



Design of a Hydrodynamic Performance Bench for Ventricular Assist Devices

Santos BJ*, Leão TF*§, Drigo E§, Fonseca J§, Andrade AJP§, Nishida BT§ and Bock EGP†

* Department of Electric, *Federal Institute of Sao Paulo, Sao Paulo, Brazil.* § *Department of Bioengineering, Institute Dante Pazzanese of Cardiology, Sao Paulo, Brazil.* Department of Mechanic, *Federal Institute of Sao Paulo, Sao Paulo, Brazil.*

Abstract. This work presents the design of a hydrodynamic performance bench (HPB) for evaluating developed prototypes of Ventricular Assist Devices (VADs) used in the treatment of patients with Congestive Heart Failure (CHF), whether as a bridge to recovery, for transplantation or as destination therapy. The HPB is essential for evaluating the performance of VADs under development in Brazil, considering variables such as rotation speed [rpm], flow rate [L/min], pressure [mmHg], and power [W]. The project involves selecting an actuator and transducers for the HPB and developing mechanical components, supervisory control, and modules. The HPB's mechanical components were designed in SolidWorks®, following rapid prototyping, and manufactured using additive manufacturing techniques. The HPB's supervisory program was developed in graphic language using the Labview® program and implemented in a development and application platform with a data acquisition system. The supervisory system's manipulated variable is the motor speed [rpm], acting via an Escon 50/4 EC-S power controller on the BLDC EC45 N339281 motor. In contrast, the controlled variable is the "VAD flow" [L/min] an HT-110 flow transducer provides. A module using particle image velocimetry (PIV) was developed for flow analysis, and all process data are stored in spreadsheets for later consultation. The HPB can assist satisfactorily in analyzing developed VAD prototypes, demonstrating the technical success of the project.

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

Introduction. Cardiovascular diseases claim the lives of about 350,000 Brazilians annually, making it the leading cause of death in the country [1]. Incidences of cardiovascular diseases, particularly chronic heart failure (CHF), have increased over the years [2-4]. While heart transplantation is the standard treatment for patients with advanced and refractory CHF, it is limited by the number of available donors and possible contraindications, rendering it unfeasible [5]. Therefore, bioengineering has highlighted the importance of developing devices for mechanical circulatory assistance, including Ventricular Assist Devices (VADs) [6,7]. These



devices aim to replace the mechanical work of either the left or right side of the heart, ensuring the necessary cardiac performance for a patient's life and providing favorable conditions for recovery (BTR), transplantation (BTT), or even complete replacement of the heart (DT) [8].

To develop efficient and non-harmful VADs for implanted patients, VAD designs and prototypes must undergo tests and validations on test benches [9-11]. The purpose of a VAD test bench is to produce unambiguous results that can be used for (i) comparison with the state of the art, (ii) validation with current manufacturing and usage standards, (iii) evaluation of the system's response to disturbance and noise, and (iv) detection and confirmation of any problems and their resolution [12].

The main VAD "in vitro" assays discussed in the literature as reliable processes to predict VAD successes are the hydrodynamic performance assay and the hemolysis assay [13-15]. The hydrodynamic performance test evaluates the VAD's ability to maintain vital conditions for the patient by keeping a flow rate of 5 L/min with approximately 110 mmHg of differential pressure between the inlet and outlet cannulas. The test generates a map of values for the pump motor's rotation speed and electric current with the respective flow and differential pressure generated, which serves as a catalog of safe device operation [15,16]. Blood or an analogous fluid with similar viscosity (usually a solution of water and a third of glycerin) can be used in this test [13].

The value map obtained for the VAD in the hydrodynamic performance test can also be used as a reference for estimating physiological values without the use of sensors using the Look-up Table (LUT) 2D technique. A hydrodynamic test for operating range determines the LUT. The correlation between rotation and current with flow and differential pressure is mapped through a three-dimensional surface [15].

The hemolysis assay assesses the possibility of pumping by the VAD causing trauma to red blood cells, releasing hemoglobin into the plasma as a by-product of the breakdown of red blood cells. The higher the rate of hemolysis, the more traumatic the flow of assisted pumping into the blood [17]. This trauma is measured using plasma-free hemoglobin (PFH). The normalized index of hemolysis (NIH) for VADs should remain between 0.004 g/100 L and 0.02 g/100 L (Nose 1998) [9]. According to the standards ASTM F1841 and ASTM F1830, the normalized hemolysis test 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 estimation of the results of the hemolysis assay is performed using Particle Image Velocimetry (PIV), which is a benchtop experiment for studying fluid dynamics that provides greater detail than sensors and devices due to the FAPESP Thematic Research Project (2013/24434-0), there is a technical cooperation agreement between the University of São Paulo and the Dante Pazzanese Institute of Cardiology, which has allowed the development of the ICBP and the AABP to be carried out with greater efficiency and accuracy. In addition, this collaboration has enabled the establishment of partnerships with national and international institutions, which have contributed to the progress of research in this area [29]. The development of VADs is of great importance for the treatment of cardiovascular diseases,



especially in cases where heart transplantation is not a viable option. Using test benches to evaluate and validate VAD prototypes is essential for developing efficient and non-harmful devices. The hydrodynamic performance assay and the hemolysis assay are the two main tests used to assess the performance of VADs. The ICBP and AABP are two VADs under development in Brazil, and the HCS is the primary system for evaluating VADs under development in the FAPESP Thematic Research Project. The collaboration between the University of São Paulo and the Dante Pazzanese Institute of Cardiology and the partnerships established with other institutions have contributed significantly to the research progress in this area.

Actuator. The study began by considering the selection of an appropriate actuator for the hydrodynamic performance bench (HPB). The selection criteria were based on the following technical considerations:

1. Selection of a commercially available motor due to its immediate availability, easy maintenance, specified operating parameters, and robust actuation guarantee provided by the manufacturer; and
2. Selection of a brushless direct current motor (BLDC), commonly used in VAD. The motor should possess physical characteristics similar to those of an implantable motor, as this will enable the performance values of the VAD prototype to be closely aligned with the importance of an "in vitro" test where the actuator is encapsulated in the VAD. This will bring us one step closer to developing a commercial product. Additionally, the control strategies used for VAD control in HPB can be evaluated, shaped, and modified to best suit the application.

