PULSE DUPLICATOR SYSTEM FOR *IN VITRO* EVALUATION OF PROSTHETIC HEART VALVES – DATA ACQUISITION SYSTEM DEVELOPED IN LABVIEW

Ovandir Bazan
University of São Paulo – Polytechnic School, Mechanical Engineering Department. Av. Prof. Mello de Moraes, 2231, Cidade Universitária, São Paulo – SP, phone: +55 11 3091-9669.
ovandir.bazan@gmail.com

Jayme Pinto Ortiz
University of São Paulo – Polytechnic School, Mechanical Engineering Department. Av. Prof. Mello de Moraes, 2231, Cidade Universitária, São Paulo – SP, phone: +55 11 3091-5335.
jportiz@usp.br

Daniela Yassuda Yamashita
University of São Paulo – Polytechnic School, Mechanical Engineering Department. Av. Prof. Mello de Moraes, 2231, Cidade Universitária, São Paulo – SP, phone: +55 11 3091-9669.
daniela.yamashita@usp.br

Abstract. After the development of a new cardiac simulator at the Polytechnic School of the University of São Paulo for hydrodynamic testing of mitral and aortic prosthetic valves, an experimental validation is necessary in order to replicate the physiologic characteristics of the human cardiovascular system. This article describes some procedures and results obtained with the data acquisition system developed in LabVIEW. The instrumentation includes two pressure transducers, signal conditioning modules, an electromagnetic flowmeter and a multifunction data acquisition module. The data acquisition program was implemented in LabVIEW to perform 3 analog input signals and a counter. Also a supervisory control system was established via Modbus-RTU protocol. The pressure and flow signals were acquired to allow a comparison with the physiological ventricular states. According to the physiology of a normal healthy person in the rest condition, the experiments were conducted with the cardiac simulator running at a heart rate of 60 bpm (beats per minute), a ventricular stroke volume of 70 mL and a cardiac output of 4.2 L/min. In this work, focused on the preliminary validation testing, the test fluid did not mimic the blood properties: water at 37ºC was used. After the operation of the hydrodynamic workbench referred to the initial conditions, the waveforms were sampled at 1 kHz. Good results were achieved for all the three analog inputs, one pulse counter and the digital trigger output established via LabVIEW. Further, the supervisory control system allowed choosing properly three heart rates to the cardiac simulator. The pressure and flow results were compared with the human physiology. Although they were very close to that required by physiology, in order to replicate them properly, the cardiac simulator should be set to achieve most suitable systolic levels. Achieved this objective, scope of the next work, the pulse duplicator may be validated.

Keywords: data acquisition system, cardiac simulator, prosthetic heart valves, ventricular and aortic pressures, hydrodynamic testing.

1. INTRODUCTION

The hydrodynamic performance testing of prosthetic heart valves is carried out by pulse duplicator systems associated with non-invasive anemometry techniques, i.e., Particle Image Velocimetry (PIV) and Laser Doppler Anemometry (LDA). Pulse duplicator systems or cardiac simulators are able to replicate the human cardiovascular physiology (Chew *et al*., 2001; Grigioni *et al*., 2004; Milo *et al*., 2003; Legendre *et al*. 2008; VLI 2009; ANS 2010). After the development of a new left heart cardiac simulator at the Polytechnic School of the University of São Paulo (EPUSP) for hydrodynamic testing of mitral and aortic prosthetic valves, an experimental validation is necessary to demonstrate that the both pressure and flow responses obtained from the simulator mimic the cardiovascular physiology. This work describes some procedures and results obtained from preliminary testing to validation, as well as a brief comparison with the data provided in human physiology.

2. MATERIALS AND METHODS

The working principle of the EPUSP cardiac simulator, described previously (Bazan and Ortiz, 2011), is based on the human left ventricle operation. In this work, the experiments are based on the complete instrumentation incorporated in the hydrodynamic workbench and lead up to the last computational version of the data acquisition and control program.

2.1 Materials

The data acquisition and control program, main focus of this work, was implemented in LabVIEW 2011 (National Instruments Corp.). A Windows XP 32bit platform in the Intel Core i7-860 processor, 2.80 GHz and 2 GB RAM was used.

In this experiment, a double-leaflet aortic valve (St. Jude Medical, 27 mm diameter, part-number 270419) and a caged-ball mitral valve (Starr-Edwards, 27 mm diameter) were used in the EPUSP left heart simulator.

