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Design of a Hydrodynamic Performance Bench for Ventricular Assist Devices

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Abstract. This work presents the design of a hydrodynamic performance bench (HPB) of Ventricular Assist Devices (VADs) for evaluations of developed prototypes. VADs are used for the treatment of patients with Congestive Heart Failure (CHF), either as a bridge to recovery, for transplantation or as destination therapy. HPB is required for the performance evaluation of VADs that are under development in Brazil. The performance evaluation of a VAD considers the rotation speed [rpm], flow rate [L/min], pressure [mmHg] and power [W]. The project consists in choosing an actuator and transducers from HPB, and developing the mechanical components, supervisory control and modules. The HPB mechanical components were designed in SolidWorks® following rapid prototyping and built by additive manufacturing. The HPB supervisory program was developed in graphic language through the Labview® program and implemented in a development and application platform with data acquisition system. The manipulated variable of the supervisory system is the motor speed [rpm] acting via an Escon 50/4 EC-S power controller on the BLDC EC45 N339281 motor. The controlled variable is the "VAD flow" [L/min] provided by an HT-110 flow transducer. A particle image velocimetry (PIV) module was developed for flow analysis. All process data are stored in spreadsheets for later consultation. HPB could assist in a satisfactory way in the analysis of the developed VADs prototypes, demonstrating the technical success of the project.

Keywords. *Test and Evaluation bench, Ventricular Assist Devices (VADs), Control and automation and Bioengineering.*

Introduction. In Brazil, cardiovascular diseases kill about 350,000 Brazilians every year, being the largest cause of death in the country [1]. The incidence of cardiovascular diseases in humans has been increasing over the years, the most serious disease being chronic heart failure (CHF) [2-4]. Heart transplantation is considered the standard treatment in patients with advanced and refractory CHF, however, it is a procedure limited by the number of available donors and possible contraindications that make it unfeasible [5]. Given the difficulty in obtaining organs for heart transplants and the current need of patients, the development of devices for pumping blood

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in mechanical circulatory assistance has highlighted importance in the area of bioengineering, among them the study of developments of Ventricular Assist Devices (VAD) [6,7], whose function is to replace the mechanical work of the left and/or right side of the heart, ensuring the cardiac performance necessary for the patient's life while providing favorable conditions for recovery (BTR), for transplantation (BTT) or even the complete replacement of the heart by the device (DT) [8].

To build efficient and non-harmful VADs for the implanted patient, it is necessary that VAD designs and prototypes undergo a series of tests and validations on test benches [9-11]. A VAD test bench aims to produce unambiguous results that can serve for [12]: (i) Comparison with the state of the art; (ii) Validation with current standards of manufacture and use; (iii) System response to disturbance and noise; and (iv) Finding any problems and confirming their resolution.

The main VAD “in vitro” assays discussed in the literature as a reliable process to predict VAD success are [13-15] the hydrodynamic performance assay and the haemolysis assay.

In the test of hydrodynamic performance, it is mainly evaluated the capacity of the VAD to support vital conditions for the patient by maintaining 5 L/min of flow with approximately 110 mmHg of differential pressure between the inlet and outlet cannulas. In addition, in this test a map of values of the rotation speed and electric current of the pump motor is generated with the respective flow and differential pressure generated, which serve as a catalog of the safe operation of the device [15,16]. In this test the pumped fluid can be blood or an analogous fluid with similar viscosity (usually a solution of water and a 1/3 of glycerin) [13].

Another application of the value map obtained for the VAD in the hydrodynamic performance test is to use it as a reference for estimating physiological values without the use of sensors by means of look-up table (LUT) 2D technique. The LUT is determined by a hydrodynamics test for operating range. There is a correspondence between rotation and current with flow and differential pressure and this correlation is mapped by means of a three-dimensional surface. This technique was patented in Brazil.

In the haemolysis assay, the possibility that pumping by the VAD causes trauma to the red cells is assessed, releasing haemoglobin into the plasma as a by-product of the breakdown of red blood cells, the higher the rate of haemolysis the more traumatic is the flow of assisted pumping into the blood [17].

The measurement of this trauma is done using the plasma free hemoglobin (PFH). The normalized index of hemolysis (NIH) should remain between 0.004 g/100 l and 0.02 g/100 l for VADs (Nose 1998) [9]. The normalized hemolysis test, according to the standards (ASTM F1841) and (ASTM F1830), should last 6 hours, in a closed circuit, at a flow rate of 5 L/min at a pressure of 100 mmHg, conditions achieved in the implantable centrifugal pump at approximately 2800 rpm [17].

An assay with estimation of the results of a haemolysis assay is performed by Particle Image Velocimetry (PIV) which is a benchtop experiment for studying fluid dynamics that has greater detail than sensors and devices that measure pressure and volume [18]. The analysis is performed on the bench using a rapid-fire camera and a laser pulsed at a uniform rate. The region illuminated by the laser is captured by the camera shot and the image is processed in computer programs. In the images, it is possible to detect particles that serve as positioning of the flow vectors [18].

In 2013, the Thematic Research project supported by the Sao Paulo State Research Support Foundation (FAPESP) was initiated with the following objectives (FAPESP 2018): application of advanced engineering methods for the construction of high-performance devices, as well as systems to evaluate them from a clinical, experimental and technological point of view. This initiative was continued and enabled a series of relevant research in the line of VAD [14, 15,19-28].

Among the VADs under development in the project is highlighted the Implantable Centrifugal Blood Pump (ICBP) [28,30] and the Apic-Aortic Blood Pump (AABP) [15]. The main system for evaluation of VADs under development in the project is the Cardiovascular System Simulator (HCS) built at the Institute Dante Pazzanese of Cardiology (IDPC), which is a tool that allows the acquisition of data from the physical connection of a VAD to the simulated cardiovascular system, under physiological conditions or with alteration of some of the cardiovascular parameters.

Due to the FAPESP Thematic Research Project (2013/24434-0), there is a technical cooperation agreement between IDPC and the Federal Institute of São Paulo, Sao Paulo campus (IFSP SPO) [31]. It is highlighted from this partnership the development of new VAD control techniques [32,34-39], biomaterials [32,40-43] and new centrifugal VAD [17,44,45].

Aiming to perform the evaluations of the VADs developed at IFSP and as a validation option to the VADs of the FAPESP Thematic Research Project (2013/24434-0) inserted in the scope of the IDPC-IFSP SPO cooperation agreement, this work aims to present the design of a Hydrodynamic Performance Bench (HPB).

