume of gas, connected with another volume (in the ideal case of infinite volume) with a "neck" (Fig. 2).

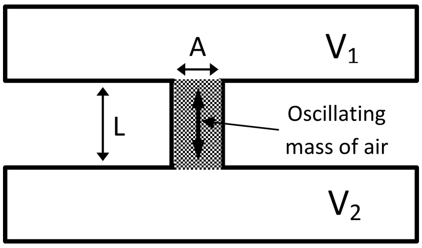

Fig. 2. Helmholtz's resonator.

The mass of gas "trapped" in the neck oscillates at the determined frequency, induced by the differences in pressure inside and outside the resonator. The frequency of oscillations in the case of the basic resonator (where $V_2 \to \infty$) can be described by (1) (Kinsler *et al.*, 2001):

$$f = \frac{c}{2\pi}\sqrt{\frac{A}{L \cdot V}}, \qquad (1)$$

where c is the velocity of the sound, A – area of the cross-section of the neck, L – length of the neck, V – volume of the gas inside the resonator.

According to Eq. (1), the resonant frequency relies on the dimensions of the neck and the volume of the resonator. This is the simplest operation that does not usually occur in technical systems. We usually encounter combinations of at least two Helmholtz resonators of restricted volumes (Fig. 2). Equation (1) cannot be effectively used in this case due to the influence of both volumes on the oscillating mass. The most common practice in those cases is an analysis of the acoustic system using the adequate electrical circuit equivalent. The combination of two resonators can be analyzed as a substitute for resonant electrical circuit (Fig. 3) (Davies, Webster, 2010).

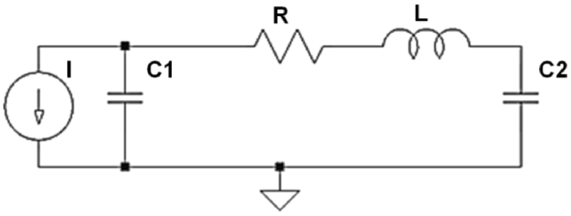

Fig. 3. The combination of two Helmholtz resonators with the corresponding electric circuit.

In the electrical model, the resistance R corresponds to the dissipation of energy due to the viscosity of gas; the capacitance C reflects the volumes of the connected resonators, while the inductance L is a representation of the properties of the neck, connecting both resonators. This is true when the size of the resonator is smaller compared to the length of the resonant acoustic wave frequency (Chanaud, 1994; Chiu, 2012).

The value of the resistance is furthermore dependent on the flow-rate of the air, however, in the case of small acoustic pressures (compared to the atmospheric one), which is the case in the discussed system, this effect can be neglected (Chanaud, 1994; Davies, Webster, 2010).

4. Practical implementation of the acoustic system in the case of the POLVAD-EXT

Measurements of the actual volume of blood in the blood part of the prosthesis should be noninvasive to the blood environment. The proposed method should not influence negatively the blood elements in order to avoid the formation of a thrombus.

There have been many approaches to this topic. The proposed system comprises measurements of the volume of the pneumatic part of the VAD. Due to the fact that the total volume of the VAD is constant (in the range of air pressures used in the heart support), the estimated volume of the pneumatic part provides also the volume of the blood part (2):

$$V_{\text{bloodpart}} = V_{\text{VAD}} - V_{\text{pneumaticpart}}. \qquad (2)$$

Additionally, the measurement system is separated from the blood environment by a membrane. The maximum output of the VAD in one cycle amounts to the total volume of the pneumatic part. In the POLVAD devices it amounts to circa 85 ml maximum.

The preliminary researches were conducted using the POLVAD-MEV device, which was equipped with an additional sensor part, connected with the sensor chamber (Fig. 4).

Inside the sensor part acoustic elements were introduced – a microphone and a speaker. The electronic system was used as a positive feedback amplifier, feeding the signal from the microphone back to the speaker. In order to limit the amplification to a certain level, the AGC (automatic gain control) element was introduced in the electric signal path. The so constructed system is excited at a single frequency, related to the actual volume of the pneumatic part, viz. the blood part of the prosthesis.

The additional sensor part along with the pneumatic part form a two chamber acoustic Helmholtz resonator.