Incorporated to the pulse duplicator, the complete instrumentation includes two disposable pressure transducers (Braile Biomédica Ind. Com. e Repr. Ltda, model BXSN, range from -30 to 300 mmHg), two amplifier circuits (12 Vcc external powered), an electromagnetic flowmeter (Carolina Medical Electronics Inc., model 501), a temperature sensor and control system (Coelmatic Ltda, model TLZ11; HRR 100 to 240 Vca), a mini-heater (MrPet-Equipaquarium Ind. Com. Ltda, 50 W / 110 Vca) and a multifunction data acquisition (DAQ) module (National Instruments Corp., model NI USB-6212 BNC: 16-Bit, 400 kS/s). The same power supply was used to the two signal conditioning modules (Nodaji Electronics Ltd., 12 Vdc, 1 A). However, the servomotor encoder simulator works with an exclusive source (Nodaji Electronics Ltd., 5 Vdc, 2 A). It was also used a shielded cable (Topflex – PVC 22800) to avoid signal noise on transmitting data from the encoder.

To the electromagnetic flowmeter calibration, a steady flow hydrodynamic workbench was used. To the pressure transducers calibrating was used a platform for measurement and elevation height of water column.

2.2 Methods

The virtual instrument, implemented in LabVIEW 2011 (National Instruments Corp.), was designed to perform three analog input signals, a pulse counter and the supervisory control system of the cardiac simulator. Two analog input canals were established to the ventricular and aortic pressures. One analog input canal was dedicated to the flowmeter signals. The counter was implemented in order to inform the ventricular stroke volume during the cardiac cycle and the control system allows setting up several operating parameters of the simulator.

For the calibration of the two pressure transducers, a platform for measurement and elevation height of water column was established in accordance with the methodology set out by Bazan and Ortiz, 2012. For each pressure transducer, the calibration experiment consisted of verifying voltages induced at each height of water column set out (on every 20 mm) to permit obtaining a curve that relates these variables. The calibration procedure was also established for some negative water column heights, precisely to avoid the full-scale phenomenon in the data acquisition of possible low pressure values (as the pressures during the diastole phase of the cardiac cycle).

Similarly, for the flowmeter calibrating experiment, a steady flow workbench was designed and constructed to provide some prescribed steady flow rates. The calibration consisted in checking the induced voltages in these flow rates and obtaining a curve, considered in the LabVIEW program.

Although the calibration procedure of both pressure transducers and the flowmeter were obtained to static values of pressure and flow, due to the sensitivity of the instrumentation and the high data acquisition rate compared to the cardiac frequencies on the pulse duplicator, the responses are consistent for rapid variations of pressure and flow.

In this work, the ventricular states of a normal healthy person at rest condition were considered as imposed parameters to the cardiac simulator operation. The virtual instrument should record and display the responses of the left ventricle duplicator to the pulse values of pressure and flow, and therefore assist the workbench validation (scope of the next work).

The counter was established to recognize the movement of the ventricle model, actuated by a servomotor (Bazan and Ortiz, 2011). The counter recognizes the pulses generated by the servomotor encoder simulator and relates them to the workbench positioning in the cardiac cycle. It is expected, as soon as possible (following the workbench validation experiment), to perform hydrodynamic measurements for characterizing speed and tension profiles in mitral prostheses, through PIV and LDA systems (Marassi *et al*., 2004; Yoganathan, Zhaoming and Jones, 2004). Because that, the pulse counter was associated with a digital trigger output in order to the synchrony establishment between the cardiac simulator and the noninvasive anemometry systems. Once each pulse corresponds to a ventricular stroke volume, it is possible to know the residual ventricular volume by counting pulses during the cardiac cycle.

The supervisory control system was designed via serial communication between the servomotor driver and the computer. This allows that the cardiac simulator can be controlled by a wide variety of parameters such as velocity, acceleration, displacement and waiting times. The serial communication platform used was the *Modbus-RTU* protocol, also through the program developed in LabVIEW.

In this cardiac simulator design, the temperature controller was not designed to be part of the data acquisition system. The temperature controller was programmed to work with 36.5±0.5ºC. The heater and temperature sensor were located into the reservoir, just before the atrium model. Although the temperature control system is not part of data acquisition, the device was put in parallel running, as a previous experiment validation. In this experiment, focused on the preliminary validation testing, the test fluid (which passes through the prostheses) did not mimic the blood properties: water at 37ºC was used.

3. RESULTS AND DISCUSSION

This section shows some procedures and results obtained for the data acquisition and control system implemented in LabVIEW, as well as the preliminary validation testing of the hydrodynamic workbench at heart rate of 60 bpm based on the regarding physiological literature.

3.1 Initial procedure

The voltage range of the multifunction data acquisition (DAQ) module (NI USB-6212 BNC) was observed at -10 to 10 Vdc and 5 Vdc to encoder simulator. Each pressure transducer and amplifier was provided together like a couple, requiring convenient 12Vdc supply. Later, it was noticed that the digital trigger output through the same DAQ module was only possible for a 5Vdc TTL.