Actuator. The first object of study was the choice of an actuator for the HPB. The choice conditions followed the following technical criteria a:

- Commercial catalogue motor, because there is immediate availability, easy maintenance, specified operating parameters and robust actuation guarantee by the manufacturer; and
- Brushless direct current motor (BLDC; type of motor generally used in VAD) with physical characteristics like those of an implantable motor, because the performance values of the VAD prototype will be close to the values of an "in vitro" test where the actuator is encapsulated in the VAD (step closer to a commercial product) and the control strategies applied in VAD control in HPB can be evaluated, and with that, easily shaped and modified to be the most suitable for this application.

Mechanical construction. The second object of study was the design of the mechanical components of the HPB. The conditions of choice followed the following technical criteria:

- Rapid prototyping, the components were designed to be easily prototyped by affordable 3D printers of the Fused Deposition Modeling (FDM) type, drastically reducing raw material expenses and machining processes;
- Modularity, the components were designed to be assembling able and replaceable with new design updates both from VADs and the HPB itself; and
- External electromagnetic coupling, to preserve modularity, the drive between HPB and VADs will be performed without physical contact or direct field, but indirectly through the axial magnetic field produced by a disc with 3 pairs of neodymium N42 magnets (the quantity and type of magnets can be freely changed) fixed on the actuator rotational axis, which interacts electromagnetically with the VAD rotor magnets.

The components will be developed following the criteria using the Computer Aided Design (CAD) program SolidWorks® (Dassault Systèmes, Vélizy-Villacoublay, France). The HPB components designed in 3D CAD were built on the C2 3D printer (3D Applications, Guarulhos, Brazil) by additive manufacturing in FDM using polylactic acid (PLA) filaments.

Transducers. The third object of study was the design of the transduction system of interesting physical phenomena for VAD performance evaluation. A sensor is a device whose output can be quantified and changes with one or more physical phenomena. This output information can be used for process monitoring and control. A transducer is a device that converts one form of energy into another. Measuring the physical variables associated with the resulting energy form allows estimation of the physical variables associated with the input energy [46]. The main variables of this project are the flow rate and the differential pressure of the VAD.

In HPB, the VAD flow will be obtained by means of the HT-110 flow transducer (Transonic Systems, Ithaca, USA). For this, it is only necessary to make the electrical connection between the analog outputs of the HT-110 flow meter with reference of the read in probe flow with the supervisory control system of the HPB. The working range of the HT110 flow transducer is 1 to 100 L/min.

In HPB, the differential pressure of the VAD will be obtained by means of two TruWave pressure transducers (Edwards Lifesciences, Irvine, USA), one located in the inflow cannula and the other in the outflow cannula of the VAD (differential pressure=pressure of the inflow cannula-pressure of the outflow cannula). To do so, it is necessary to perform an engineering adaptation of the TruWave pressure transducer, since this device is originally designed to be used together with a multiparametric hospital console (not available for use in HPB).

The adaptations for use of the TruWave pressure transducer are:

- Amplify the signal, the pressure transducer has a resolution of 5.0 μ V/V/mmHg ± 1%, this value must be amplified to a standard working range in electronics (0 to 5 V) however within the interesting range for VAD analysis (0 to 300 mmHg). For this, the INA122 signal amplifier (Texas Instruments, Dallas, USA) will be used;
- Straight line equation, with the established range of interest, it is necessary to identify the mathematical relationship of the pressure straight line in input measurement unit (mmH2 O) by the desired measurement unit (mmHg); and
- Processing, with the straight-line equation established, it remains to acquire the input signal and process it through an algorithm containing the straight-line equation and filters to reduce noise associated with signal amplification (physical filter with capacitors and digital filter with average and Kalman).

Data acquisition and system control. The fourth object of study was the design of the HPB control and data acquisition system. For the satisfactory acquisition and storage of HPB results, a supervisory program with the following technical criteria is required:

- Human Machine Interface (HMI): for the operation of HPB as a test bench it is necessary that the process data are intuitively inserted, aiming the overall integrity of the tests;
- Stable control of the actuators: the HPB actuator drive is performed by means of an electronic controller (driver), for this to occur it is necessary that the transmission and acquisition standards are respected, in a homogeneous flow, avoiding oscillations in the system that compromise the operation and the analyzed data;
- Acquisition of data from sensors: HPB aims to collect key data to perform the performance evaluation of VAD. This is possible through signal transducers such as current (A), voltage (V), flow (L/min) and pressure differential (mmHg). Moreover, the control of the HPB is exerted on a complex variable (non-Newtonian fluid in acceleration) subject to momentum, disturbances and noises throughout the test, so a closed-loop actuation system with feedback of the controlled variable is mandatory; and
- Data storage: the validation of the performance of the VAD will be performed later with the use of value map and relations of the properties, so it is necessary that the data throughout a series test or long duration are faithfully stored in spreadsheets of later simple handling.

The HPB supervisory program was developed in graphic language through the Labview® program (2015, National Instruments, Austin, USA) and implemented in a development and application platform (PXIe-8840, National Instruments, Austin, USA) with the signal acquisition/activation and amplification modules (NI PXIe-6361 and PXI4022, National Instruments, Austin, USA).

The manipulated variable of the supervisory system is the motor speed (rpm) acting via an Escon 50/4 EC-S power controller (Maxon Motor, Sachseln, Switzerland) on the BLDC EC45 N339281 motor (Maxon Motor, Sachseln, Switzerland).

The controlled variable is the “VAD flow” (L/min) provided by an HT-110 flow transducer. The process data are: pressure differential (mmHg) supplied by a TruWave pressure transducer, current (mA) and voltage (V) supplied by the power controller itself, and the speed of the motor feedback (rpm) also supplied by the power controller.

For accuracy and confidence in maintaining the chosen speed throughout the tests, a controller with closed-loop stability algorithm must be implemented [47].

The advantage of using a Proportional-Integral (PI) control as a stability filter is its easy digital implementation and to its versatility, providing satisfactory results even in the presence of noise and disturbances [37].

Using the Ziegler-Nichols Threshold Sensitivity Method to adjust the Proportional- Integral-Derivative parameters [37] a PI control algorithm was created for the current and speed actuator, this allows system stability even with significant variations in process characteristics. For the highest efficiency in controlling the HPB actuation, the chosen motors were parameterized and calibrated for the power controller in the Escon Studio® program (Maxon Motor, Sachseln, Switzerland).

To evaluate the HPB supervisory control system, two tests were performed: Test 1 to evaluate the transmission and data acquisition of the supervisory control system; and Test 2 to evaluate the stability of the chosen motor speed maintenance.

Test 1 was performed to evaluate if the motor speed values chosen in the HPB supervisory control system are being effectively reproduced in the motor (reading by means of a tachometer) and if the process data is being processed and faithfully reproduced in the HMI screen.

