NON INVASIVE BLOOD VOLUME MEASUREMENT IN PNEUMATIC VENTRICULAR ASSIST DEVICE POLVAD

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For monitoring, optimizing and automatic control of heart supporting process it is necessary to measure ventricular assist device output function. It can be performed by flow measurement through the outlet cannula or by estimation of temporary blood chamber's volume. In article several physical measurement methods were explained and their usefulness to clinical application was compared.

Keywords: artificial heart, ventricular assist device (VAD), heart supporting.

1. INTRODUCTION

Mechanical heart supporting is one of possible treatment methods in case of circulatory system insufficiency [1, 2]. From energetic point of view this process delivers a lacking energy to insufficient vascular system by extra blood flow forcing [3, 4]. It is realized by ventricular assist device (VAD) application. The pneumatic, Polish Cardiac Assist System POLCAS had been developed in Foundation for Cardiac Surgery Development in 1996 and it has been clinically used since 1999. System consists of two principal components: extracorporeal ventricular assist device POLVAD (Fig. 1) and pneumatic driving unit POLPDU-401 (Fig. 2). Monitoring, optimizing and control of heart supporting requires information about VAD's output, defined as blood volume pumped through the device during single cycle.

Fig. 6. Extracorporeal, pneumatic ventricular assist device POLVAD (FRK, Zabrze)

Fig. 7. Clinical pneumatic driving unit POLPDU-401-1 (FRK, Zabrze)

2. OBJECT SPECIFICATION AND METHOD'S REQUIREMENTS

Pneumatic ventricular assist device POLVAD consists of following components: polyurethane made blood and pneumatic housings, disc's valves seated on titanium rings and three-layers, flexible membrane, separated by graphite powder. The blood actuating is a result of membrane movement caused by air pressure changes in pneumatic chamber. The spherical shaped membrane is pliable and flexible, and it crimps irregularly during displacing between systolic and diastolic positions (Fig. 3a…d).

Fig. 8a Full ejection – the membrane is totally displaced and stretched.

Fig. 3b Beginning of filling – the membrane starts wrinkling.

Fig. 3c Filling midpoint – the membrane crosses a mid-plane of chamber (maximal membrane shape distortion).

Fig. 3d End of filling – the membrane shape backs to regular, wrinkles dimension decrease.

The membrane shape irregularity is one of main obstacle during blood volume measurement process. For the sake of patient safety and clinical operational requirements, an additional measurement methods' requirements are: noninvasiveness, minimal contact with blood (total separation is preferred) and low sensibility to disturbance. At last, whichever changes of existing VAD's construction at blood part (including valves, interior of cannulas, blood chamber and membrane) are strongly undesirable. A sufficient method's accuracy is about 10[%].

At present, in extracorporeal VAD, it is possible to realize noninvasive pump output measurement by use of ultrasonic flow meter with sensor attached to cannula [5, 6], but it is uncomfortable and it requires an extra operation performed by medical staff. Moreover, this kind of measurement is impossible in application of implantable device.

3. EXPERIMENT CONDITIONS AND REFERENCE METHOD

All experiments were performed on pneumatic ventricular assist device POLVAD. In most cases as an operation liquid the prepared ram's blood was used. Static volume reference measurement was performed directly, by column of liquid pressure measurement in vertically fixed, opened to atmosphere tube. Dynamic volume reference was realized by ultrasonic flow meter (Transonic TS106) with sensor mounted on cannula [12]. The accuracy of static and dynamic references were ±1[%] and ±5[%], respectively.

4. INVESTIGATED METHODS' REVIEW

The investigated methods of blood volume measurement in pneumatic ventricular assist device POLVAD were discussed below.

The fundamental of *impedance method* is a volumetric electrically blood conducting [7]. Changes of blood chamber volume correspond to changes of its electrical impedance. Titanium valves' rings (Fig. 4) were used as an electrodes directly connected with blood. The idea of measuring process was explained on Fig. 5. To avoid of plasma electrolysis system was supplied by relatively low (50…1000[μA]) stimulating current. In order to eliminate conductors resistance the 4-wire, technical impedance measurement method was applied [8].

For wide band of current frequencies (1[Hz]…250[kHz]) impedance had only real part. Characteristics of electrical impedance versus blood chamber volume for various stimulation current values were shown on Fig. 6. The best polynomial interpolation (R^2=0.9992) was achieved for 50[μA] current value.