Besides voltage range, also other factors that affect the digitalized signal quality were considered: mode, resolution, gain, sample rate, precision and signal noise. Regarding the mode, it was decided to work with a single point measuring system. Thus, the three analog inputs were grounded at the same GND terminal (NI, 2009). The encoder and trigger output required digital GND terminals. Concerning resolution, the multifunction data acquisition module has 16 bits. The gain was established from the signal amplifiers and unit conversion from mmH_2O to mmHg, in the virtual instrument. The sampling rate was 1 kHz. The accuracy and signal noise were considered inherent to the grounding type. For best results, one low-pass filter was designed in the program considering that the noise frequencies were above the pressure and flow signals.

The calibration procedures for the pressure transducers and the flowmeter are explained in the following section.

3.2 Pressure transducers and flowmeter calibration procedures

In the first version of the LabVIEW program, some measurements were made with the uncalibrated pressure transducers. The pressure variations were simulated using a syringe attached to each transducer. This preliminary version of data acquisition for two analog signals allowed verifying induced voltages at each 20 mm of water column, as described in the methodology. The following Fig. 1 shows the calibration curves of the two pressure transducers.
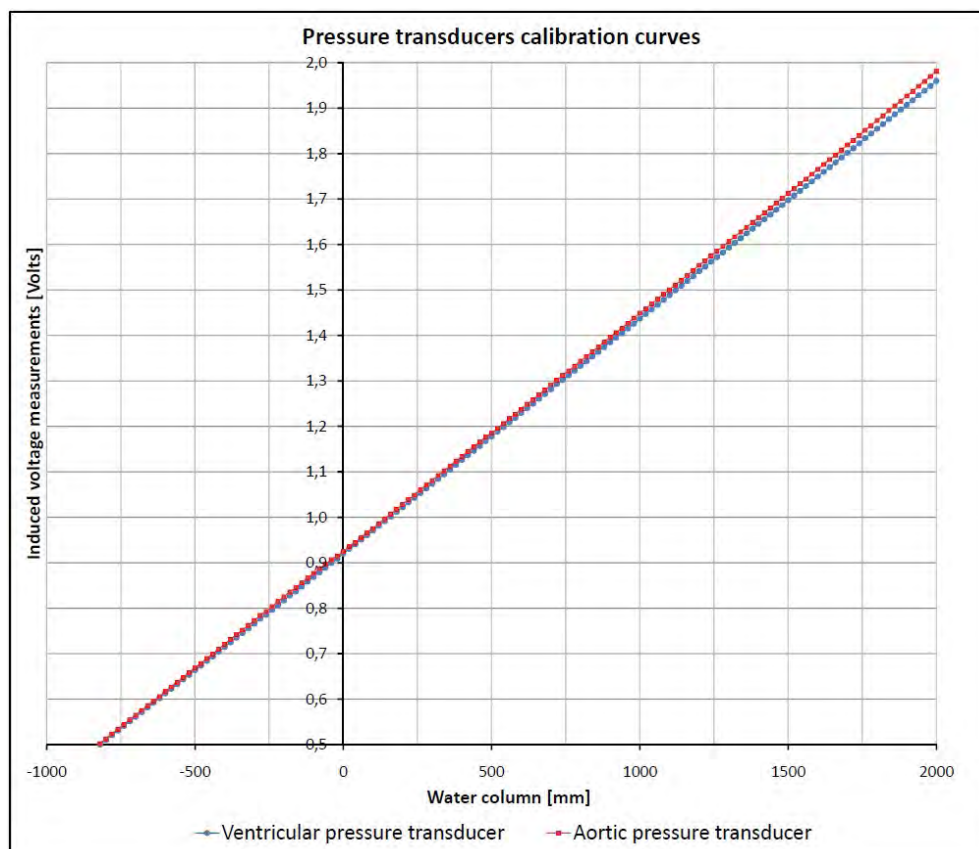