This test was performed with the BLDC 475521 motor (Maxon Motor, Sachseln, Switzerland) as actuator, because although this motor does not have the physical dimensions indicated for encapsulation inside a centrifugal VAD, it has a wide working range (0 to 62000 rpm) enabling more comprehensive control tests.

Test 2 was performed to evaluate the stable maintenance of the motor speed in the presence of pumping resistance variations caused by the physiological system. For this the speed was adjusted increasing with 1000 rpm step (1000 - 4000 rpm) and decreasing with 1000 rpm step (4000 - 1000 rpm) in the HPB supervisory control system and the response of the motor without load and with load was examined by means of contact tachometer. Further, the response of the control in the presence of disturbance (inducing a load on the motor) and noise (proximity to electromagnetic devices) will be checked. This test was performed using the definitive actuator of HPB.

Validation applications. In 2018, FAPESP made a public call in Brazil for the development of paracorporeal radial centrifugal VAD within a fostering program called PITCHGOV. PITCHGOV is a program of the Government of Sao Paulo/Brazil aiming to solve challenges of public management through the connection between public power and startups. At HPB, the performance curve of the paediatric VAD developed for this project was raised [48].

Santos developed an Intelligent Local System (ILS) for VAD, which is an intelligent embedded system with integration of real-time data processing, reconfigurable architecture and with communication protocols based on the concepts of Healthcare 4.0. To legitimize the feasibility of ILS as a VAD controller solution, the physiological multi objective control (MOPC) technique for VAD proposed by Leao T, et al. [34] was chosen as a proof of concept. For the correct operation of the MPOC technique of VAD is required the formation of the LUTs (value maps) of the estimators for each specific motor of the VAD to be controlled. In HPB, the map of values of the VAD prototype to be controlled by the MOPC embedded in the ILS was raised [39].

Particle image velocimetry module. The fifth object of study was the design of a VAD flow test module by particle image velocimetry (PIV). This test is effective to study the turbulence and stagnation areas of the VAD. In this module, the supervisory control system processed the image of the pump rotor rotation speed (transparent housing model of the analysed VAD) captured by a fast pulse camera coupled with a high intesity laser (540 nm, 5000 mW) and the data acquisition [17]. The fast pulse camera is a Hero 8 Black (GoPro, San Mateo, USA).

The laser serves to give fluorescence to the particles captured with the camera for mapping the velocity field, and to do this, it must be triggered like a strobe to give the effect of "freezing" the movement of the rotor during pumping. The fluid used is water with reflective particles of lamellar Polyvinyl Chloride (PVC) or silver with a particle size between 0.1 and 0.5 mm.

The PIVLab toolbox works with image pre-processing, evaluation and post processing. For post-processing the user determines the acceptable speed limits, this value can also be determined automatically by comparing each speed component with upper and lower limits, using the average speed and the standard deviation of the speed. Noise reduction in the data is done by mediated filtering, considering a penalized least squares method.

Results. The motor chosen for HPB actuation for meeting the two criteria defined in the actuator choice was the BLDC EC45 N339281 motor (Maxon Motor, Sachseln, Switzerland). Figure 1 shows the BLDC EC45 motor N339281.

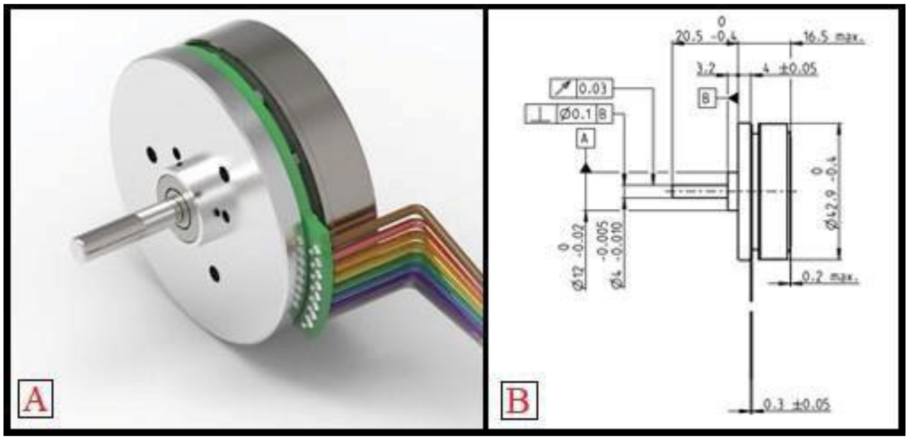


Figure 1. HPB actuator: A) Representation of the Maxon BLDC EC45 N339281 motor; and B) its physical dimensions.

The components developed to meet the three criteria defined in the mechanical construction of HPB are presented in Figure 2. With all the mechanical components of HPB available, the verifications of the fixation between the components and the mechanical interaction of transmission and absence of contact were performed, as well as the resistance of the material to wear and fatigue in working regime. Figure 3 shows the assembly of the HPB components built on a 3D printer.

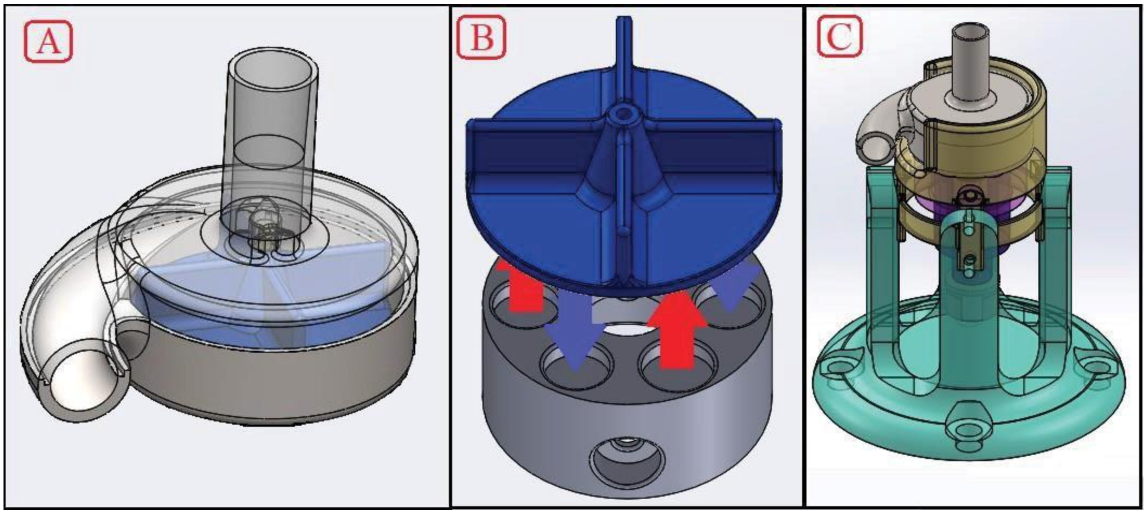


Figure 2. Components modeled in 3D CAD: A) The VAD under development at IFSP SPO; B) The drive by magnetic coupling between the HPB rotor and the VAD; and C) Assembly in 3D CAD of the mechanical components of HPB.