Fig. 9. Disc valve with titanium ring (electrode)

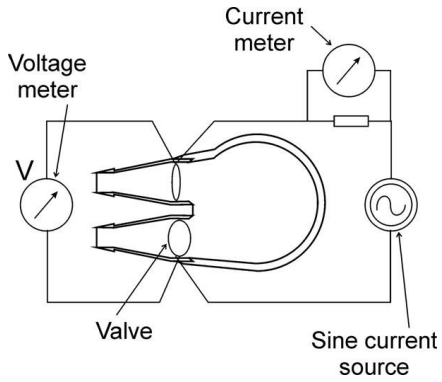

Fig. 5. Block diagram of impedance method

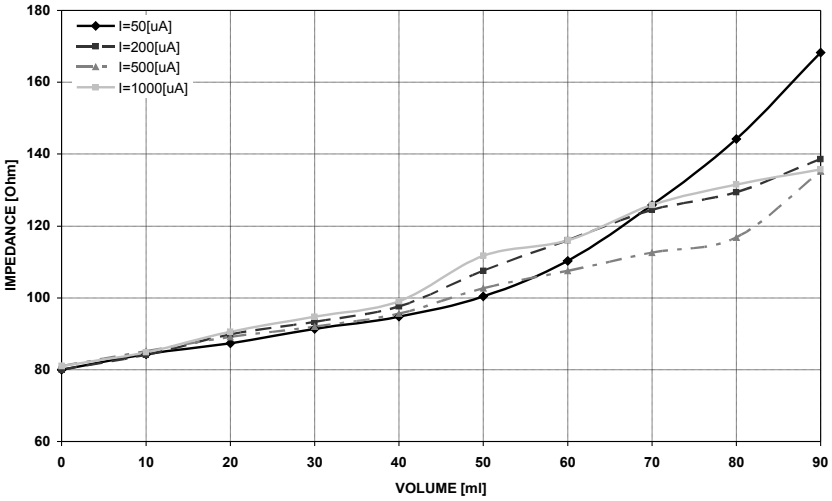

Fig. 6. Electrical impedance vs. blood chamber volume

For low stimulating currents (50, 100[μA]) the method's relative error was less than 2[%], for greater currents error was increasing up to 5[%]. Additionally, low method's disturbance sensitiveness was observed.

Conductive properties of blood were exploited in *capacitance method*. Its physical basis is changes of conductor (blood) – dielectric (air) proportion which transposes into various electrical capacity of system. The block diagram of measurement system was presented on Fig. 7. Capacitance was digitally measured by bridge method with an accuracy of ±0.8[%]. Electrical capacitor was formed on external surface of housings by carbon or aluminum covering. The membrane covering tests were performed, but conductive layer was breakable and it was chipping from membrane after several cycles of works. First experiments made on isotonic salt solution (0.9[%] NaCl) explained, that process is sensitive to external impedances

(like impedance between ground and human body). To avoid this effect the conductive, grounded insulating shield was introduced.

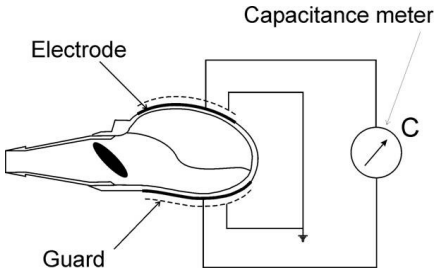

Fig. 7. Block diagram of capacitance method

Next experiments were performed on ram's blood and isotonic salt solution. The capacitance – volume characteristic comparison (Fig. 8) indicates good matching of obtained curves apart from medium type. This fact means that in respect of dielectric features, physiological saline may be substitute of blood.

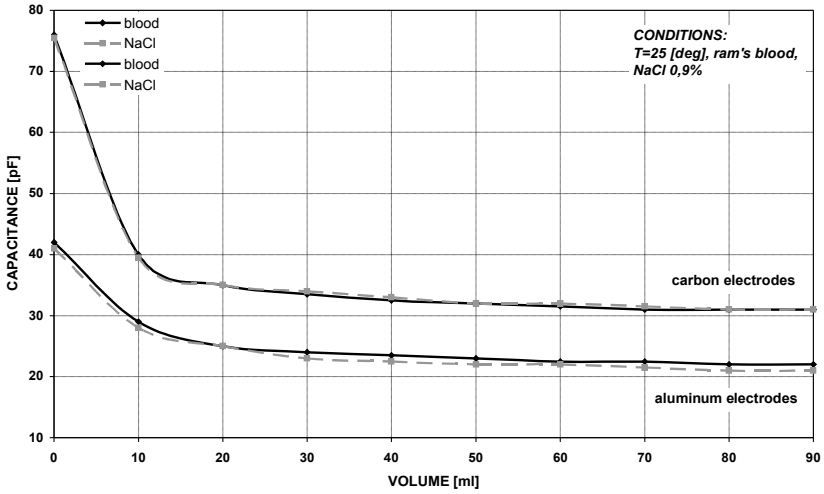

Fig. 8. Characteristic C=f(V) for various types of medium and electrodes material

Apart from electrodes' material, in wide volume range, capacitance characteristic contains a flat part, where low changes of measured value caused increasing of method's error. The relative error value was variable, dependently on volume, and amounted from 5[%] (for volumes between 0 and 20[ml]) to 20[%] (for volume greater than 50[ml]). In spite of device insulating the strong influence of external disturbing impedances were observed.