Figure 1. Calibration curves of pressure transducers

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Then, was performed the electromagnetic flowmeter calibration. As stated in the methodology, it was necessary to use a steady flow workbench (a closed-loop hydraulic circuit) with some known flow ranges (CME, 1989). The verification of the induced voltages for each established steady flow range allowed correlating these variables. Figure 2 shows the calibration curve obtained for the flowmeter, based on three flow ranges allowed in the current steady flow workbench. Each steady flow induces a voltage which was read from the NI USB-6212 BNC module.
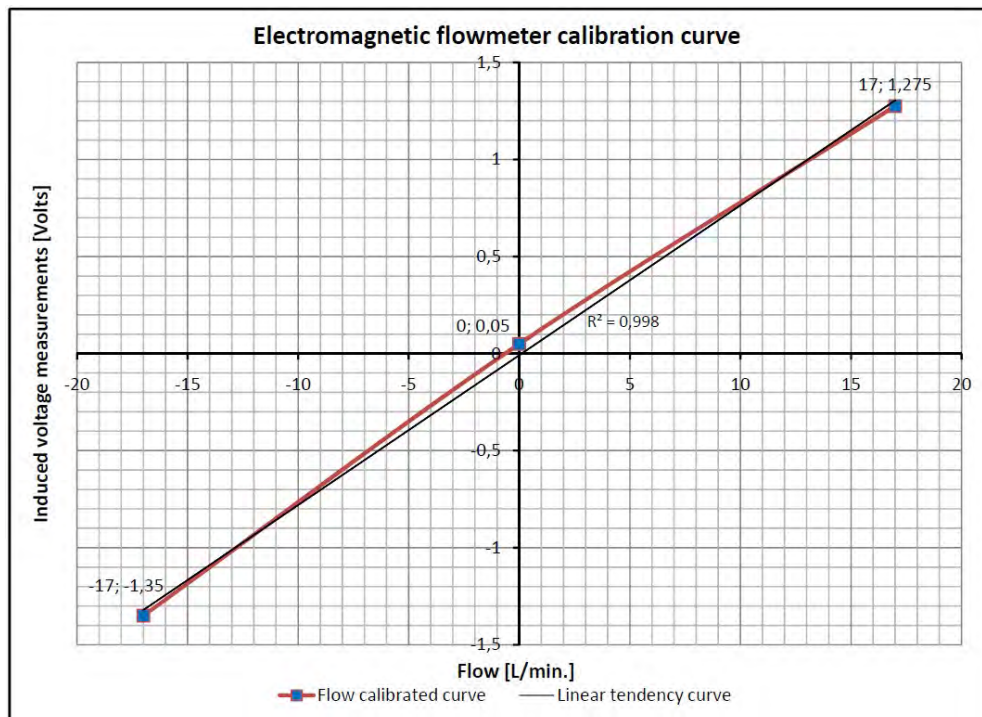

Figure 2. Flowmeter calibration curve

The cardiac cycle phase change (systole and diastole) usually induces the regurgitation phenomenon (Chew *et al.*, 2001; Grigioni *et al.*, 2004; Yoganathan, Zhaoming and Jones, 2004). Regurgitation results from reverse flow during valve closure and leakage (Yoganathan, Zhaoming and Jones, 2004). To register this phenomenon, it is necessary validate the flowmeter calibrating curve including negative flows. In the flowmeter calibration procedure (CME, 1989), it is possible due a change on flowprobe's assembly, changing inlet and outlet connections in the hidraulic circuit, corresponding to the same flow in the opposite direction.

The three resulting calibration curves, i.e., the both ventricular and aortic pressure transducers (Fig. 1) and the flowmeter (Fig. 2), were added to the LabVIEW program analog input structures.

The full program can be seen in the next section.

3.3 Data Acquisition and Supervisory Control Program

Regarding the pressure canals, after the initial version of the program used for the calibration of the pressure transducers, it was also implemented in LabVIEW the unit conversion (originally in Volts) to mmH_2O and then to mmHg. Also was established a way to display the two pressure waves and to save the data acquisition in the external file. After entering the two pressure calibration curves on the program, pressure ports were strategically allocated in the pulse duplicator system: at the upper part of the left ventricle model (where the mitral and aortic prostheses are located) and at the middle region of the aortic root model. Also the pressure transducers were physically referenced at the same plane respecting the pressure ports in the cardiac simulator (representing common reference for the manometric heights). In the pressure analog inputs structure was used a low-pass filter (Butterworth) of 20 Hz first order to minimize the effects of signal noise.

This procedure was similar to the flow signal. The validation curve obtained was inserted in the program and a low-pass filter (Butterworth of 10 Hz), associated with a median filter of 100 elements, were arranged to reduce the signal noise. The flowmeter probe was allocated to detecting flow after the aortic valve, from the aortic root model, during the diastole phase of the cardiac cycle.

As stated in the methodology, also a pulse counter input was established through the DAQ module. The pulse counter recognizes the TTL waves generated by the servomotor encoder simulator and referring them to the position of the servomotor and model of the ventricle. For this positioning, a digital trigger output (TTL, 5 Vdc) was associated for the synchronized actuation of the noninvasive anemometry systems. The pulse counter allows knowing the ventricular stroke volume during the cardiac cycle, because each pulse corresponds to a ventricular positioning and proper ejection volume. Also it was possible to construct a PxV diagram (pressure *versus* volume graph) from the combined analysis of both ventricular pressure and ventricular residual volume data (Fonseca *et al*. 2011).

All these three analog input signals and the pulse counter was implemented through the same device: the multifunction data acquisition module (NI USB-6212 BNC, 16-Bit, 400 kS/s).

