artificial heart, ventricular assist device (VAD),
blood pressure measurement, separated pressure sensors

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

Information about blood pressure at the inflow and outflow connectors as well as inside a Ventricular Assist Device (VAD) supplemented with information about pressures inside the pneumatic part enables to adjust operational parameters of the VAD in the optimum manner. Practical implementation of a method that makes it possible to measure blood pressure at plurality of points is a really sophisticated task in terms of technical and technological issues. On one hand it is mandatory to assure appropriate metrological properties of the entire measurement path, on the other hand the measuring transducers must be reliably separated from blood. Internal surfaces of these VAD parts that come in direct contact with blood must be smooth and uniform; it is extremely essential due to a risk of blood coagulation on any unevenness of surfaces. The paper presets the solution for measurements of blood pressure inside the VAD, where the suggested solution meets the assumed metrological criteria as well as very stringent safety requirements.

1. INTRODUCTION

The basic parameters that are crucial for efficient operation of a Ventricular Assist Device (VAD) include pressure values across its connectors: the control connector (so called pneumatic part), the inflow and outflow connectors as well as inside the VAD between the valves (so called blood area). When pressure values are known, it is possible to take decisions about readjustment of the control parameters that govern operation of the VAD during the filling and ejection phases, both at start-up of the device and when flow resistance in the circulatory system is altered. Information about amplitude and shape of pressure waveforms across the aforementioned locations of the VAD makes it also possible to monitor error-free operation of the device itself, in particular its valves [3,4,5].

Negative pressure across the control connector enforces displacement of the VAD membrane that results in suction of blood via the inflow valve to the interior of the blood area. On the contrary, overpressure across the control connector makes the membrane to move backward and to ejects blood to the outflow connector via the outlet valve. Pressure distribution at monitored locations of the VAD subjects to cyclical variations during each phase of the VAD operation.

Measurement of pressure across the control connector is relatively easy. Here we have to measure pressure of air that is secured against direct contact with biological tissues. Therefore the measurements can be carried out with use of typical pressure transducers with the sensors that can be directly affected by the agent supplied at the pressure that is to be measured.

Measurement of blood pressure is much more sophisticated problem in terms of technical implementation. The key problem in that case is the need to guarantee very stringent separation of the transducer and blood. The need of separation is imposed by several issues. First and foremost, when the transducer were directly introduced into the blood flux it would be mandatory to assure biocompatibility of materials that are used for its manufacture. Although disposable transducers for measurements of blood pressure at the application points are already available, their operation time is limited to several dozen of hours [6]. It is much insufficient for patients with cardiac failure where their circulation systems need aid for many weeks and the VAD must operate reliably over all that time. The second substantial hazard to patients is the possibility of blood coagulation at locations where transducers are introduced, which lead to formation of blood clots. Such clots may develop at any point where blood flow through the VAD is stagnated, including areas with surface discontinuities. The sensor of the pressure transducer is a foreign body inside the VAD and is never perfectly aligned with internal surfaces of the VAD, which may lead to

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blood coagulation. Therefore it is necessary to find out a new approach to measure blood pressure of patients in order to avoid direct contacts between the measurement transducer and patient's blood and with homogeneity of all internal surfaces inside the VAD. The applied separations method must guarantee that metrological properties shall be kept at the sufficient level down the entire measurement path.

2. DESIGN OF A SEPARATED PRESSURE TRANSDUCER

2.1. METROLOGICAL ASSUMPTIONS AND SELECTION OF A MEASURING TRANSDUCER

The range of measurements, with consideration to monitoring of emergency conditions during the filling and ejection phases, was assumed within the range from -150 to +400 mmHg with the accuracy of ±5% and the bandwidth of 100 Hz. Design requirements assume that the system for pressure measurements shall be operated up to three years with no deterioration of physical and metrological properties.

Selection of a measuring transducer should be ruled by its essential parameters that shall have to be taken into account. These parameters include: range of measured pressure, conversion accuracy, dimension of the device and its long-term measurement accuracy.