Ventricular assist devices have specific blood chamber's shape, which guarantee blood circulation and washing a places of membrane fixing [9]. Any flow stagnation areas, surface checks, feather edges and obstacles along blood flux are places, where thrombus formations will be growing. By that reasons any construction changes at blood part are not recommended.

Pneumatic part requirements are not so strict and it is possible to mount sensors inside pneumatic chamber or along pressure drain.

The membrane position detecting by usage of ultrasonic beam reflection effect was applied in *ultrasonic method* (Fig. 9). The frequency of ultrasound wave was 40[kHz]. Because of long piezoelectric element reverberation time (comparable with expecting pulse return time) the acoustic path was divided by two portions with separately ultrasound elements: receiver and transmitter. To eliminate offset (originated from driving pressure) and noises, received signal was filtering in 2nd order analog band pass filter (Fig. 10). The following criterions of return pulse identification were tested: constant threshold, two following carrier amplitudes difference and two following carrier amplitudes quotient.

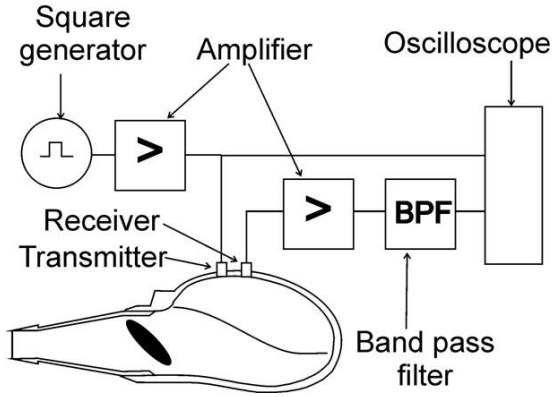

Fig. 9. Block diagram of ultrasonic method

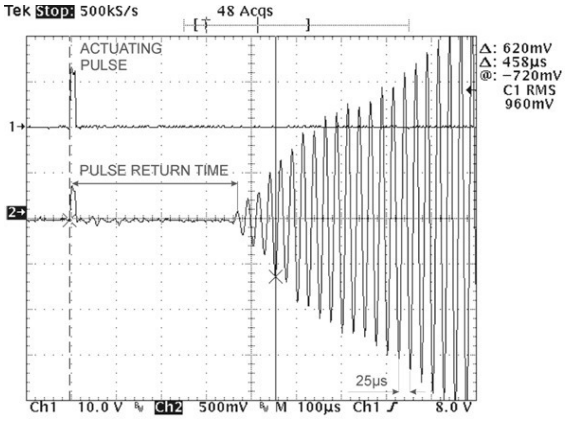

Fig. 10. Reflected pulse visualization

Pulse return time vs. volume dependence for all tested pulse recognition criterions was presented on Fig. 11. For great volumes membrane was masking receiving element and significantly decreasing of SNR (signal-to-noise ratio) was observed. It caused difficulties with proper pulse recognition and in consequence incorrect return time estimation. Maximal characteristic slope was obtained for quotient criterion of pulse identification. Relative measurement error was 8[%] for volumes less than 80[ml]. Driving pressure changes caused offset addition to output signal. This effect can be used to control air pressure in pneumatic chamber, however it is easy to remove by analog filtering.

Acoustic resonant properties of pneumatic chamber were exploited in *acoustic method* which idea was presented on Fig. 12. Membrane moving caused deformations of chamber's form and related changes of its resonant frequencies [10]. The stimulation signal was acoustic noise of 2…8[kHz] frequency.