Figure 3 shows the compressed block diagram (with *sub* virtual instruments) implemented in LabVIEW, containing the data acquisition system described.
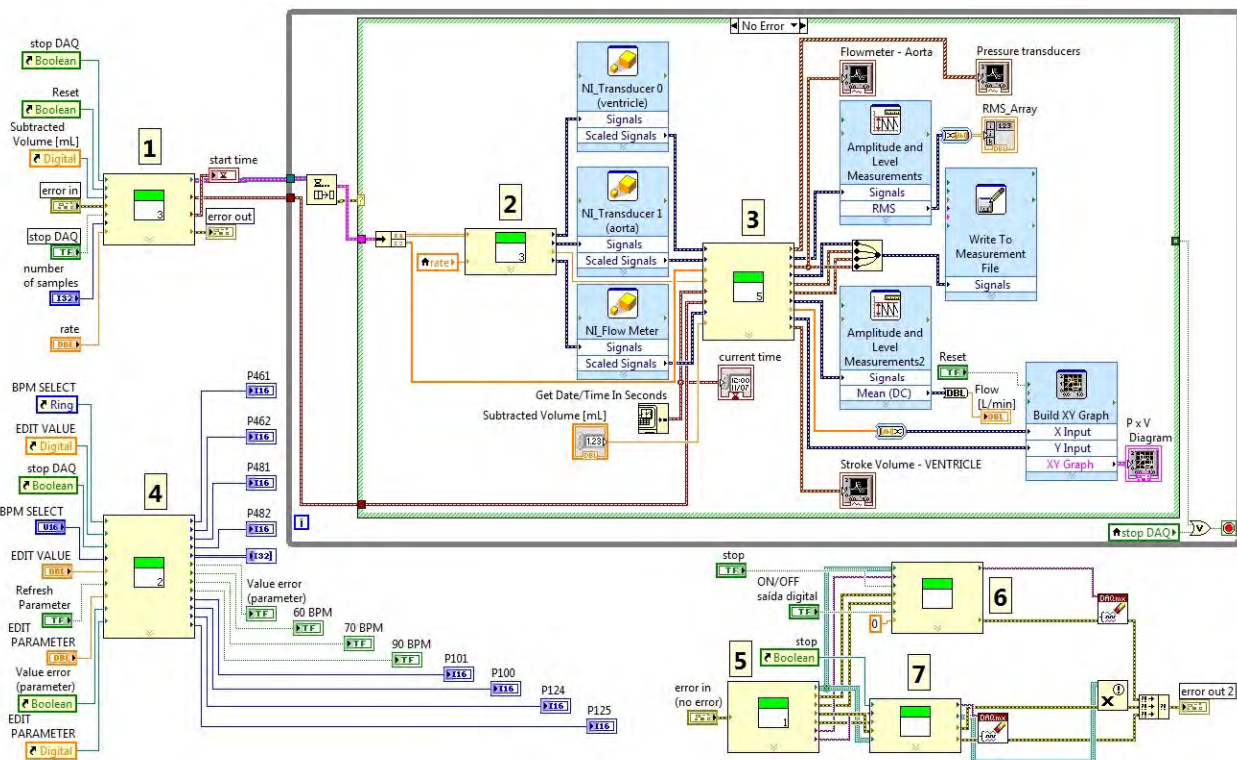

Figure 3. Compressed Block Diagram (LabVIEW 2011) implemented to perform three analog input signals, a pulse counter, the digital trigger output and the supervisory control system.

Figure 3 shows the full program, organized in three main structures: data acquisition (Fig. 3, n. 1 to 3), the digital trigger output (Fig. 3, n. 5 to 7) and the supervisory control system (Fig. 3, n. 4).

The three analog input signals and pulse counter acquisitions are configured (Fig. 3, n. 1) and passed into a main structure loop, containing filtering (Fig. 3, n. 2), calibration curves (pressure transducers and the flowmeter), signal manipulation (Fig. 3, n. 3), and also presenting waveforms. The pulse counter was established to inform the ventricular stroke volume and to show the pressure *versus* ventricular residual volume plots (PxV graph) along the cardiac cycle.

Although the supervisory control and trigger blocks are independent of the data acquisition structure, it was designed at the same program in order to compile them simultaneously, ensuring the synchronization between data acquisition and other tasks. Thus, the part of the program referred to the data acquisition is processed in parallel respect the supervisory control and the trigger structures.

On the supervisory control system block, the servomotor parameters were set up by serial communication. It was used the *Modbus-RTU* protocol (free universal). The parameters are manipulated by some variables, which can be seen in Fig. 3, n. 4, in blue. Basically, they were designed to perform the ventricular actuation independently of each heart rate. Currently, the program can command three heart rates: 60, 70 and 90 bpm.