Mechanical construction. The study's second objective was to design the mechanical components of the HPB. The choice conditions followed the technical criteria as listed below:

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

The components were developed following these 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 objective of this study was to design the transduction system to evaluate the interesting physical phenomena of the VAD performance. A sensor is a device that quantifies output and changes with one or more physical phenomena. The output information can be used for process monitoring and control. On the other hand, a transducer is a device that converts one form of energy into another. By measuring the physical variables associated with the resulting energy form, it is possible to estimate the physical variables related to the input energy [46]. In this project, the main variables are the flow rate and differential pressure of the VAD. The HT-110 flow transducer (Transonic Systems, Ithaca, USA) will be used to obtain the VAD flow in the HPB. This only requires the electrical connection between the analog outputs of the HT-110 flow meter and the 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 the HPB, the differential pressure of the VAD will be obtained through 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). However, an engineering adaptation of the TruWave pressure transducer is necessary, as this device was initially designed to be used with a multiparametric hospital console, which is not available for use in the HPB. The adaptations required for the use of the TruWave pressure transducer are as follows:

1. Amplification of the signal: The pressure transducer has a resolution of $5.0 \mu\text{V/V/mmHg} \pm 1\%$. This value needs to be amplified to a standard working range in electronics (0 to 5 V) within the interesting range for VAD analysis (0 to 300 mmHg). The INA122 signal amplifier (Texas Instruments, Dallas, USA) will do this.
2. Straight line equation: With the established range of interest, it is necessary to identify the mathematical relationship of the pressure straight line in the input measurement unit (mmH₂O) by the desired measurement unit (mmHg).
3. Processing: With the straight-line equation established, the input signal can be acquired and processed 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).

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

Data acquisition and system control. The study's fourth objective was to design the HPB control and data acquisition system. To achieve satisfactory acquisition and storage of HPB results, a supervisory program that meets the following technical criteria is required:

1. **Human Machine Interface (HMI):** To operate HPB as a test bench, it is necessary to intuitively insert process data to ensure the overall integrity of the tests.
2. **Stable control of the actuators:** The HPB actuator drive is controlled by an electronic controller (driver). For this to occur, the transmission and acquisition standards must be respected, and a homogeneous flow must be maintained to avoid system oscillations that compromise the operation and the analyzed data.
3. **Acquisition of data from sensors:** HPB collects critical data, including current (A), voltage (V), flow (L/min), and pressure differential (mmHg), to evaluate the performance of VAD. The control of HPB is exerted on a complex variable (non-Newtonian fluid in acceleration) subject to momentum, disturbances, and noise throughout the test. Therefore, a closed-loop actuation system with feedback of the controlled variable is mandatory.
4. **Data storage:** The VAD's performance will be validated later using value maps and property relations. Therefore, data throughout a series of tests or a long duration must be faithfully stored in spreadsheets for later simple handling.

The HPB supervisory program was developed in graphic language using the Labview® program (2015, National Instruments, Austin, USA) and implemented in a development and application platform (PXIe-8840, National Instruments, Austin, USA) with 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 includes pressure differential (mmHg), supplied by a TruWave pressure transducer, current (mA) and voltage (V), provided 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 a closed-loop stability algorithm must be implemented [47]. Using the Ziegler-Nichols Threshold Sensitivity Method to adjust the Proportional-Integral-Derivative parameters [37], a Proportional-Integral (PI) control algorithm was created for the current and speed actuator. This allows system stability even with significant variations in process characteristics. The advantage of using a PI control as a stability filter is its easy digital implementation and versatility, providing satisfactory results even in noise and disturbances [37]. The chosen motors were parameterized and calibrated for the highest efficiency in controlling the HPB actuation for the power controller in the Escon Studio® program (Maxon Motor, Sachseln, Switzerland).



Two tests were performed to evaluate the HPB supervisory control system: Test 1 evaluated the transmission and data acquisition of the supervisory control system. Test 2 evaluated the stable maintenance of the motor speed in the presence of pumping resistance variations caused by the physiological system.

Test 1 was performed to evaluate whether the motor speed values chosen in the HPB supervisory control system were effectively reproduced in the motor (reading using a tachometer) and whether the process data was being processed and faithfully reproduced on the HMI screen. The BLDC 475521 motor (Maxon Motor, Sachseln, Switzerland) was selected as the actuator for this test. Although this motor does not meet the physical dimensions required for encapsulation inside a centrifugal VAD, its wide operating range (0 to 62000 rpm) allowed for more comprehensive control tests.

Test 2 was conducted to evaluate the motor's stable speed maintenance in the presence of variations in pumping resistance caused by the physiological system. The speed was adjusted in increments of 1000 rpm, both increasing (1000 - 4000 rpm) and decreasing (4000 - 1000 rpm), using the HPB supervisory control system. Using a contact tachometer, the motor's response was examined with and without load. The control system's response to disturbances, such as induced motor load and electromagnetic noise from nearby devices, was also evaluated. The definitive actuator of HPB was used for this test.

Validation applications. In 2018, FAPESP issued a public call in Brazil for the development of a para corporeal radial centrifugal VAD under a fostering program called PITCHGOV. PITCHGOV is a program of the Government of Sao Paulo/Brazil that addresses public management challenges by connecting public power and startups. At HPB, the performance curve of the pediatric VAD developed for this project was obtained [48].

Santos developed an intelligent embedded system (IES) for VAD that integrates real-time data processing, reconfigurable architecture, and communication protocols based on the concepts of Healthcare 4.0 [49]. The physiological multi-objective control (MOPC) technique for VAD proposed by Leao T et al. [34] was chosen as a proof of concept to validate the feasibility of IES as a VAD controller solution. To ensure the proper operation of the MPOC technique of VAD, the formation of the LUTs of the estimators for each specific motor of the VAD to be controlled is required. At HPB, the map of values of the VAD prototype to be held by the MOPC embedded in the ILS was obtained [39].

Particle image velocimetry module. The fifth aspect of the study involves the development of a VAD flow test module utilizing particle image velocimetry (PIV) to examine the turbulence and stagnation areas of the VAD. The module captures the idea of the pump rotor rotation speed using a transparent housing model of the analyzed VAD by a fast pulse camera coupled with a high-intensity laser (540 nm, 5000 mW) and the data acquisition process [17]. The short pulse camera utilized is the Hero 8 Black (GoPro, San Mateo, USA).