In order to allow measurements of the volume, the system was equipped with a microcontroller circuit, realizing the frequency measurements. The frequency-

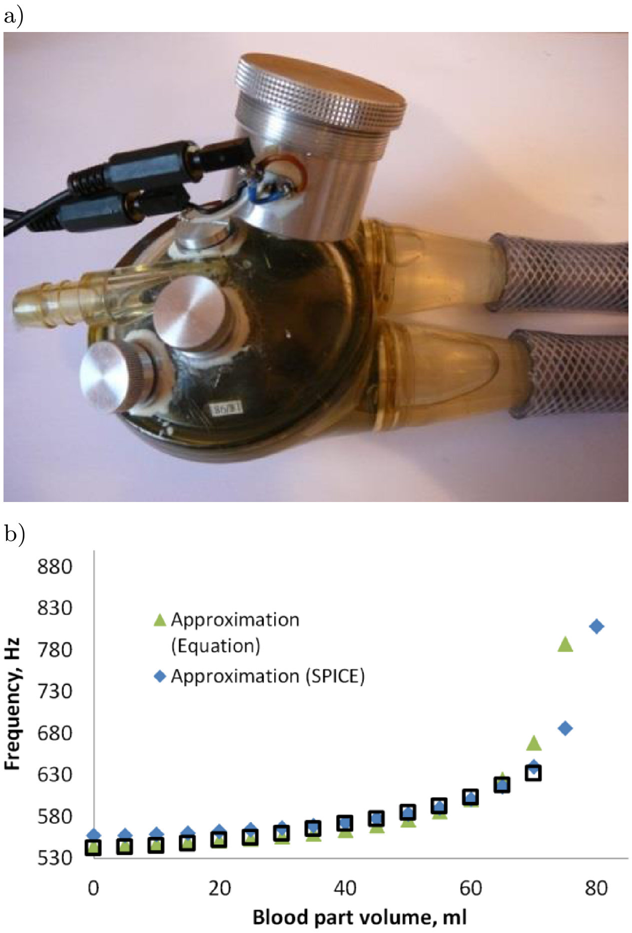

Fig. 4. POLVAD-MEV with the sensor part (a) and theoretic and practical results of the measurements (Konieczny *et al.*, 2009; 2011).

volume characteristics were stored in the memory of the microcontroller.

Simulations of the equivalent electric circuit using the SPICE application (Fig. 3) have shown a high conformity of practical and theoretical results (Fig. 4b).

The resonant frequency of the measurement system increased with the increasing volume of the blood part (the decreasing volume of the pneumatic chamber).

It can be seen that the theoretical results coincide with the results of measurements in a wide range of blood part volumes. Problems occur at high blood part volumes (low volumes of the pneumatic part) where the oscillations are too weak to be detected. It is, however, clear that we deal here with Helmholtz's resonance (Konieczny *et al.*, 2009; 2011).

5. The implementation of the method in the model of POLVAD-EXT

Preliminary researches conducted on the old-type POLVAD-MEV device proved to be successful. It was decided that the researches should be extended to the model of a new VAD, developed within the frame of the Polish National Artificial Heart Program. The model of the developed prosthesis POLVAD-EXT was provided by the Foundation of Cardiac Surgery Development. It has a modular construction, therefore it may be slightly modified to fit the acoustic system. At this point, the additional sensor chamber had to be modified. The one used with the POLVAD-MEV is too big, and its shape is improper for possible clinical application in the future. Instead, an additional part was added on top of the whole pneumatic part. It is lower than it was before, so it does not increase the height of the VAD, but provides enough volume for the operation of the sensor. The modification includes additional apertures connecting the pneumatic chamber and additional volume, and introduces the acoustic transducers into the additional chamber. Furthermore, the additional apertures allow faster leveling of the pressure in both the sensor and the pneumatic parts of the VAD (Fig. 5).

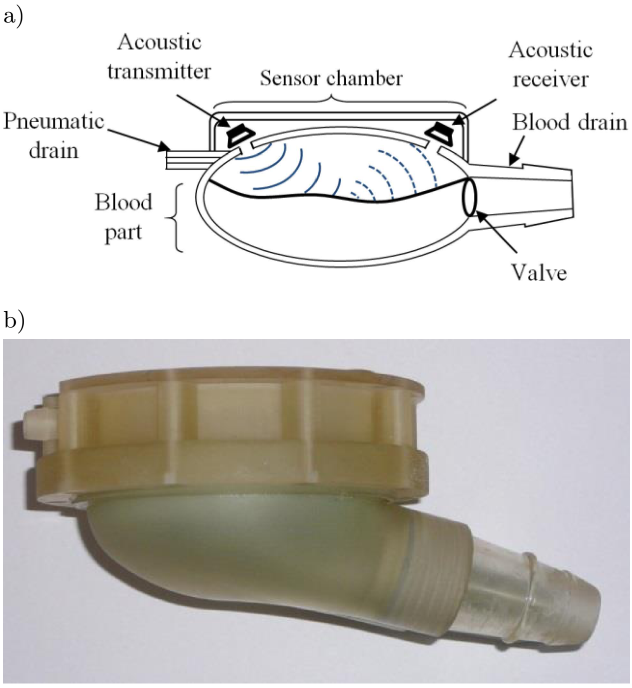

Fig. 5. Idea of the POLVAD-EXT model equipped with an additional sensor chamber (a) and the practical realization (b).