To accomplish the pulse generation (digital trigger output, in Fig. 3, n. 7) it was also necessary a further pulse counter from encoder (Fig. 3, n. 6) and proper generation tasks for communication with the multifunction data acquisition module (Fig. 3, n. 5).

3.4 Data Acquisition Results from the Pulse Duplicator System

According to the physiology of a normal healthy person in the rest condition, the experiments were conducted with the cardiac simulator running at a heart rate of 60 bpm (beats per minute), a ventricular stroke volume of 70 mL (Guyton and Hall, 2006) and a cardiac output of 4.2 L/min. The servomotor driver, the two power supplies, the electromagnetic flowmeter, the temperature sensor and control system, the mini-heater and the DAQ module were turned on. Figure 4 shows the complete configuration to the data acquisition on the pulse duplicator system.
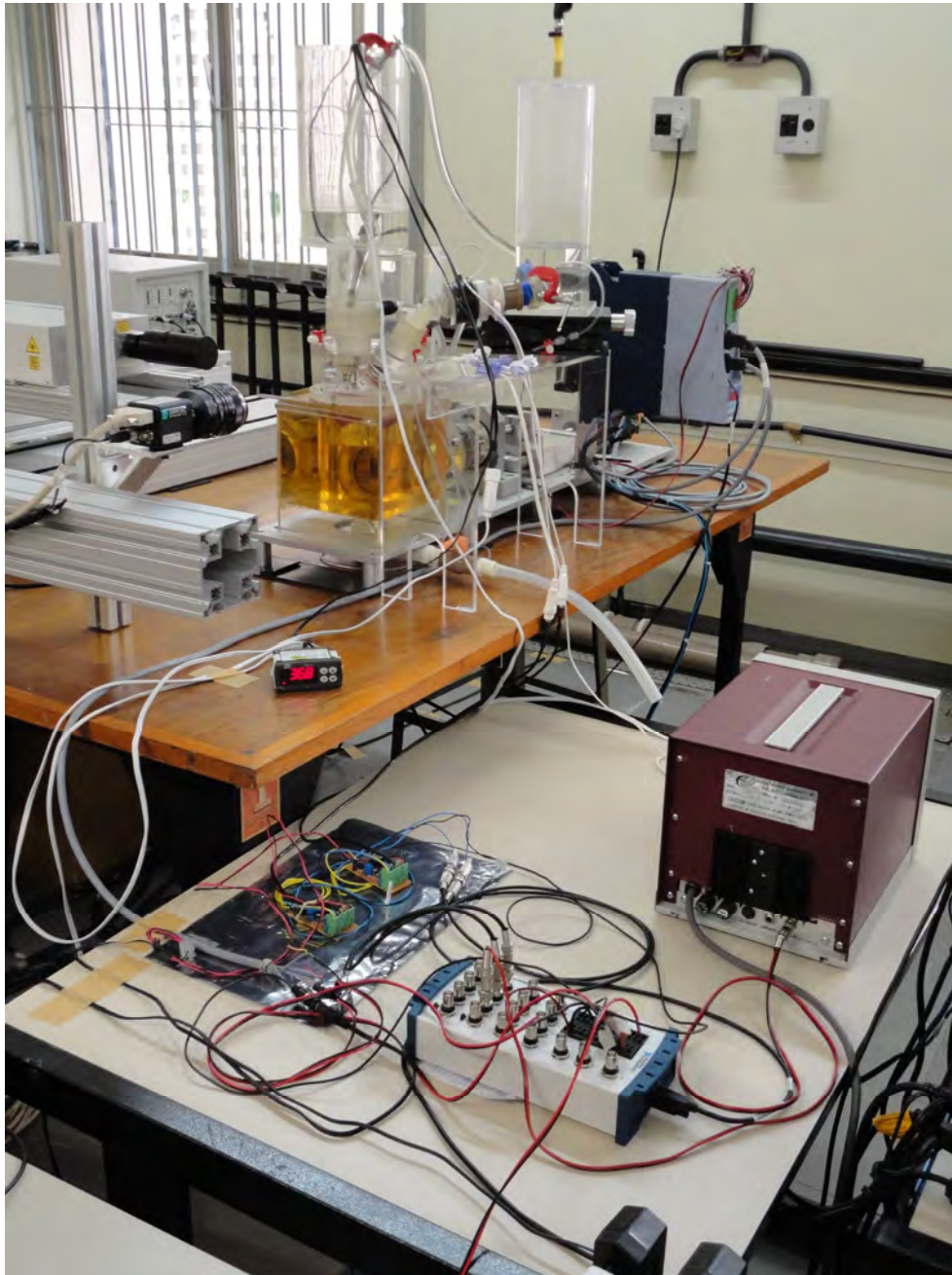

Figure 4. Complete configuration ready to start the data acquisition experiment
Above: pulse duplicator system and peripheral instrumentation
Below (from left to right): two pressure transducer amplifiers,
DAQ module with the plugged cables and the flowmeter

With the heater controller showing 37ºC, the program in LabVIEW was set up to work at 1 kHz (*sample rate*) and 1000 samples (*number of samples*). The supervisory control system was configured to work with 60 bpm, sending parameters to the servomotor driver via *Modbus-RTU* protocol.