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

The PIVLab toolbox is utilized for image pre-processing, evaluation, and post-processing. The user determines the acceptable speed limits for post-processing, which can be determined automatically by comparing each speed component with upper and lower limits, using the average speed and the standard deviation of the rate. Noise reduction in the data is achieved by mediated filtering using a penalized least squares method.

Results. The actuator selection process for HPB involved two criteria met by the BLDC EC45 N339281 motor (Maxon Motor, Sachseln, Switzerland). As depicted in Figure 1, this motor was chosen as the optimal choice for the actuation of the HPB system.

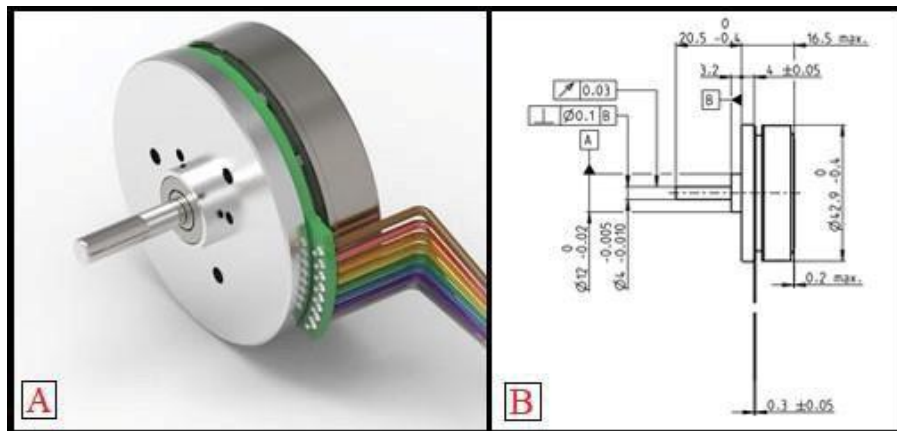


Figure 1. HPB actuator: A) Representation of the Maxon BLDC EC45 N339281 motor; and B) its physical dimensions.

The mechanical components developed to satisfy the three criteria defined for the construction of HPB are displayed in Figure 2. With all the mechanical members available, examinations were conducted to verify the fixation between the components, the mechanical interaction of the transmission, the absence of contact, and the material's resistance to wear and fatigue in working conditions. The assembly of the HPB components, created using a 3D printer, is depicted in Figure 3.

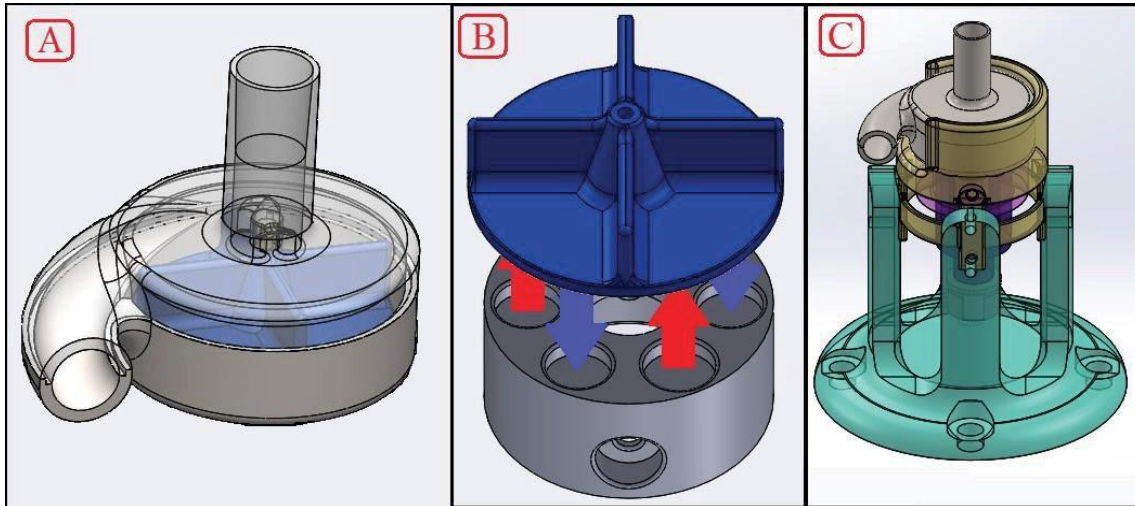


Figure 2. Components modeled in 3D CAD: A) The VAD under development at IFSP SPO; B) The drive by magnetic coupling between the HPB rotor and the VAD; and C) Assembly in 3D CAD of the mechanical components of HPB.

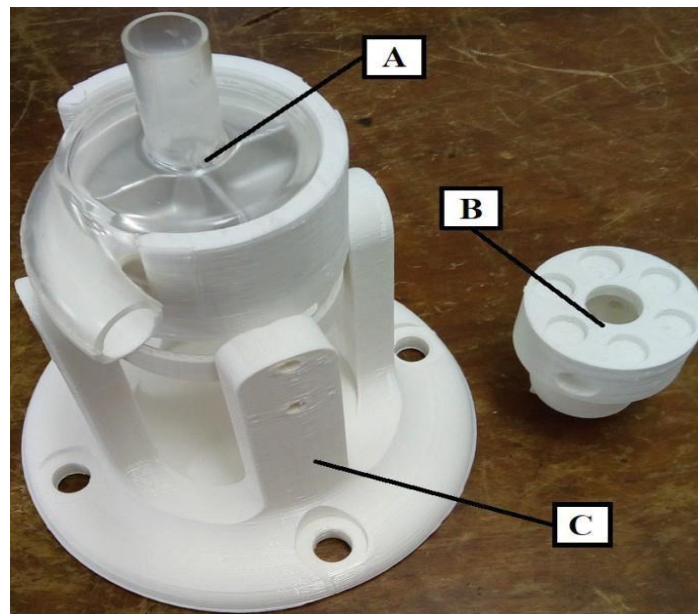


Figure 3. The assembly of the HPB mechanical components built on the 3D printer: A) VAD prototype at IFSP; B) The magnetic coupling between the HPB mechanical components and the VAD rotor; and C) HPB assembly with VAD docked.