The measurement system underwent extensive modifications, both in the electronic and the acoustic parts, aiming at an improvement of the measurement properties (Opilski *et al.*, 2011). The main change in the acoustic elements concerns the microphone. Due to the noise generated by the operating titanium valves, the microphone was saturated, hindering the measurements. The resulting noise occurred at lower frequencies (<200 Hz), therefore it was distant from the frequencies of the acoustic resonance (<~900 Hz). It was decided that a miniature speaker must be used instead of a microphone. Its natural characteristics made it resilient to the noise at low acoustic frequencies, therefore the measurement system was made immune to the sound generated during the operation of the VAD. The electronic part was modified too. The final circuit took the following form (Fig. 6).

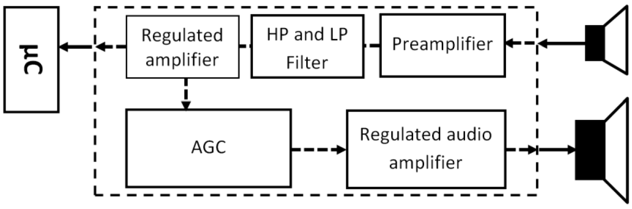

Fig. 6. Block diagraph of the final version of the measurement system.

In the case of the new sensor chamber, as well as additional modifications of the electronic circuit, the measurements system excites at different frequencies. Due to the irregular shape of the additional sensor part, considerably different from the spherical one, and the additional apertures, the theoretical analysis using an equivalent electric circuit proposed by Chanaud (1994) was not accurate. Also, an additional calibration was required. The modified VAD and measurement system were tested dynamically at the Foundation of Cardiac Surgery Development, using a hybrid physical model of the human cardiovascular system (Kozarski *et al.*, 2003; Ferrari *et al.*, 2005). The model allows to simulate the hemodynamic conditions occurring in the human cardiovascular system, including the impedances of the blood duct. The measurement system was investigated in the presence of reference methods of measuring the volume – ultrasound Transonic flow rate metres. Additionally, the pressure was measured in the air drain and the blood drains. The air pressure was measured by both the reference and the acoustic measurement system, and was used to synchronize the results of measurements acquired by both measurements stands (Fig. 7).

The measurements were taken at different speeds of operation of the VAD (AHR) as well as for different driving pressures (SDP and DDP pressures, respectively).

The system successfully passed the examination (Konieczny *et al.*, 2012a; 2012b). It was decided that the electronics should be miniaturized in order to reduce the influence of interferences, and the algorithm of measurements should permit higher acquisition speeds. The modifications of the electronic circuit concerned the frequencies of the filters as well as the complete redesign of the algorithm and data transmission protocol. Slightly miniaturized electronics was reintroduced in the next model of the prosthesis (Fig. 8).

The frequency-volume characteristics were incorporated in the application in LabView environment. The circuit was calibrated in the course of static measurements at the Department of Optoelectronics. The characteristics can be seen in Fig. 8b. The dynamic measurements were performed at the Foundation of Cardiac Surgery Development, using the physical model of the human cardiovascular system. The researches were performed using a blood-like liquid (based on a water glycerin solution). The presentation and acquisition of the measurements results were prepared in a program in Labview environment. The application allowed to measure the actual volume of the blood-like liquid in the VAD and to measure the pressure in the air drain for the previously mentioned synchronization of data of acoustic and reference measurements systems. The independent, reference measurement system acquired the liquid flow-rate, pressures in blood drains as well as the pressure in the air drain for the purpose of synchronization.