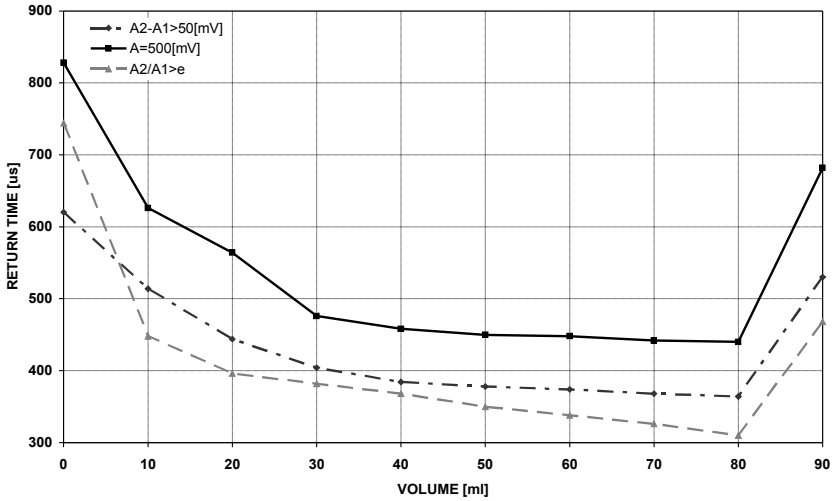

Fig. 11. Pulse return time characteristic for various criterion of pulse identification

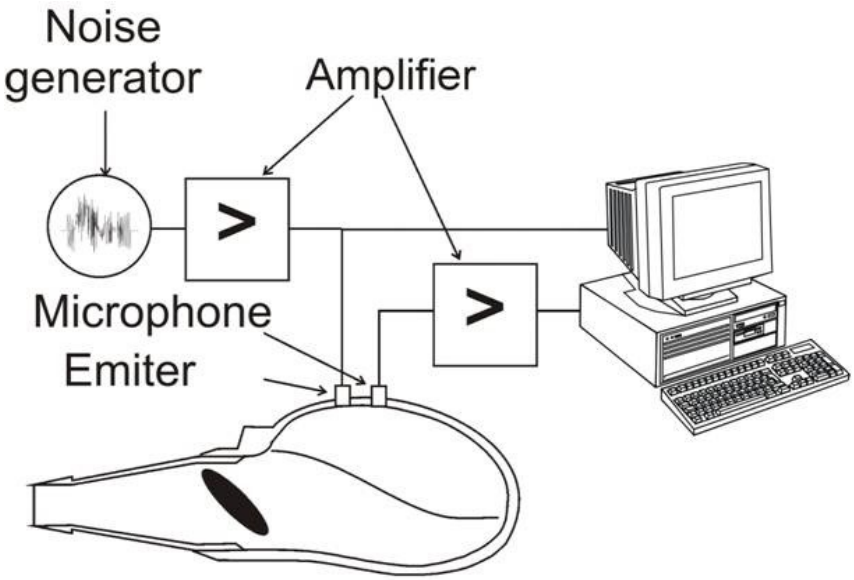

Fig. 12. Block diagram of acoustic method

Stimulation acoustic noise was transformed by chamber's resonant characteristic which caused amplification or suppression of its harmonic components. This modified signal was processed by Fourier transformation. Additional experiments revealed, that location of frequency pick within the range of 4…6,5[kHz] corresponds to volume changes in blood chamber. To unequivocally pick position estimation on frequency axis the polynomial approximation of spectrum was being computing and its maximum was being determining (Fig. 13).

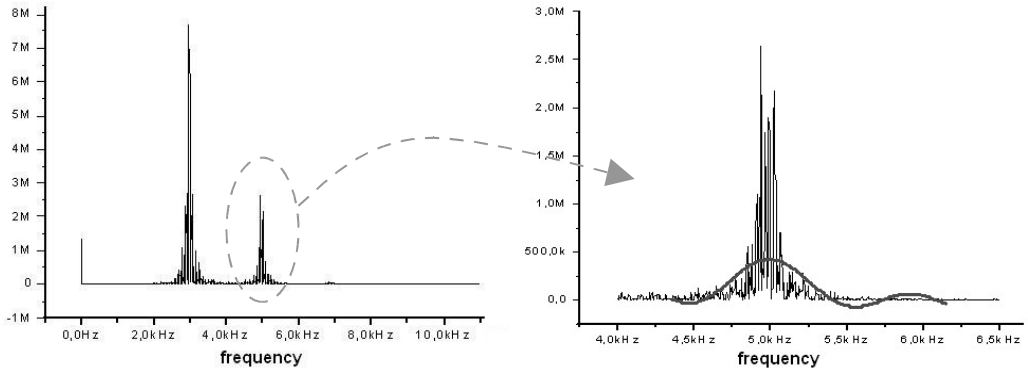

Fig. 13. Fourier and polynomial received acoustic signal analysis

Several orientation of acoustic emitter and receiver were tested. The best solution turned out elements' location at the opposite sites of pneumatic chamber, close to membrane fixing place, so as to detector could receive only acoustic waves reflected from membrane and intrinsic surface of chamber [11]. After polynomial approximation of spectral characteristics and their maximal values determination, the final method's transfer function was created (Fig. 14). Obtained curves for ejecting and filling phases are similar (correlation coefficient =0.9972). Divergences between characteristics for volumes between 35…45[ml] correspond to membrane movement through a mid-plane of pneumatic chamber and maximal crimping irregularity.