The electrical schematic for adapting the TruWave pressure transducer for use in the HPB is presented in Figure 4.

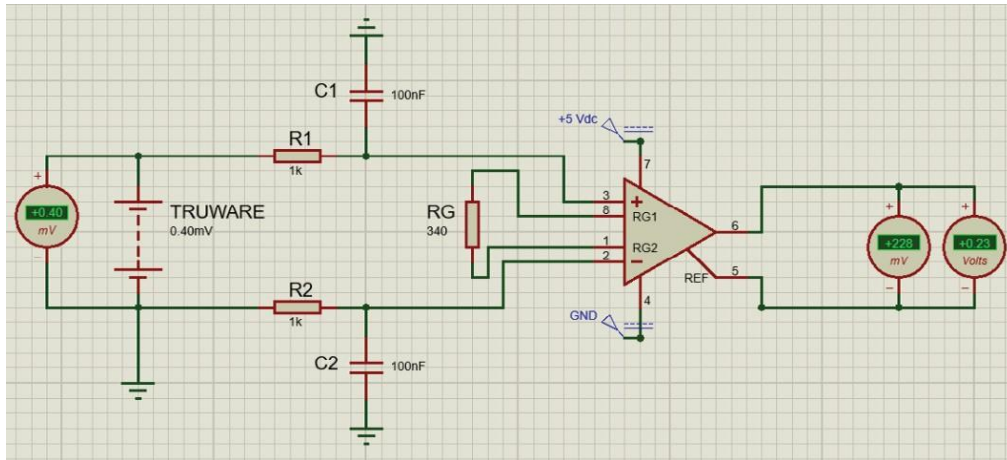


Figure 4. Electrical diagram for amplification of the pressure transducer signal.

The experimental survey of the straight-line equation with mathematical correlations of pressure transduction is depicted in Figure 5. In contrast, Figure 6 illustrates the straight-line equation utilized for the TruWave pressure transducer as a pressure variable within the HPB supervisory control system.

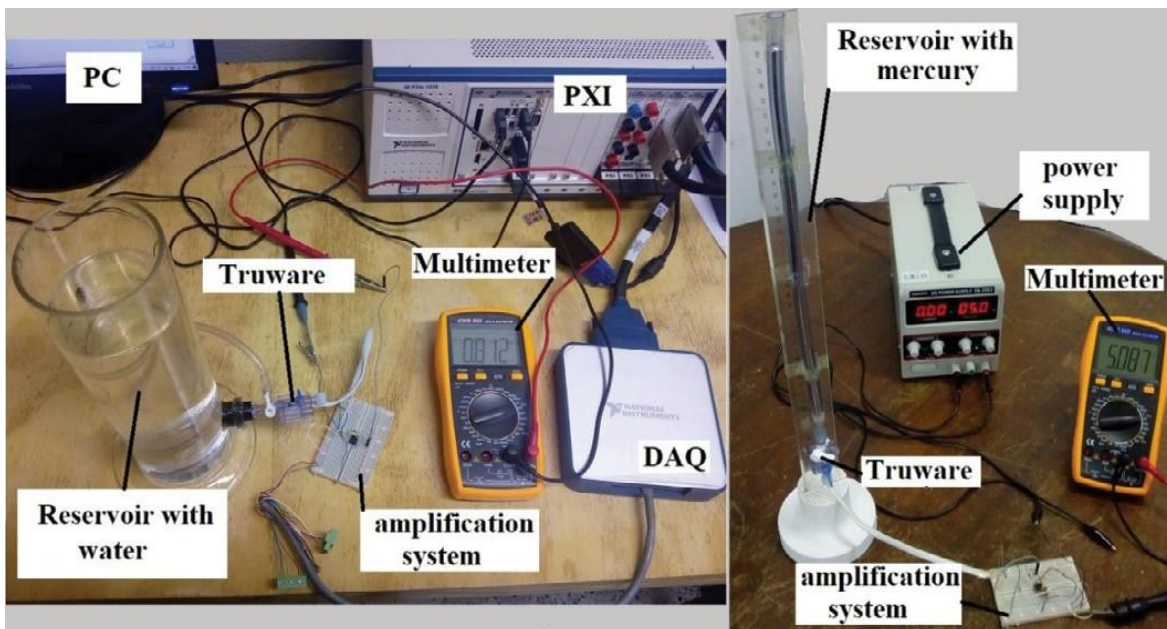


Figure 5. Tests for determining the straight-line equation of the pressure transducer.