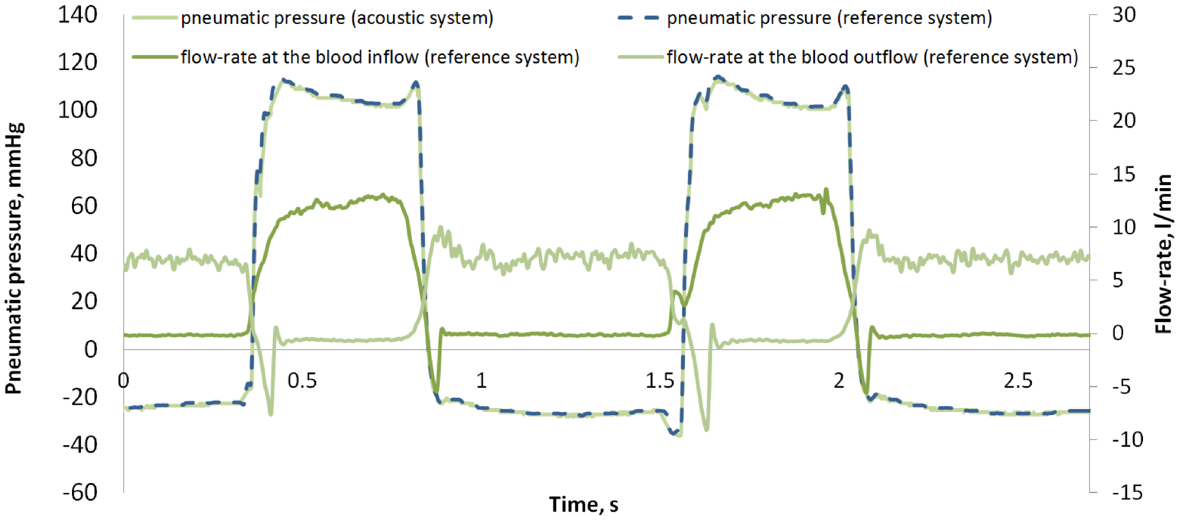

Fig. 7. Exemplary waveforms used in the synchronization of the results of measurements.

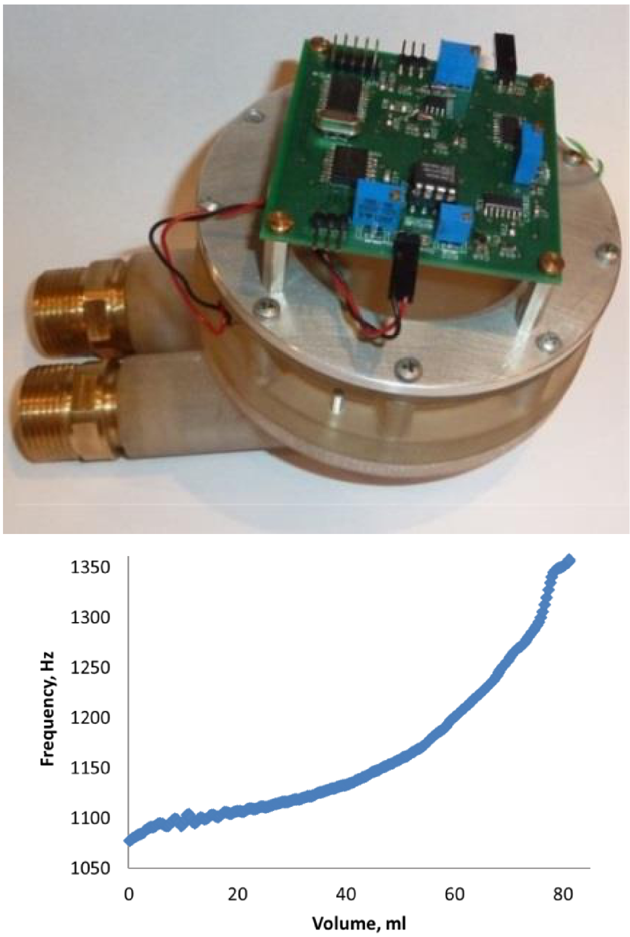

Fig. 8. Electronic system applied in the new model of the VAD and its frequency-volume characteristics.

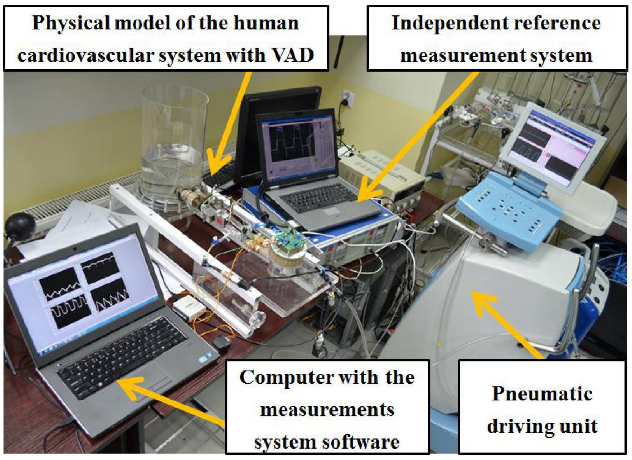

Fig. 9. Physical model of the human cardiovascular system with the VAD with the acoustic measurement system.