With consideration to the foregoing requirements, the following two pressure–transducers were selected from the offer available from the market:

- NPC-100 – relative pressure transducer dedicated to invasive measurements of blood pressure offered by GE Sensing [6],
- FPBS-04A – absolute pressure transducer dedicated to industrial applications from FUJIKURA [2].

Figure 1 shows overall dimensions and appearance of pressure transducers selected for further investigations.

Due to different methods how parameters related to accuracy and thermal properties of the both transducers are specified it is really difficult to make a direct comparison between the two devices. Anyway, rough recalculation of parameters for these two devices proved that the NPC-100 demonstrates slightly better metrological properties.

The selected pressure transducers were subject to thorough investigations during the subsequent phase of the project in order to verify their parameters. Consequently, the FPBS-04A unit should be chosen as a target solution and incorporated into the VAD. For further investigations the NPC-100 transducer shall be used as a reference device, but without separation. The FPBS-04A is designed to measure absolute pressure, which enables to use it in a sealed enclosure at the location of installation. The NPC-100 measures relative pressure thus it must be supplied with atmospheric air as a reference pressure level. It is the feature that makes to reject the NPC-100 converter as unsuitable for installation inside VAD.

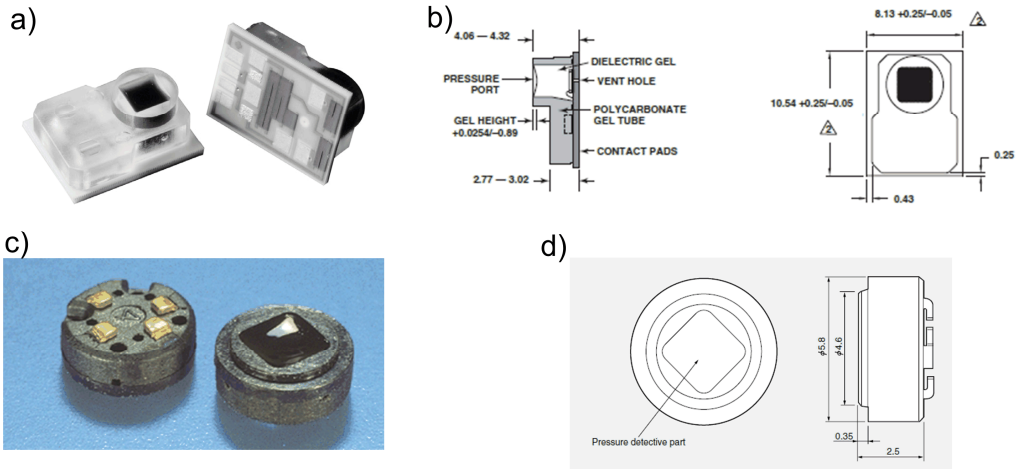

Fig. 1. Dimensions and external view of pressure converters: (a, b) – NPC-100; (c, d) – FPBS-04A (drawings from [2, 6]).

As about the operation principle, the both transducers are the piezoresistive bridges. Pressure of the medium is received via protective silicone gel that transfers the force to the sensor of the transducer (resistive components of the measuring bridge), which leads to voltage fluctuations across the bridge diagonal branch, where the voltage alteration is proportional to the pressure value.

Verification of measurement paths was carried out with use of an electronic measuring circuit shown in figure 2. The circuit is made up of a differential input amplifier and a signal pre-amplifier. Then the signal is subjected to low-pass filtration in order to eliminate interferences with higher frequencies and the active filter provides additional gain of the signal. The manufacturer of the FPBS-04A bridge recommends to supply the device from an electric current source – it is the electric supply circuit that has been designed for the test circuit. The power supply for the NPC-100 is supplied from a source of reference voltage featured with high accuracy and stability of output voltage.

With regard to the FPBS-04A transducer it is necessary to offset the measurement point of the bridge so that the zero voltage is obtained at the output of the measuring amplifier when atmospheric pressure is supplied to the input. However, the adopted solution has one drawback, namely the output voltage of the transducer varies in pace with fluctuations of atmospheric pressure. For an experimental solution such a shortcoming is acceptable as steady atmospheric pressure can be assumed for the entire duration of measurements and the measured readouts shall be deemed as relative values referenced to the pressure level recorded after having the measurement circuit switched over to measure atmospheric pressure. For a target solution, when such a switchover shall be no longer possible, a correlation circuit shall be provided to make the measurement results independent on variations of atmospheric pressure.