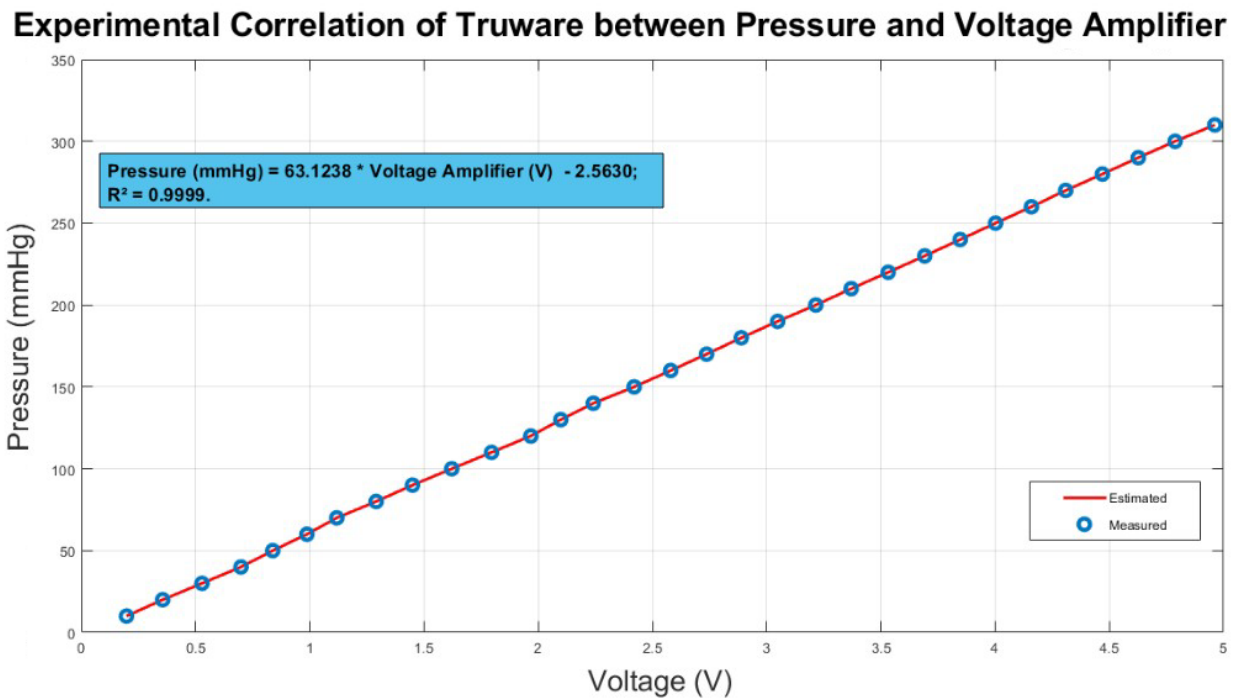
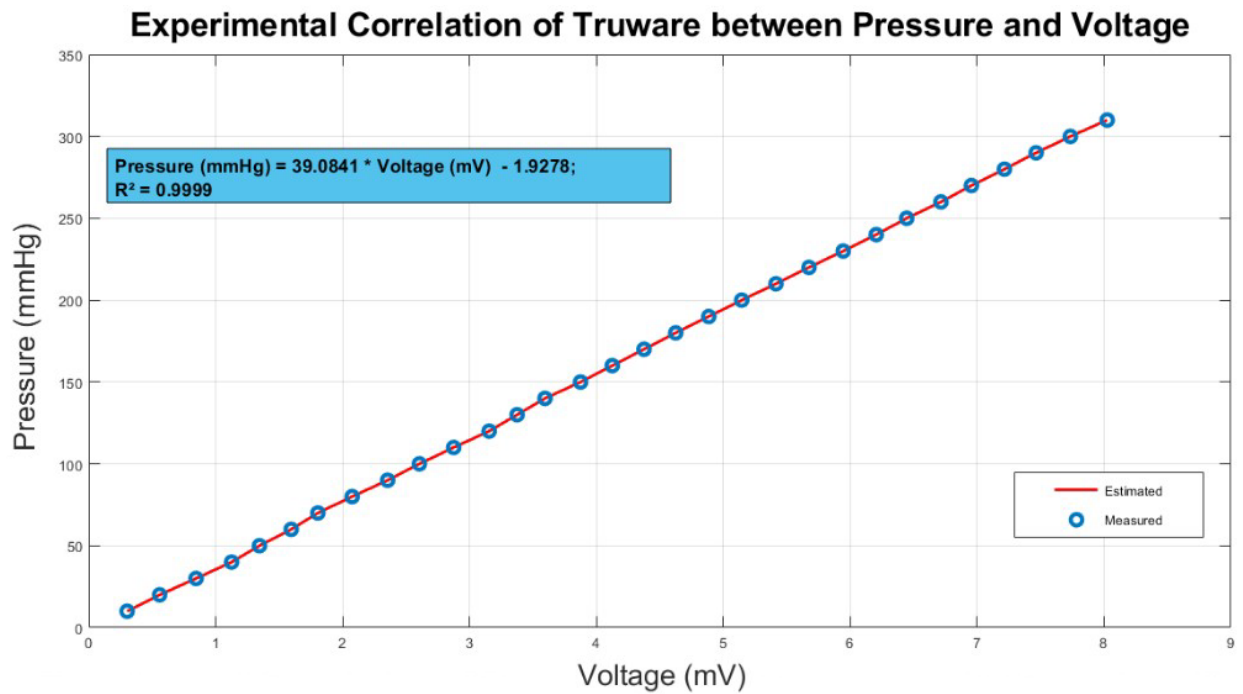


Figure 6. Equation of the correlation straight-line of the pressure transducer.

Figure 7 depicts the reconfiguration of the Escon 50/4 EC-S power controller ports aimed at integrating with HPB's supervisory system. Figure 8 displays the motor calibration procedure within the Escon Studio® virtual environment, where speed levels were adjusted in the program (blue color), and the motor tried to follow (red color) without exceeding the expected current levels. This relation identified the optimized gains of the Proportional-Integral (PI) control.

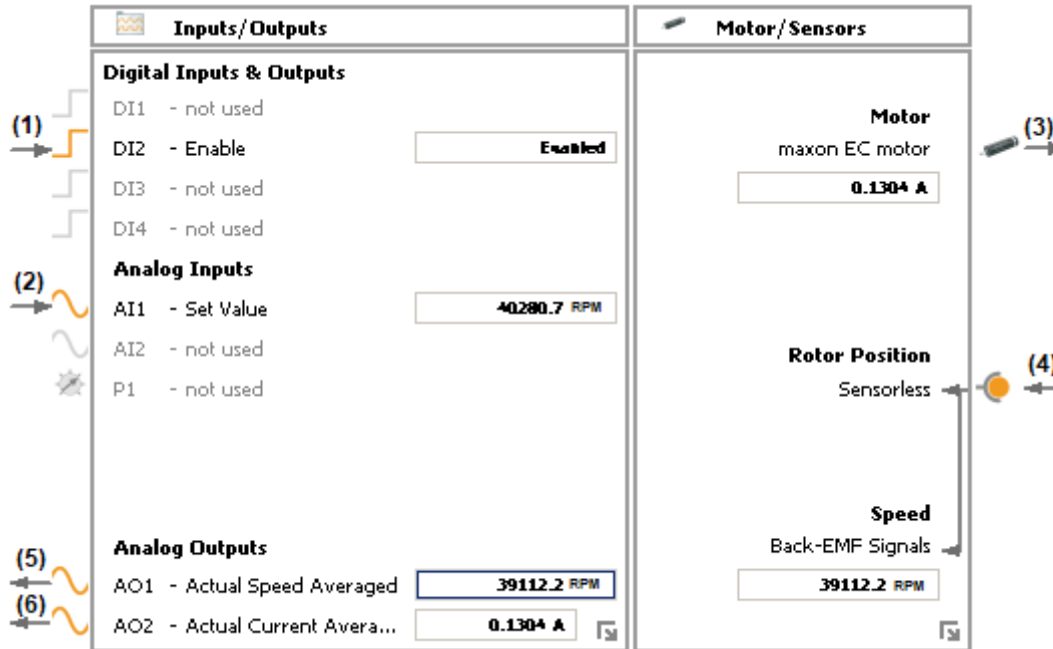


Figure 7. Schematic of the power controller ports: 1) On/Off digital button; 2) Speed variation by voltage analog input [0 – 4 V]; 3) Motor driving; 4) Estimated reading (sensorless) of the motor speed; 5) Analog output indicating the motor speed variation [0 - 4 V]; and 6) Analog output indicating the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