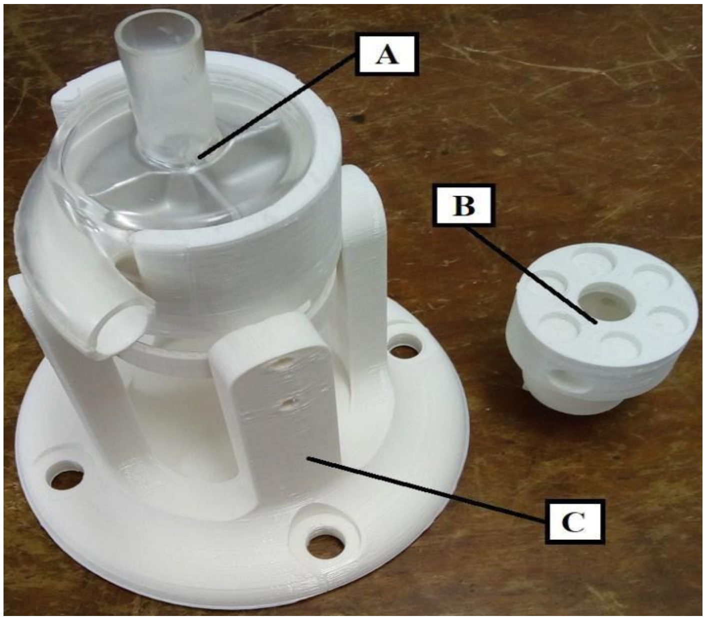


Figure 3. The assembly of the HPB mechanical components built on the 3D printer: A) VAD prototype at IFSP; B) The magnetic coupling between the HPB mechanical components and the VAD rotor; and C) HPB assembly with VAD docked.

Figure 4 shows the electrical schematic for the adaptation of the TruWave pressure transducer for use in the HPB.

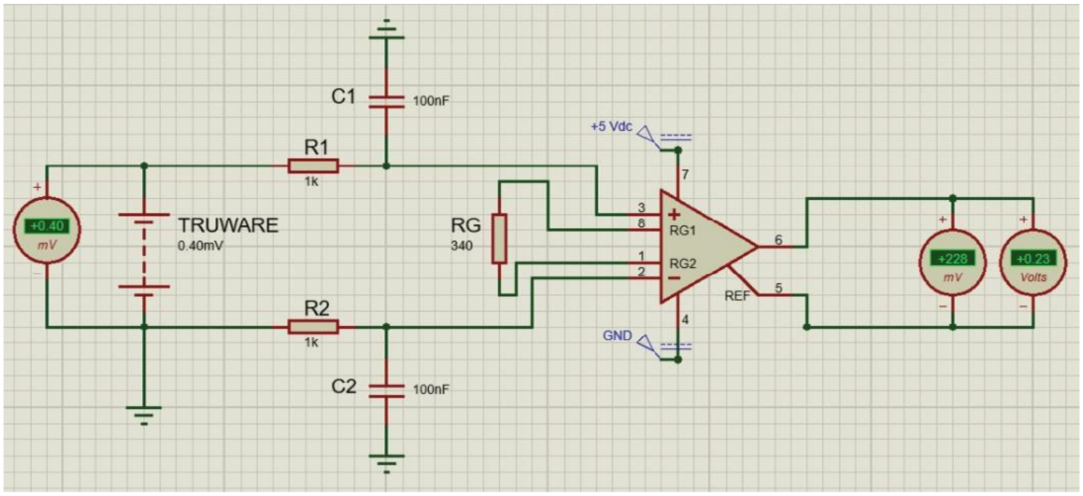


Figure 4. Electrical diagram for amplification of the pressure transducer signal.

Figure 5 shows the tests for the experimental survey of the straight-line equation with the mathematical correlations of pressure transduction. Figure 6 shows the straight-line equation for use of the TruWave pressure transducer as a pressure variable within the HPB supervisory control system.

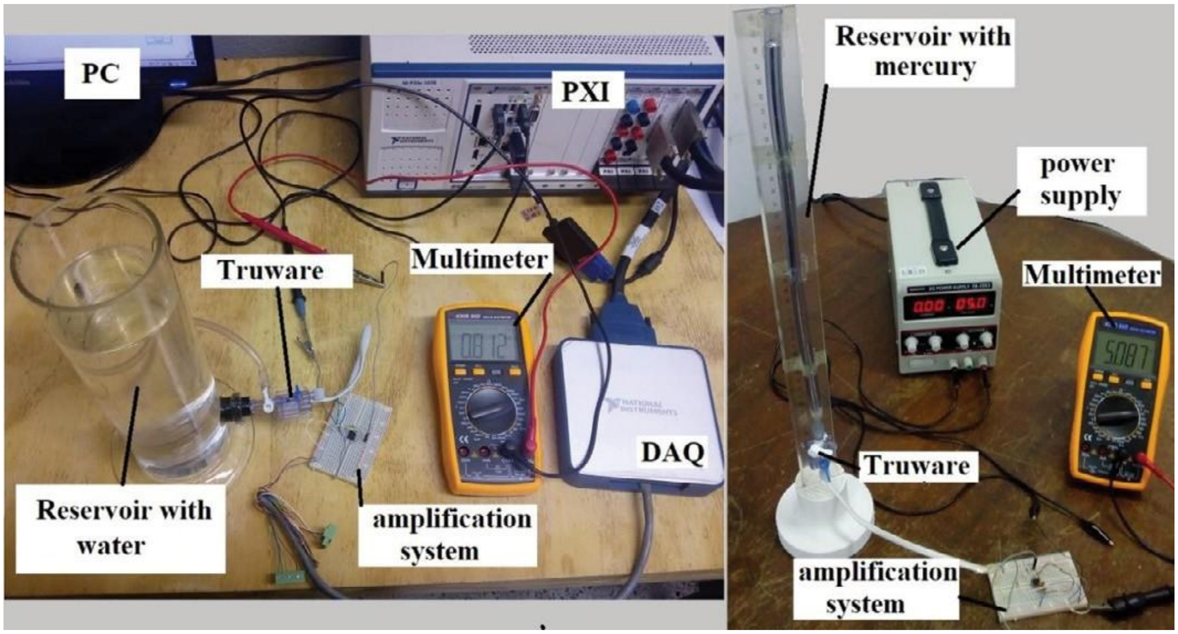


Figure 5. Tests for determining the straight-line equation of the pressure transducer.