Input amplifiers of both the FPBS-04A and NPC-100 transducers were connected to analog inputs of the CAVASCREEN apparatus. For reference purposes an additional path for pressure measurements was constructed with use of the NPXG-2 transducer from PELTRON [7]. The measuring path that involved the NPXG-2 was connected, via a matching circuit, to a subsequent analog input of the CAVASCREEN apparatus that was responsible for A/D conversion (with the sampling frequency of 500 Hz) of input signals and further transmission of output data to a collaborating PC computer (Fig. 2). The waveforms of measured pressure were visualized and recorded with use of self-developed application software BioimpCO that run on the PC computer.

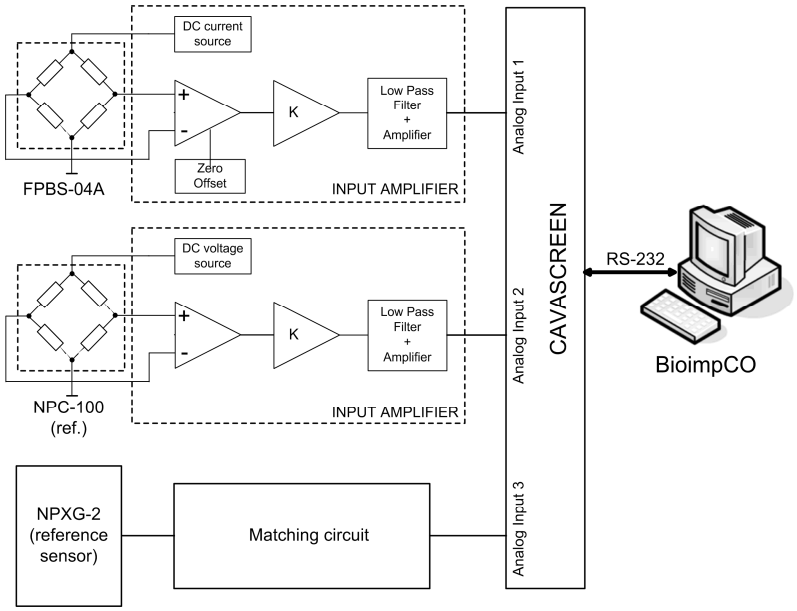

Fig. 2. Details for construction of the electronic module within the measurement path.

2.2. DESIGN OF THE MEMBRANE SEPARATOR

Transducers for measurement of blood pressure were provided with a membrane separator. It is a typical solution for industrial applications for pressure measurements of agents that should be kept away

from direct contacts with pressure sensors (e.g. caustic liquids, food industry, etc.) [8]. For this solution the membrane was made of biocompatible polyurethane (the same material that is used to make the VAD) and silicon oil was used as a separating liquid. Separating liquid fills the area between a pressure sensor and a membrane in order to transfer impact of pressure forces exerted by blood to the measuring transducer. Therefore non-compressibility of the filling liquid is crucial for accuracy of measurements.

At first, polyurethane membranes with various thickness values were made to investigate effect of the membrane thickness and diameter onto accuracy how well static and dynamic pressure is reproduced onto the output voltage. The completed investigations demonstrated applicability of polyurethane membranes, where the best metrological results were achieved for membranes with the thickness of 0.35 mm. These measurements served as the basis to assume dimensions of membranes for piezoresistive sensors of the FPBS-04A type and the attempt was made to make a measurement spout with use of the mould injection method. The internal diameter of the spout was assumed the same as the diameter of both the inflow and outflow connectors of the VAD as well as the thickness of spout walls. The applied mould injection method guarantees necessary smoothness of that membrane side that comes in contact with blood. For the applied technology the membrane thickness of 0.6 mm was achieved. Assembly details for installation of the pressure transducer on the measuring spout are explained in figure 3.