Measurements were carried out at three different rates of AHR (50, 70 and 100 bpm – beats per minute): lower than usual, the regular one, faster than usual. Exemplary results are shown in Fig. 10. Measurements of the volume using the system based on Helmholtz's acousticresonator and the volume measurements derived from flow-rate sensors are presented.

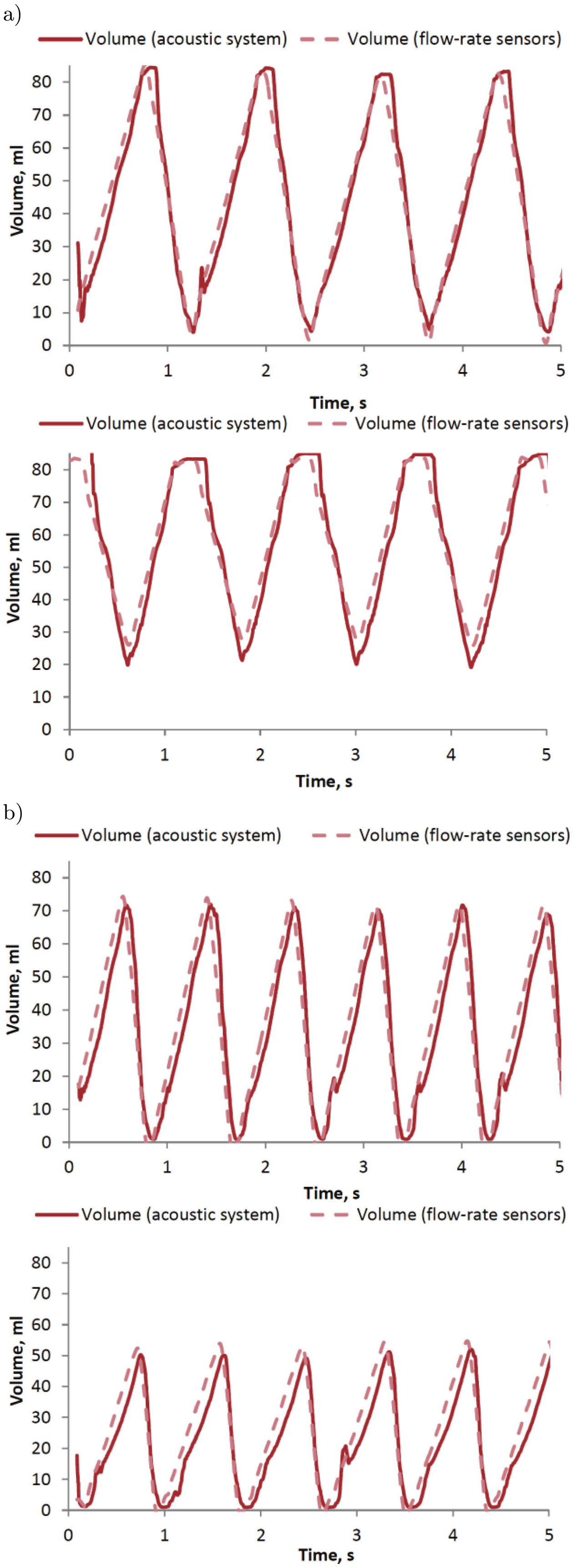

Fig. 10. Exemplary results of dynamic measurements concerning the heart support speeds of 50 bpm (a), 70 bpm (b) (beats per minute).