The maximum volume of the ventricle was adjusted to 235 mL. This induces a ventricular volume range between 165 and 230 mL during the cardiac cycle, once the ventricular stroke volume was adjusted to 70 mL.

With the left heart simulator operating under these conditions, it was possible to get the data acquisition of ventricular and aortic pressures, flow and ventricular stroke volume, through the computational program in LabVIEW. Figure 5 presents the front panel (LabVIEW 2011) with the ventricular and aortic pressures, the aortic flow, the PxV diagram and the ventricular stroke volume obtained.
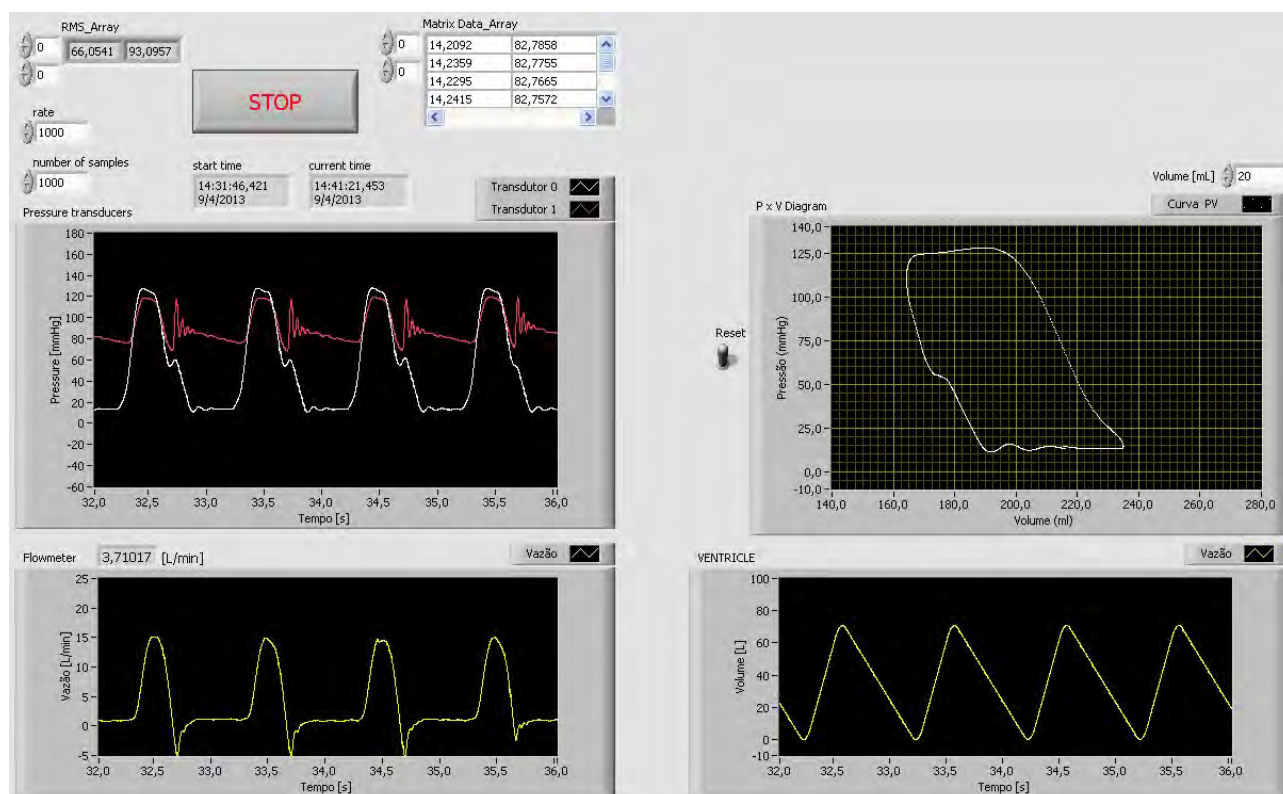

Figure 5. Front panel (LabVIEW) with ventricular and aortic pressures, aortic flow,
PxV diagram and ventricular stroke volume obtained

With the pulse duplicator system running at 60 bpm, inside the models of ventricle and aortic root, the maximum values of systolic pressures acquired were, respectively, 128 mmHg and 118 mmHg (according to Fig. 5, combined white and red waveforms). The range of pressure values acquired were, 118 mmHg and 78 mmHg into the aortic root model (systemic pressure, in red) and 128 mmHg and 13 mmHg inside the ventricle (in white). From the flowmeter signals (see Fig. 5, yellow waveform, on the left), the mean value of flow was 3,7 L/min. Peak values of flow (15 L/min.) were detected to the ventricular ejection phase (systole), through the aortic root model, where the flowmeter probe was allocated. Furthermore, it is possible to verify the ventricular volume range from 0 to 70 mL (cf. Fig. 5, yellow curve, on the right) and the PxV diagram obtained (according to Fig. 5, above, on the right).