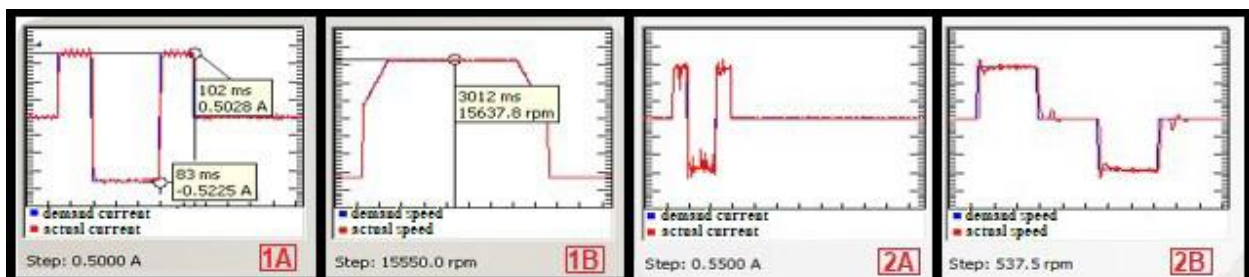


Figure 8. PI control calibration for BLDC 475521 and N339281 motors: 1A) Current demand on BLDC 475521 motor; 1B) Speed demand on BLDC 475521 motor; 2A) Current demand on BLDC EC45 N339281 motor; and 2B) Speed demand on BLDC EC45 N339281 motor.

The motor speed is adjusted, and the real-time values of process data are sampled in HPB's supervisory control system, as shown in Figure 9. These process data include the motor feedback speed (rpm), motor current (mA), VAD flow rate (L/min), and differential pressure between the inlet and outlet cannula (mmHg).

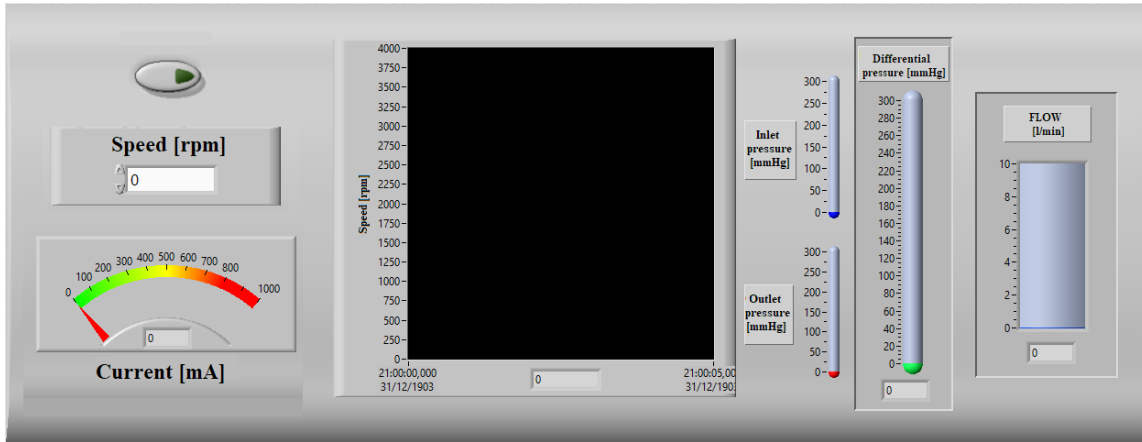
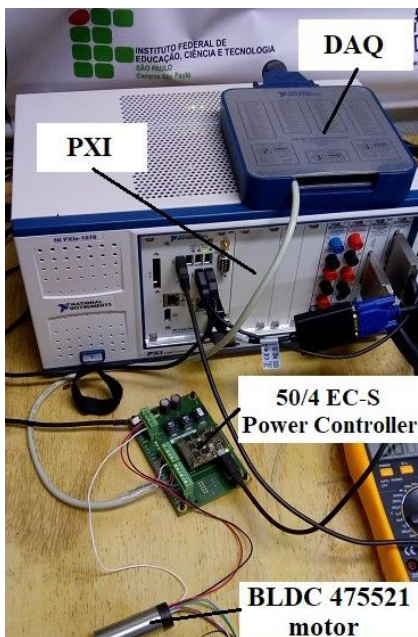


Figure 9. HMI of the HPB supervisory control system.

The results obtained from Test 1 of the HPB supervisory control system, utilizing the BLDC 475521 motor (Maxon Motor, Sachseln, Switzerland), are presented in Figure 10.



	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.

Figure 11 depicts the transfer functions with Proportional-Integral (PI) gains for the current and speed of the HPB actuator, as well as the system response with PI control following the reference set in the supervisory control system of HPB. Figure 12 shows the second test of the HPB supervisory control using the final HPB actuator inserted in the assembly of the mechanical components of HPB, along with the corresponding results obtained.

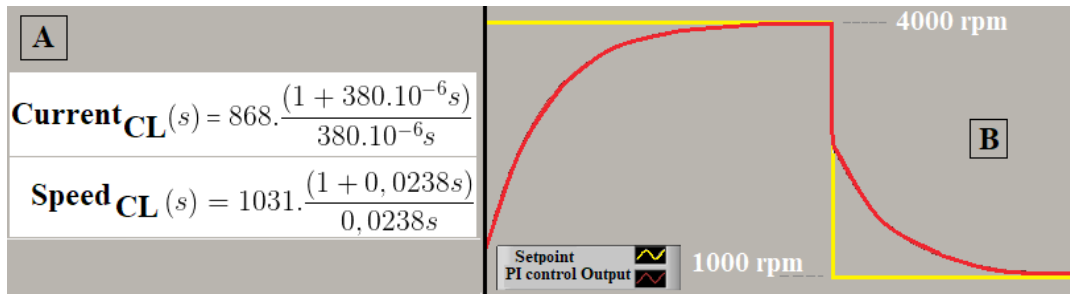


Figure 11. PI control of HPB supervisory control system: A) PI gains of the actuator current and speed; and B) Response graph of the HPB supervisory control system.