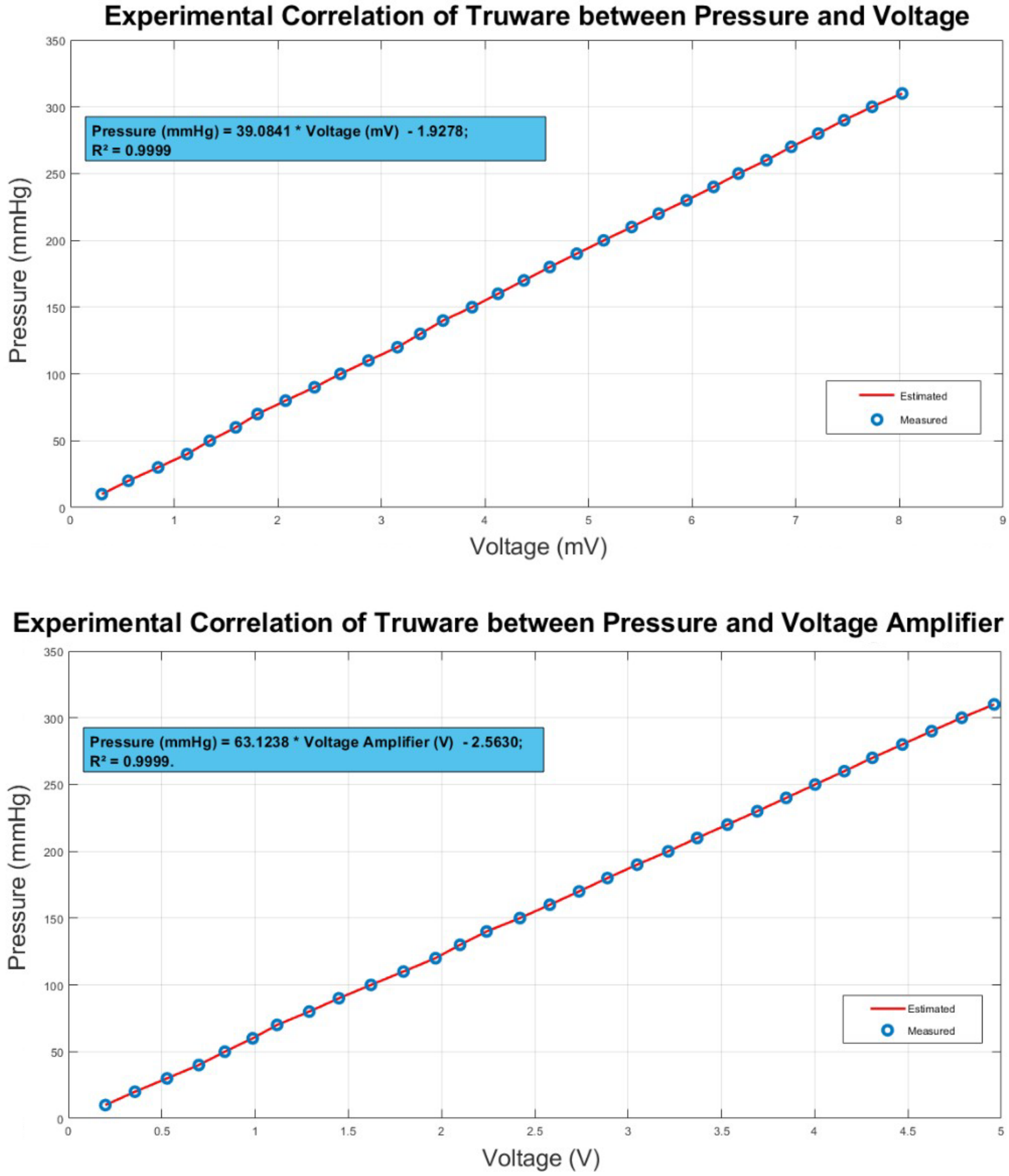
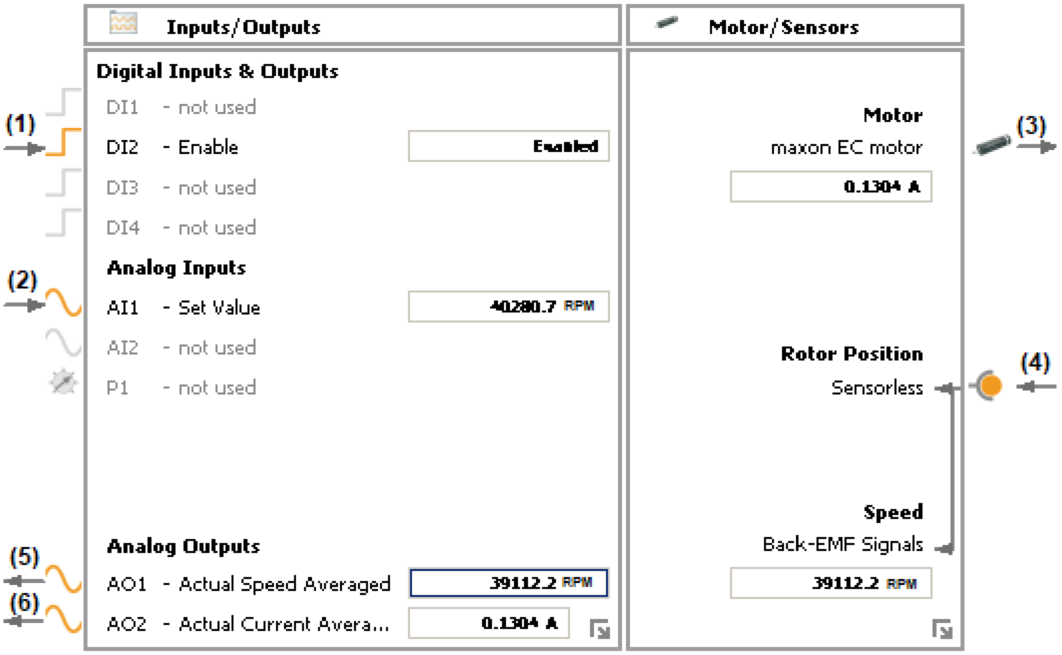


Figure 6. Equation of the correlation straight-line of the pressure transducer.

Figure 7 shows the reconfiguration of the Escon 50/4 EC-S power controller ports aiming the integration to HPB's supervisory and Figure 8 shows the calibration of the motors inside the Escon Studio® virtual environment, where speed levels were adjusted in the program (blue colour) and the motor tried to follow (red colour) without overloading the expected current levels, from this relation the optimized gains of the Proportional-Integral (PI) control were identified.