The discussion of the data acquisition program is seen in the next section. All these results acquired of both flow and pressure values obtained for the simulator operating at 60 bpm were compared with the physiological ventricular states literature and are discussed below.

3.5 Discussion

The proper operation of the final version of the program, main objective of this work, had several preliminary steps. Initially, each data acquisition task (pressure, flow and encoder pulses) was done by a specific program. Verified the proper operation of each partial program, it was added to work jointly with the previous program. Finally, the digital trigger and supervisory control system were also added.

For all instruments used jointly, it can be said that the transmitting data from the encoder is impossible by a non-shielded cable. For them, the multifunction data acquisition module (NI USB-6212 BNC) could not count properly due to signal noise and interference. Meanwhile, once used the shielded cable (Topflex - 22800 PVC) to avoid signal noise on transmitting data from the encoder, good operability can be found for all applications.

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As expected, the calibration of both pressure transducers and the flowmeter has shown that the voltage and considered unit indexes are linearly correlated. Nevertheless, in the flowmeter, had been found higher signal noise. Precisely for this reason, to the flow signals were placed a low-pass filter configured at lower frequencies (10 Hz), and a median filter of 100 elements (10-fold reduction compared to the number of samples).

For the DAQ module, the digital trigger output is only possible for 5 Vdc. This restriction does not affect the synchrony function with the LDA and PIV systems that will be used because they work with this same voltage on the digital inputs. The trigger responses from the program were found via digital oscilloscope.

Regarding the program developed in LabView, good results have been found for different values of number of samples and acquisition rate. However, this work shows only the configuration to work at 1 kHz (sample rate) and 1000 samples (number of samples). Although only waveforms at 60 bpm have been shown, good results were also found for all predetermined heart rate designed (60, 70, and 90 bpm).

The supervisory control project via *Modbus-RTU*, inserted in the same program, also had several preliminary steps, followed by testing. Improvements could include other frequency ranges for the cardiac simulator, as well as a full closed-loop control system.

Finally, concerning preliminary testing of validation, the acquired data obtained from the EPUSP left heart simulator (according to Fig. 5) have been compared with the human physiological literature (Guyton and Hall, 2006). Although the results were very close to that required by physiology, in order to replicate them properly, the cardiac simulator should be set to achieve most suitable systolic levels: 120 mmHg to the both ventricular and systemic pressures. The volume dosage of both air and water in the compliances, as well an adjustment of the peripheral and characteristic resistances, arranged along the hydraulic circuit of the pulse duplicator, will allow achieve these pressure levels. The expected average flow rate was 4.2 L/min, since the hydrodynamic workbench was adjusted to replicate a ventricular stroke volume of 70 mL/min for each cardiac pulse (with a heart rate of 60 bpm). As shown in Fig. 5, flow was lower (3.7 L/min.). This indicates that there was mitral regurgitation in the ventricular ejection phase (systole). In fact, it was already expected for the mitral prosthesis (caged-ball valve) used here. Clinically these prostheses fell into disuse some years ago and its production was discontinued. Anyway, the electromagnetic flowmeter had rapid and appropriate response, considering that waveforms were recorded exactly during the ventricular ejection period. Furthermore, the values obtained for the regurgitant volumes (reverse flow) were suitable considering those in the fluid mechanics of heart valves literature, i.e., approximately 5 ml/beat (Yoganathan, Zhaoming and Jones, 2004).

Based on the complete data acquisition performed in this work, it is still possible to say that the cardiac simulator has good repeatability for the pressure and flow parameters. This should be demonstrated in the next work, regarding the pulse duplicator validation.

4. CONCLUSION

In conclusion, the data acquisition and supervisory control system developed in LabVIEW has shown good results for three analog inputs, one pulse counter and a digital trigger output, further conciliated to the control via *Modbus-RTU* protocol, allowing three heart frequencies to the cardiac simulator. The pressure and flow responses obtained in the data acquisition proved the good repeatability for the pulse duplicator. To mimic the human left heart properly, adjustments in some workbench devices (particularly the both peripheral and characteristic resistances and the compliance chambers) should be made. It is also necessary to verify the ventricular states for some cardiac frequencies. Achieved this objective, scope of the next work, the pulse duplicator may be validated.

5. ACKNOWLEDGEMENTS

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