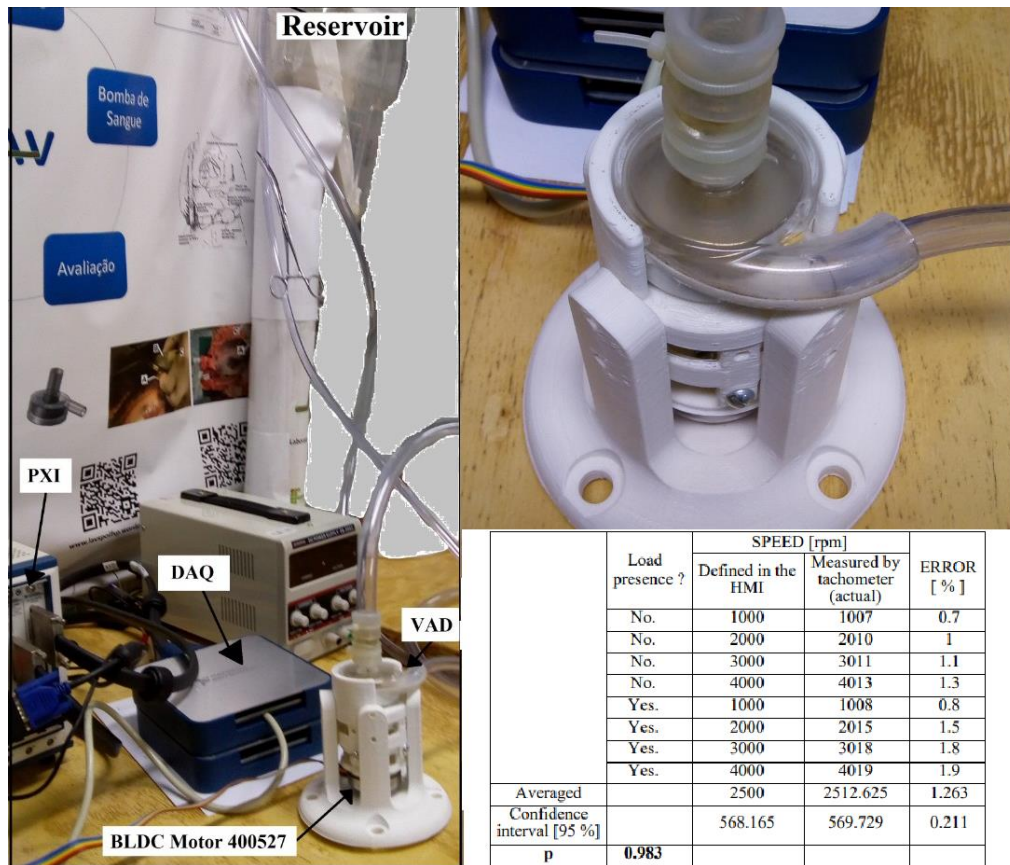


Figure 12. Test 2 of the HPB supervisory control system.

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

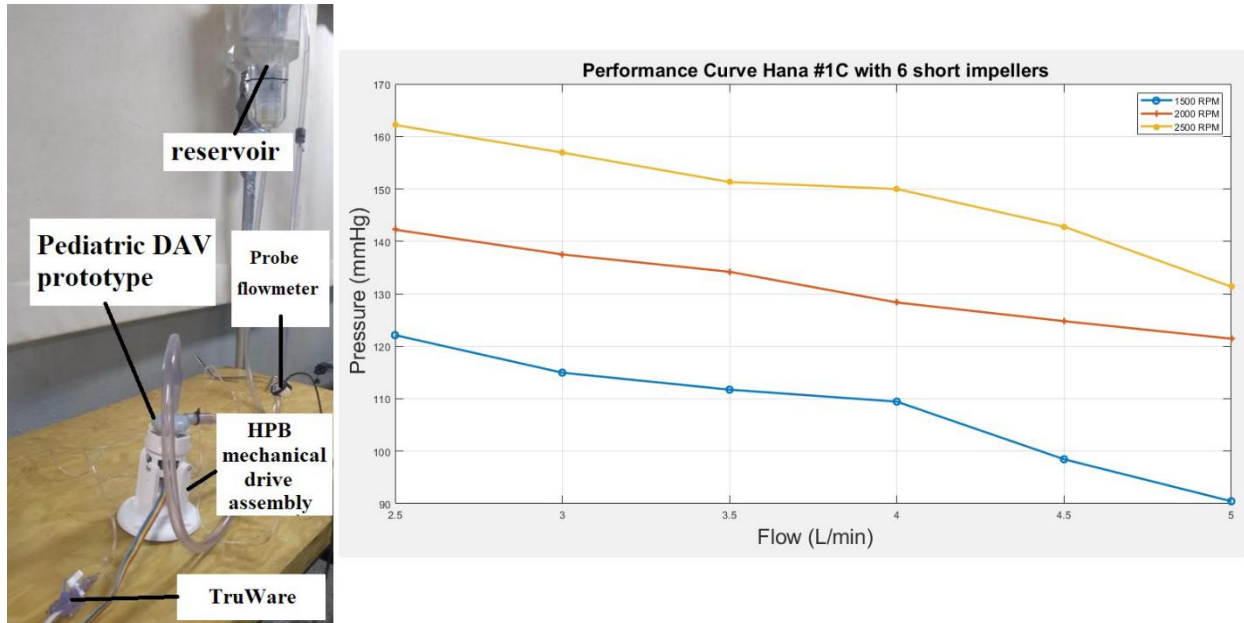


Figure 13. Hydrodynamic performance test on the HPB of a pediatric VAD prototype and performance curve.

Figure 14 presents the test conducted in HPB to determine the LUTs of the estimators for physiological control of the VAD.