Inputs/Outputs

Digital Inputs & Outputs
DI1 - not used
DI2 - Enable: Enabled
DI3 - not used
DI4 - not used

Analog Inputs
AI1 - Set Value: 40280.7 RPM
AI2 - not used
P1 - not used

Analog Outputs
AO1 - Actual Speed Averaged: 39112.2 RPM
AO2 - Actual Current Avera...: 0.1304 A

Motor/Sensors

Motor
maxon EC motor: 0.1304 A

Rotor Position
Sensorless

Speed
Back-EMF Signals: 39112.2 RPM

Figure 7. Schematic of the power controller ports: 1) On/Off digital button; 2) Speed variation by voltage analog input [0 – 4 V]; 3) Motor driving; 4) Estimated reading (sensorless) of the motor speed; 5) Analog output indicating the motor speed variation [0 - 4 V]; and 6) Analog output indicating the motor current variation [0 - 4 V].

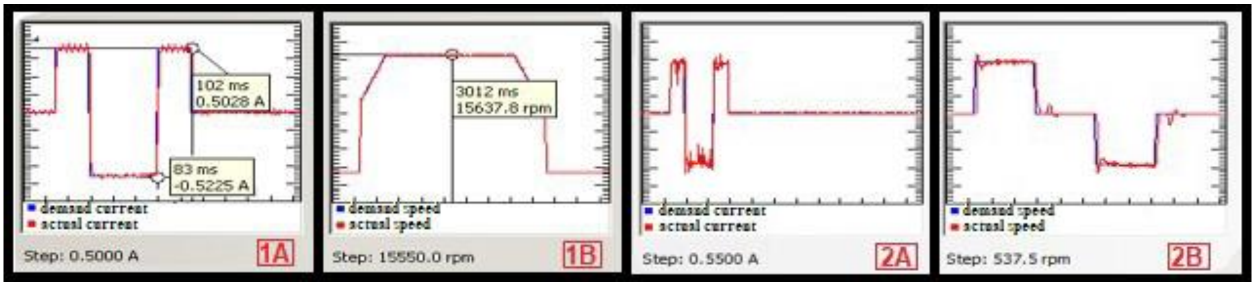


Figure 8. PI control calibration for BLDC 475521 and N339281 motors: 1A) Current demand on BLDC 475521 motor; 1B) Speed demand on BLDC 475521 motor; 2A) Current demand on BLDC EC45 N339281 motor; and 2B) Speed demand on BLDC EC45 N339281 motor.

In the supervisory control system of HPB (Figure 9) the motor speed is adjusted and sampled the real-time value of the process data of the motor feedback speed (rpm), Motor current (mA), VAD flow rate (L/min) and Differential pressure between the inlet and outlet cannula (mmHg).

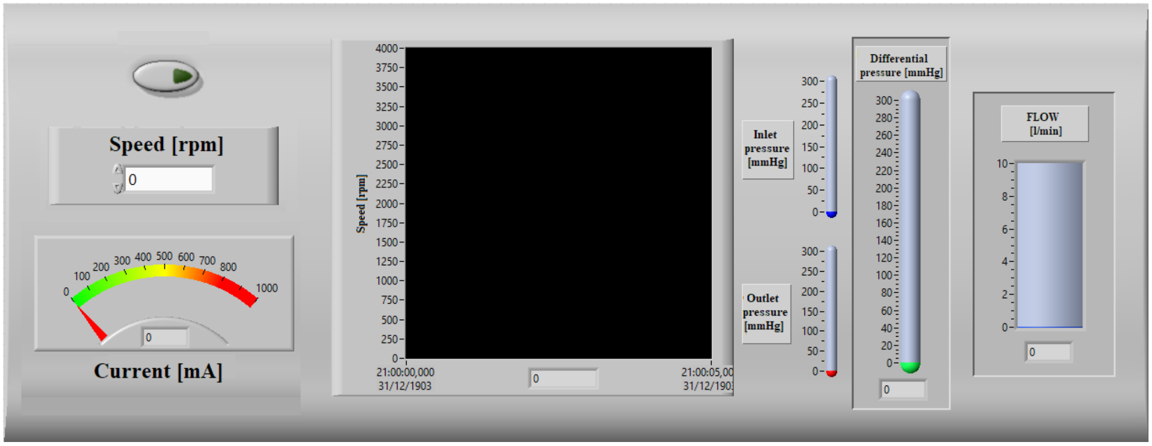
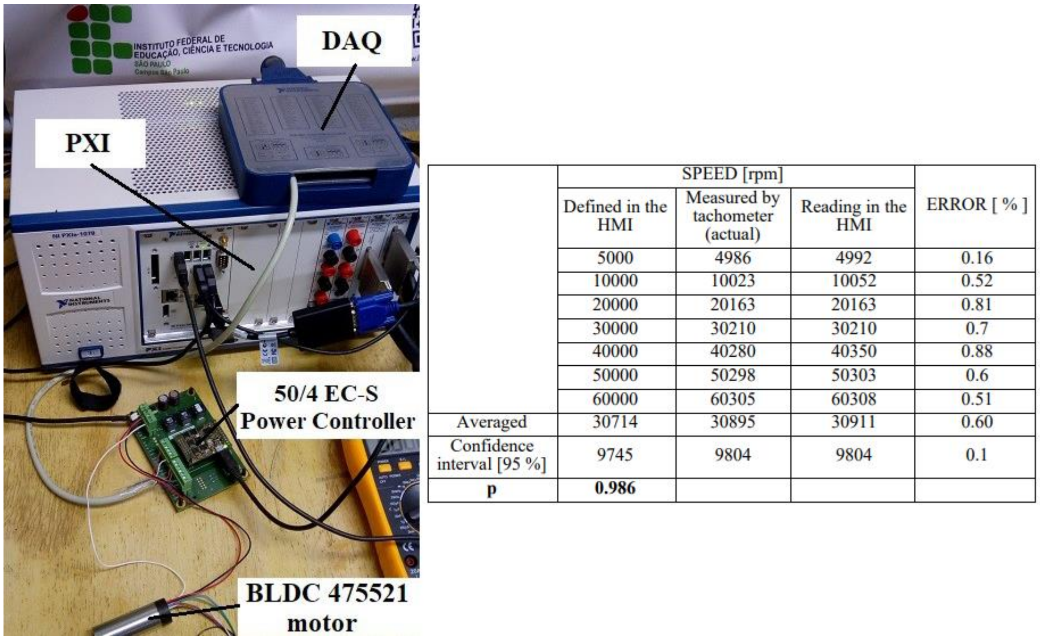


Figure 9. HMI of the HPB supervisory control system.