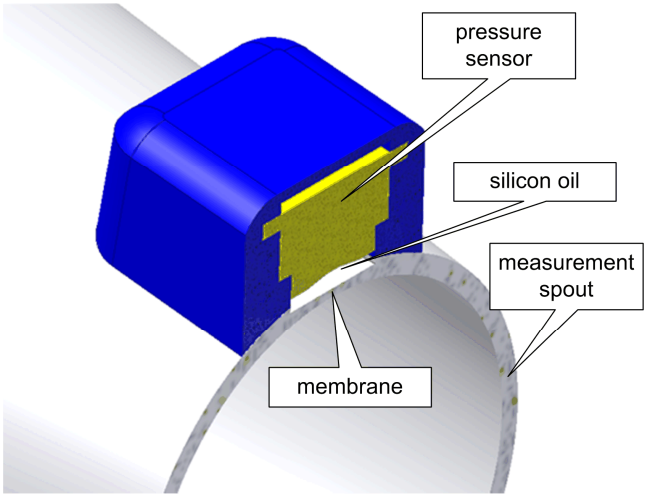

Fig. 3. Simplified diagram for assembly of a separated pressure transducer on a measurement spout.

Results for test of metrological accuracy for a membrane that was made with such non-uniform and large thickness revealed unacceptable hysteresis of the conversion characteristic curve for the entire measurement path. Moreover, the effect of so called zero drift was also observed due to extensible properties of the membrane. That effect is caused by some inertia of the membrane elasticity, i.e. it returns to its original shape and dimensions with a slight delay after the tensioning force causing distortions is removed. Failing test result for the membrane manufactured by means of the mould injection technology is not the premise to reject such a trustworthy method for making the membrane, however it needs expensive technological alterations and further investigations.

Finally, the membrane that separates the pressure transducer from blood circulation was made with use of the laminating technology, where the membrane with the thickness of 0.3 mm was deposited in openings with the diameters of 10 mm and designed as sockets for FPBS-04A transducer. After application of membranes manufactured with use of the new technology both static and dynamic tests demonstrated very good accuracy of pressure measurements that was only ±2.25 mmHg for the entire assumed range of measurements.

For target solutions the pressure transducers shall be installed in sockets of the VAD device, designed as its homogenous parts and provided with local reinforcements. Bottom of each socket shall be made as a thinned wall (membrane), whilst the exiting shapes of inner surfaces of the VAD shall be preserved. The measurement transducer installed inside the socket must be hermetically sealed in a way that enables introduction and appropriate insulation of wires connected to the measurement system.

3. RESULTS OF COMPLETED EXPERIMENTS

Metrological verification of the newly designed separated pressure transducer comprised determination of its characteristic conversion curve. For that purposes a measurement path was assembled incorporating the reference NPC-100 transducer, accurately graduated in mmHg, the measuring spout with the examined separated pressure transducer installed thereon, a pressure source and a pressure equalization tank. Components of the measuring system were mutually connected with use of high-pressure drains. During the experimental phase only water was used as a pressure transmission liquid. Arrangement of the measuring spout together with drains and the NPXG-2 transducer is shown in Figure 4a.