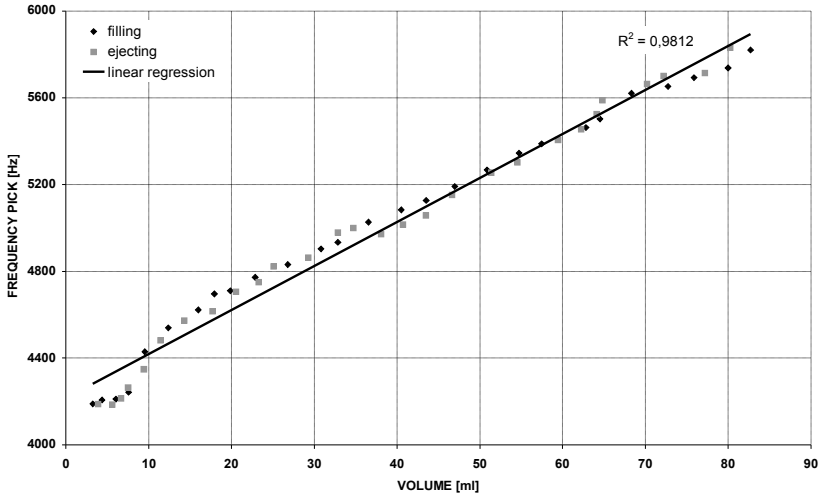

Fig. 14. Resonant frequency pick vs. blood chamber volume

The linear and 3rd order polynomial approximation of curves gave good correlation coefficients, 0.978 and 0.995 , respectively. Dynamic experiments were performed for various load pressures (80…300[mmHg]), pump's operation frequencies (10…100[BPM]) and driving pulse-duty factor (40…60[%]). Characteristics were repeatable with accuracy of 10[%].

5. RESULTS AND DISCUSSION

All investigated methods were compared (Table 1) in respect of their principal features related to usefulness in final, clinical device application.

For impedance method the best accuracy was obtained, but it depended on specific resistance of blood which is related to blood's and plasma's biochemical features. By that reason the method's calibration must be introduced (for example maximal filling or ejecting detection by pneumatic driving analysis or proximity sensor applying). The sensitivity value is sufficient for precise measurement of impedance changes by typical meters. Electronic device improvement would allow to decrease the stimulation current a few times. Significant disadvantages of impedance method are direct connection with blood and conductive valves' rings usage necessity.

For the sake of low precision and low noise immunity, capacitance method is useless in practical applications. Moreover, low value of electrical capacity changes within the operation range makes measurement process difficult and complicated.

The main advantages of ultrasonic and acoustic methods are excellent insulation and no need of pump's construction modifications at blood part. The measured value changes within the operation range is enough to gauge by typical methods and apparatuses. The limitation of ultrasonic's method useful range is emitter and receiver masking by membrane in full filling point and related low SNR of receiving signal. In acoustic method a problems with technical realization of small dimension emitter occurred. All tested devices were too large and their fixing on pneumatic chamber did not allow for application in finally VAD construction, especially implantable one. Moreover, a numerical calculations required large processor capacity and, in consequence, were narrowing of time method's efficiency to 10 measurements per second. A solution of this problem may be application of parallel analog filters set or FFT computation in dedicated signal processor.

Table 1. Measurement methods comparison

	ACCURACY	INSULATION	NOISE IMMUNITY	SENSITIVITY
IMPEDANCE	2…5[%]	R=150[Ω]	high	1.2[Ω/ml]
CAPACITANCE	4…20[%]	R=20[GΩ] C=27[pF]	low	0.8…3[pF/ml]
ULTRASOUND	8[%]	∞	high	1.6[μs/ml]
ACOUSTIC	10[%]	∞	medium	15[Hz/ml]

6. CONCLUSIONS

None of investigated methods are completely satisfying and suitable for direct application. Taking into consideration an accuracy, insulation and metrological properties, the most appropriate to develop is acoustic method. It is necessary to study of other physical phenomena's in order to analysis of their usability in application of clinical device.

ACKNOWLEDGEMENTS

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