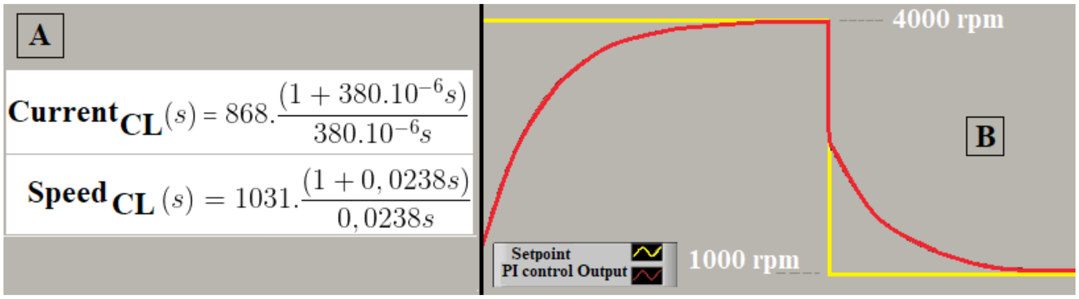
Figure 10 shows test 1 of the HPB supervisory control system using the BLDC 475521 motor (Maxon Motor, Sachseln, Switzerland) and also the results obtained.



	SPEED [rpm]			ERROR [%]
	Defined in the HMI	Measured by tachometer (actual)	Reading in the HMI	
	5000	4986	4992	0.16
	10000	10023	10052	0.52
	20000	20163	20163	0.81
	30000	30210	30210	0.7
	40000	40280	40350	0.88
	50000	50298	50303	0.6
	60000	60305	60308	0.51
Averaged	30714	30895	30911	0.60
Confidence interval [95 %]	9745	9804	9804	0.1
p	**0.986**			

Figure 10. Test 1 of the HPB supervisory control system and results.

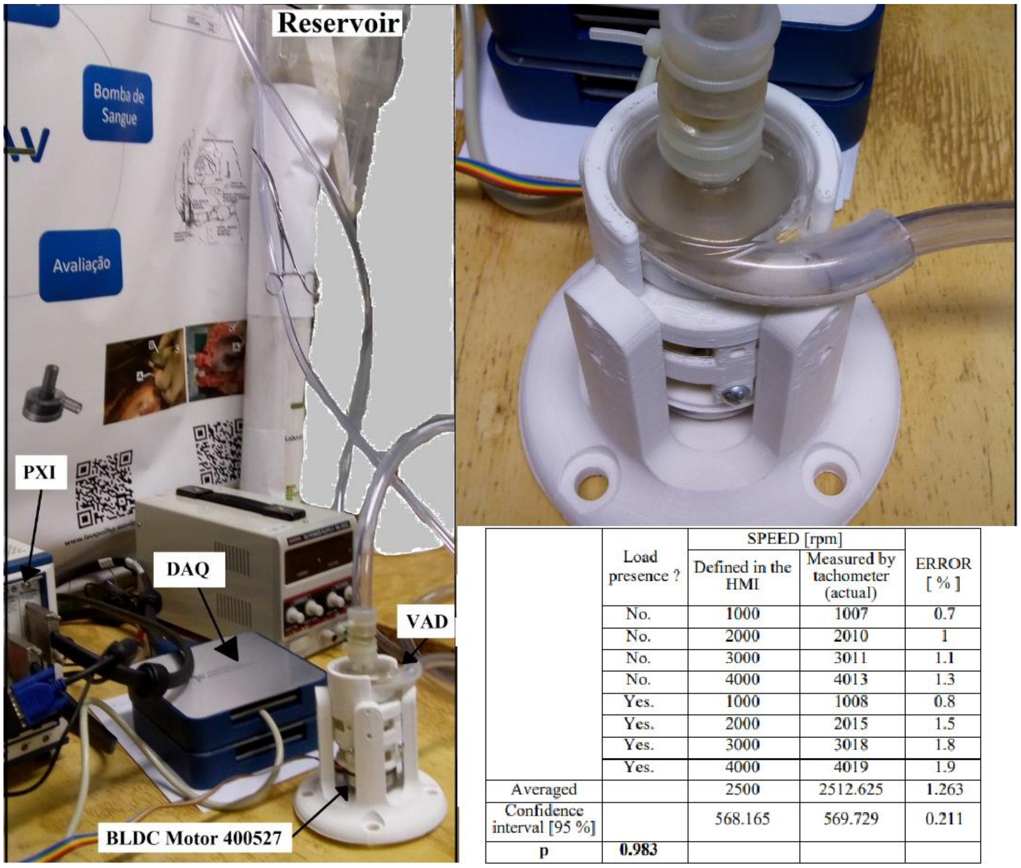
In Figure 11, the transfer functions with PI gains for current and speed of HPB actuator and the system response with PI control following the reference set in the supervisory control system of HPB. And in Figure 12 is shown the test 2 of HPB supervisory control using the definitive actuator of HPB inserted in the assembly of the mechanical components of HPB and also the results obtained.



$$\text{Current}_{\text{CL}}(s) = 868.\frac{(1+380.10^{-6}s)}{380.10^{-6}s}$$

$$\text{Speed}_{\text{CL}}(s) = 1031.\frac{(1+0,0238s)}{0,0238s}$$

Figure 11. PI control of HPB supervisory control system: A) PI gains of the actuator current and speed; and B) Response graph of the HPB supervisory control system.



	Load presence ?	SPEED [rpm]		ERROR [%]
		Defined in the HMI	Measured by tachometer (actual)	
	No.	1000	1007	0.7
	No.	2000	2010	1
	No.	3000	3011	1.1
	No.	4000	4013	1.3
	Yes.	1000	1008	0.8
	Yes.	2000	2015	1.5
	Yes.	3000	3018	1.8
	Yes.	4000	4019	1.9
Averaged		2500	2512.625	1.263
Confidence interval [95 %]		568.165	569.729	0.211
p	**0.983**			

Figure 12. Test 2 of the HPB supervisory control system.

Figure 13 shows the hydrodynamic performance test of a prototype pediatric VAD developed and its respective performance curve.