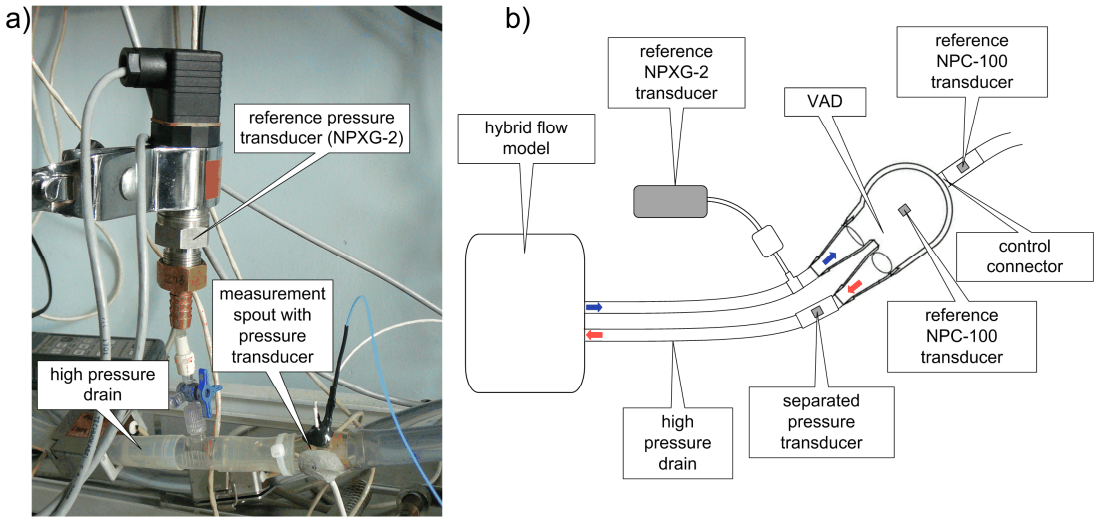

Fig. 4. (a) Measurement spout within the test system and (b) the test system with the hybrid flow model.

The pressure variations started from the standstill to the overpressure values and then reversed to negative pressures. Pressure was being changes in the monotonous manner in order to find out whether any hysteresis occurs for the conversion characteristic curve of the separated converter under test. The newly designed pressure transducer demonstrated nearly perfect linearity with only negligible hysteresis and met all the other, already imposed, metrological requirements (Fig. 5).

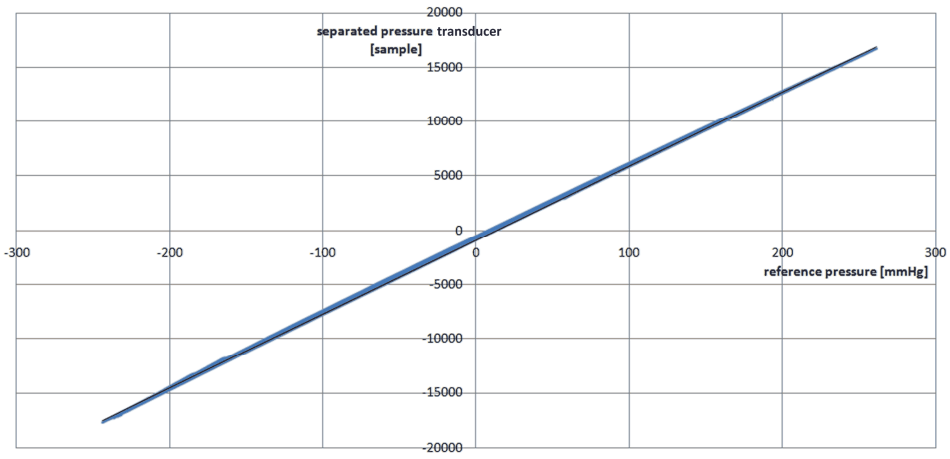

Fig. 5. Characteristic conversion curve of the separated pressure transducer under test.

The same measurement arrangement was used to carry out test of dynamic properties demonstrated by a pressure transducer, where pressure was supplied from a generator of variable hydraulic pressure. The recorded waveforms are shown in figure 6. The applied input function comprised rectangular pressure pulses (Fig. 6a) with the amplitude of 75 mmHg as well as pulses of physiological shape

(Fig. 6b) with the same amplitude of ca. 75 mmHg. For the both cases no distortion of recorded waveforms was observed nor was the bandwidth narrowed for the separated path of pressure measurements.

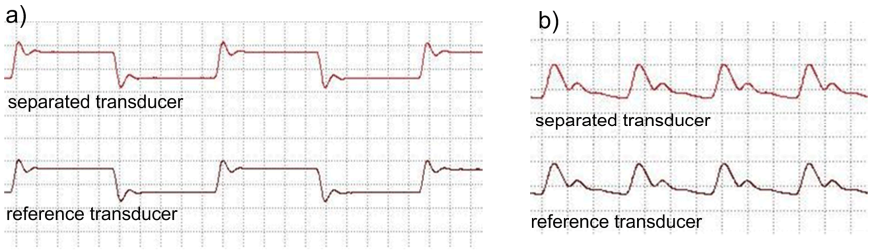

Fig. 6. Recorded dynamic responses to pressure waveforms (a) of rectangular pulses and (b) of pulses with physiological shapes (for the reference waveform 1 square cell = 50 mmHg).