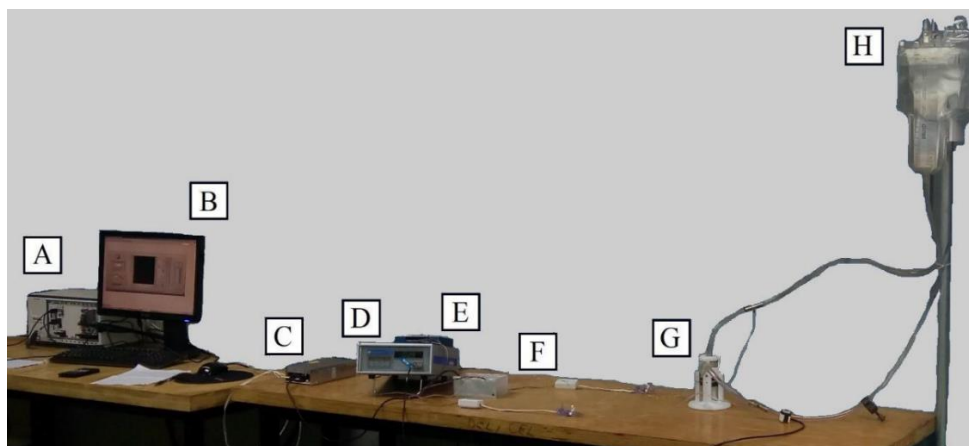


Figure 14. Test at HPB to map values to estimators: A) PXIe-8840; B) HPB; C) Power supply; D) HT-110 flowmeter; E) DAQ data acquisition and actuator; F) Escon 50/4 EC-S power controller; G) VAD prototype; and H) Reservoir.

In Figure 15, the flow test of a blood pump developed for cardiopulmonary bypass at the IDPC is presented and conducted in the HPB using Particle Image Velocimetry (PIV) to visualize the flow pattern and quantify the flow velocity distribution.

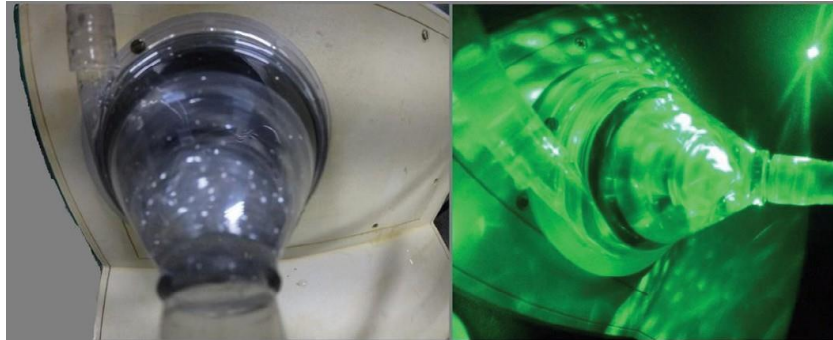


Figure 15. PIV flow test on HPB.

Discussion. An HPB is an essential tool for evaluating the performance of a VAD prototype. It is an experimental setup that mimics the hemodynamic conditions of the human circulatory system, allowing the assessment of device performance under various physiological conditions. In this discussion, we will explore the construction of an HPB, the multiple components that make up the setup, and the relevant works in this area. The structure of an HPB typically involves integrating several features, including a VAD, a pump, a flow measurement system, and pressure transducers. The VAD is connected to the pump, which provides the necessary blood flow to the device. The flow measurement system comprises a flowmeter that measures the blood flow rate in the design and a pressure transducer that measures the pressure at various points in the system. These measurements allow the calculation of different hemodynamic parameters, such as flow rate, pressure drop, and power consumption. The pump provides the necessary flow of blood to the VAD and must be able to operate under the physiological conditions of the human circulatory system. Various types of pumps are used in HPBs, including roller pumps, centrifugal pumps, and axial flow pumps. The choice of pump depends on the specific requirements of the tested VAD.

The flow measurement system is another critical component of an HPB. Accurate flow measurements are essential for the evaluation of VAD performance. Several methods for measuring flow in an HPB include electromagnetic flowmeters, ultrasonic flowmeters, and thermal flow sensors. The choice of a flow measurement method depends on the specific requirements of the VAD being tested. Pressure transducers are also a critical component of an HPB. They measure the pressure at various points in the system, allowing for the calculation of different hemodynamic parameters. Multiple pressure transducers exist, including piezoresistive transducers, capacitive transducers, and optical fiber sensors. The choice of pressure transducer depends on the specific requirements of the VAD being tested.



The construction project of HPB yielded satisfactory results. It is noteworthy that (i) the actuator chosen was appropriate, (ii) the mechanical construction was functional in its interaction with the VAD, (iii) the utilization of fast prototyping reduced costs and development time, and (iv) the modular design of the mechanical components of HPB allowed for generalization of use in evaluating the performance of various types of devices. The data acquisition and system control project also yielded satisfactory results. It is highlighted that the transducers provided reliable results, and the PI control actuation was stable throughout testing, 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 practical value. This indicates that the data will remain complete during long-term VAD performance tests. Real-time sampling of the necessary variables for VAD performance classification was satisfactory (0.6 ± 0.1 ; statistical significance, $p= 0.986$; $\alpha= 0.05$), with all data stored in spreadsheets. Overall, the construction of an HPB is a crucial step in the development and testing of VADs. The construction of an HPB is a complex process involving integrating several components, including a VAD, a pump, a flowmeter, pressure sensors, a data acquisition system, and control software. However, the benefits of having an HPB in developing and testing VADs are numerous. Evaluating hydrodynamic performance and validating computational fluid dynamics simulations is crucial in ensuring the safety and efficacy of VADs for clinical use. Moreover, HPBs can facilitate identifying design flaws, optimizing pump performance, and developing control algorithms for VADs.

Conclusion. The HPB established at the IFSP SPO is a valuable tool for evaluating the progress of VAD prototypes, thereby affirming the technical achievements of the project. Future efforts will focus on devising a comprehensive automation system for testing the hydrodynamic performance curve of VADs. Additionally, the PIV module will undergo expansion to augment the HPB's capabilities.

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Authors ORCID (<http://orcid.org/>)

Bruno Jesus dos Santos - 0000-0001-5176-4711

Tarcisio Fernandes Leão - 0000-0003-4884-5638

Eduardo Guy Perpetuo Bock - 0000-0003-3962-9052