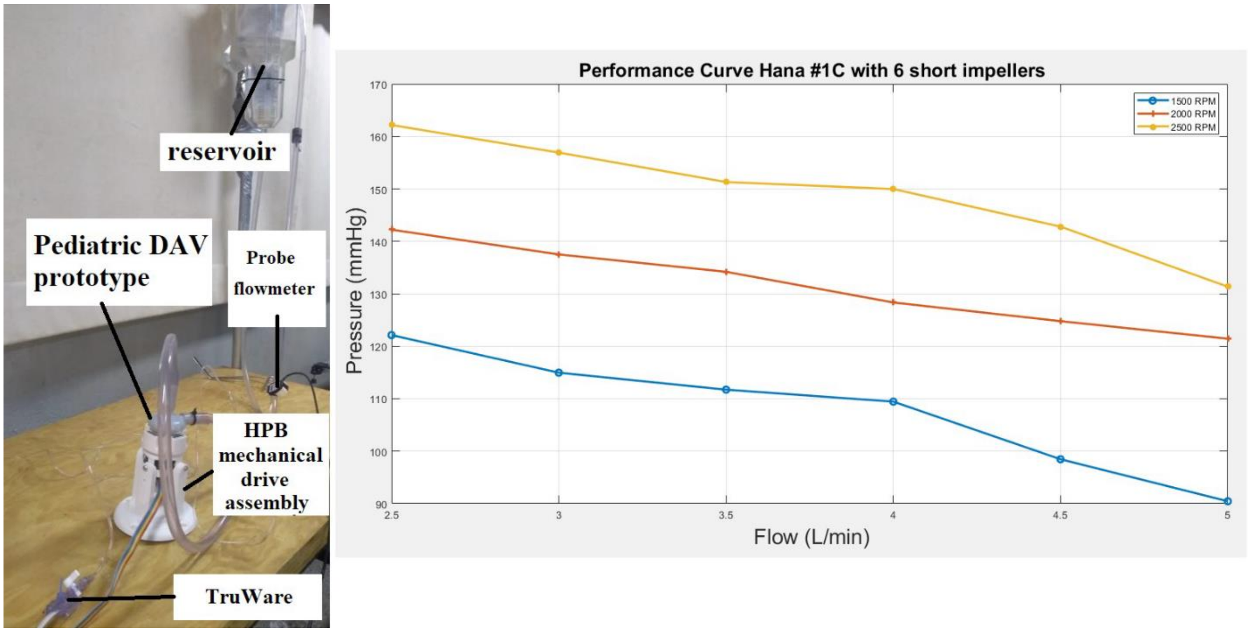


Figure 13. Hydrodynamic performance test on the HPB of a pediatric VAD prototype and performance curve.

In Figure 14, the test in HPB for determining the LUTs of the estimators of a physiological control of VAD.

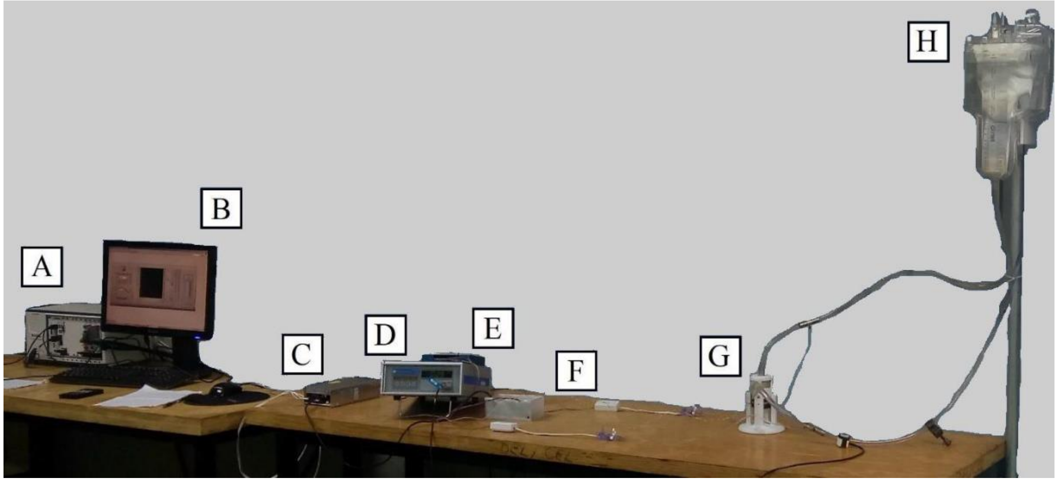


Figure 14. Test at HPB to map values to estimators: A) PXIe-8840; B) HPB; C) Power supply; D) HT-110 flowmeter; E) DAQ data acquisition and actuator; F) Escon 50/4 EC-S power controller; G) VAD prototype; and H) Reservoir.

Figure 15 shows the flow test by PIV in the HPB of a blood pump for cardiopulmonary bypass developed at the IDPC.

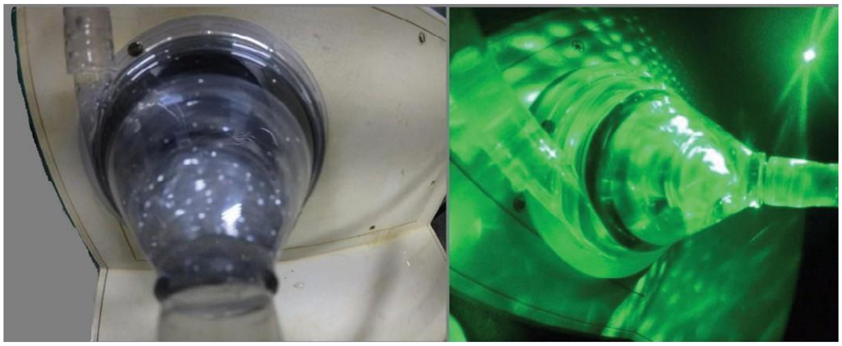


Figure 15. PIV flow test on HPB.

Discussion. The project of HPB construction presented satisfactory results, being highlighted that, the: (i) actuator was adequate; (ii) mechanical construction was functional in the interaction of the actuator with the VAD; (iii) fast prototyping reduced the cost and the necessary time for the project development; and (iv) mechanical components of HPB being modular allowed generalization of the use for performance evaluation of different types of developed.

The data acquisition and system control project presented satisfactory results, being highlighted that the transducers presented reliable results; The PI control actuation was stable throughout the test, with less than 2% error in steady state (1.263 ± 0.211; with statistical significance, $p = 0.983$; $\alpha = 0.05$) between the set value and the effective value, which is an indication that in the performance of VADs tests for a long time the data will continue to be complete; The data acquisition was satisfactory with real-time sampling of the main variables necessary for the classification of the VAD performance (0.6 ± 0.1; with statistical significance, $p = 0.986$; $\alpha = 0.05$), with all data stored in spreadsheets.

Conclusion. The Hydrodynamic Performance Bench (HPB) built in the Federal Institute of Sao Paulo campus São Paulo (IFSP SPO) could assist in the analysis of the development of VAD prototypes, based on this it is possible to affirm the technical success of the project. In future works it will be designed the total automation system of the VAD hydrodynamic performance curves test. Also, the use of the particle image velocimetry module will be expanded.

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