The final experiment consisted in recording pressure waveforms within the measuring path that was made up of the VAD, the measuring spouse, reference pressure transducers and a workbench for hydrodynamic tests with a hybrid model of a blood circulation system (Fig. 4b). More information about the hybrid flow model can be found in [1]. The pressure transmission liquid was water (40% of the mixture) and glycerine (60% of the mixture), so viscosity of the mixture was very similar to the one of human blood. The pressure waveforms recorded at various locations of the hydraulic path and of the VAD are shown in figure 7. The pressure waveforms were obtained with the heart rate HR = 50bpm and the control pressure of 195/-70 mmHg. The waveforms in figure 7 are out of the amplitude scale to improve their readability, therefore no information about values of recorded pressure can be found from them. The separated pressure transducer introduced no distortions to the shapes of recorded waveforms and demonstrated sufficiently broad bandwidth (the waveform marked as P1 in figure 7).

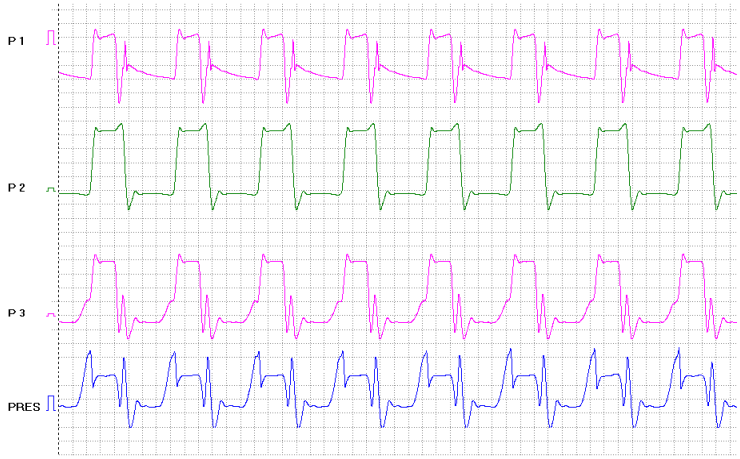

Fig. 7. Pressure waveforms recorded at various locations of the VAD during the experiment with the hybrid flow model (P1 – separated transducer – pressure in the outflow connector; P2 – reference NPC-100 transducer – control side; P3 – reference NPC-100 transducer – pressure inside the blood part of the VAD; PRES – reference NXPG-2 transducer –pressure in the inflow connector).

4. CONCLUSIONS

The paper outlines design details of a separated pressure transducer dedicated for measurements of blood pressure inside a Ventricular Assist Device (VAD). Due to direct contact of the measuring transducer with patient's blood it was necessary to separate the sensor of the transducer from the liquid under the pressure to be measured. To achieve biocompatibility, the separating membrane of the transducer was made of the same material as of the VAD. Unfortunately, manufacturing of a membrane with satisfying metrological properties and being a homogenous part of the VAD proved infeasible during a single mould injection process due to imperfectness of the available technology. Therefore the membrane was made with use of a lamination process, has uniform and much less thickness and

demonstrates desired properties, but is not a homogenous part of the entire VAD, which may entail a risk of blood coagulation on discontinuous surfaces. It is why further investigations are necessary to develop a technology that shall enable to make the measuring membrane as a homogenous component of the VAD.

The already completed initial investigations of metrological properties demonstrated by the suggested solution have proved that the initially assumed accuracy of measurements was achieved. The test with dynamic variations of the input pressure, including the physiological input function, also demonstrated very good dynamic properties of the proposed solution.

Further efforts shall be carried on with the aim to improve metrological properties demonstrated by the present solution of the blood pressure transducer and to tune its design and technological parameters. It is also necessary to miniaturize the electronic part of the measurement system. The scope of further investigations for the proposed solution includes the effect of temperature variations, electromagnetic compatibility, electric safety and mechanical strength of membranes.

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