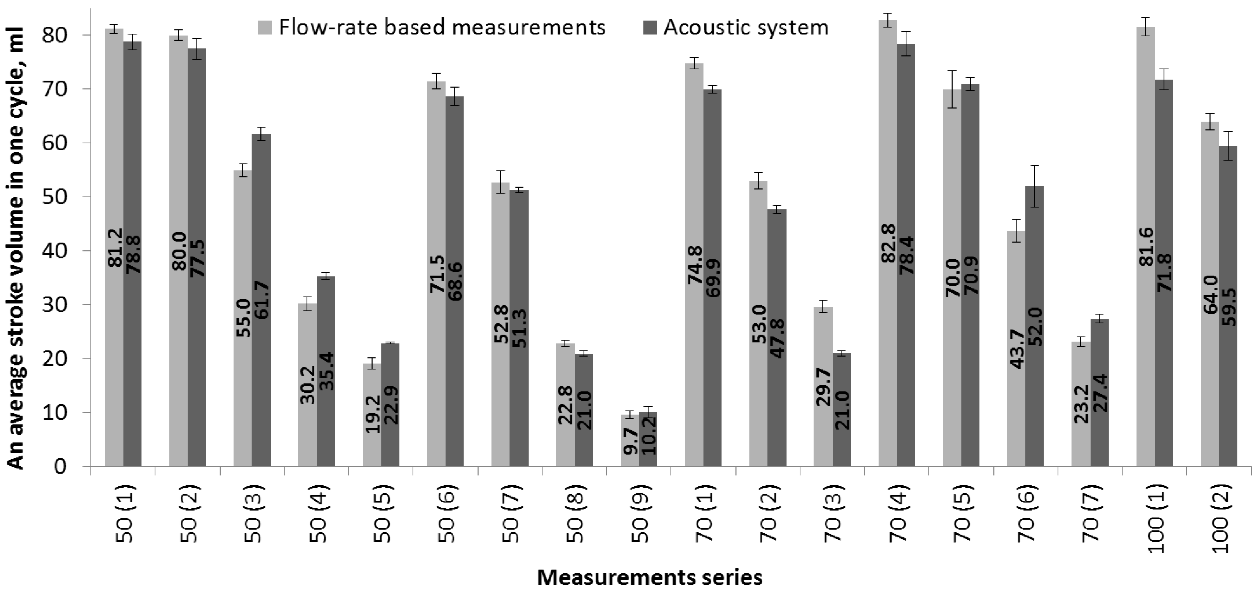

Fig. 11. Average maximum volume of the liquid ejected from the blood part of the prosthesis, during 5 consecutive filling/emptying cycles of the operation of VAD for acoustic and flow-rate based measurement systems.

It can be seen that the curves provided by the acoustic measurement system are very similar to those obtained by using blood flow-rate measurements. The differences are caused by averaging 5 consecutive frequency measurements using the "moving average" method, and are especially noticeable at the rate of 110 bpm. At a regular speed of the heart support the method provides satisfying results.

Figure 11 shows the relations between an average maximum volume ejected from the blood part of the prosthesis (stroke volume) in the course of 5 consecutive filling/emptying cycles of the operation of the VAD in all the series of measurements. The results of the volume measurements acquired using the proposed acoustic method and acquired with the reference flow-rate measurement method are shown. A direct comparison of the results shows a strong conformity of the results acquired using both methods. Modifications of the acoustic method (including the increase in the speed of acquisition) allowed to improve the accuracy and repeatability of measurements. Furthermore, the reduction of the intensity of the acoustic wave, required for a proper functioning of the system, has been decreased – reducing the power consumption required by the acoustic measurement system.

At this point the measurements of high volumes of the blood chamber (>75 ml), are burdened with higher uncertainties, due to the loss of acoustic signal at limited volumes of the pneumatic chamber. In the range of 0–75 ml, the uncertainties of measurements are lower than 10%. A further considerable miniaturization of the electronic part of the measurement system is possible.

6. Conclusions

The proposed method of measurements, basing on the principle of Helmholtz's acoustic resonance, is an original approach to the problem of estimating the actual blood chamber volume of the operating ventricular assist device all over the world.

The conducted researches consisted both of the theoretical analysis – researching the possibility of using Helmholtz's acoustic resonance in the POLVAD type device; and the development of the physical model of the measurement system – tested both statically at the Department of Optoelectronics and dynamically using the professional measurement system at the Foundation of Cardiac Surgery Development. The method was applied in a model of POLVAD-EXT (a prototype of Religa-EXT device). The results of measurements were verified using medically approved reference flow-rate sensors (Transonic).

The results of researches shown in this paper prove that the method can be used for measurements (noninvasive to the blood environment) with uncertainties of maximum 10%. This accuracy is sufficient according to the relevant medical environment. At the current stage of researches concerning this problem all over the world, there is no clinically applied method allowing measurements with a similar accuracy.

Both the method and the proposed physical implementation are a subject of the patent procedure (Pustelny *et al.*, 2012).

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