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DESIGN, MANUFACTURE AND TESTS OF AN EXPERIMENTAL PULSATILE FLOW BENCH

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Abstract. *Stent is a medical device that can be defined as a metal or polymer cylinder, usually in the form of a mesh, which is placed in the lumen of an anatomical vessel (such as an artery or a bile duct) with the aim of reopening the passage of that vessel. which is wholly or partially obstructed, usually in order to maintain normal blood flow. Due to its application directly influencing the patient's health, there is a need to research ways to improve the physical and chemical properties, making stent technology more reliable without compromising biocompatibility. Thus, the present work proposes the development of an experimental pulsatile flow bench, according to the ASTM 2477-7 Standard, which will allow the performance of tests on Stents, simulating the conditions to which this device will be submitted when inserted in the human body. The execution of the project was divided into five stages: initially, the informational project was carried out, where a bibliographical survey was carried out on the already existing equipment, aiming to determine the requirements and specifications. Then, the conceptual project was executed, where it was sought, through schematic drawings and diagrams, to create a concept that best met the aforementioned requirements and specifications. Next, the preliminary project was elaborated, where the materials were defined and the dimensioning of the bench was executed. After that, the detailed design and manufacture of the prototype was carried out. Finally, equipment instrumentation tests were carried out, allowing it to be controlled and monitored, thus guaranteeing the reliability of the test. As a result, it was possible to observe that the bench was able to simulate pulsatile cycles with pressure variation between 0 mmHg and 220 mmHg, the heating system worked properly, showing variations of up to 4 °C in 15 minutes of test, with an average variation of 2 bpm being observed during the execution of the tests. Thus, it was concluded that it was possible to develop a low-cost pulsatile flow experimental bench with a control system that enabled the remote monitoring of pressure, temperature and beats per minute data, allowing the performance of tests as recommended in ASTM 2477-7.*

Keywords: *Pulsatile flow, Experimental bench, Stents, Closed-loop flow.*

1. INTRODUCTION

The constant quest for a longer and more quality life has challenged science, especially medical and technological, to seek solutions to provide more health to humanity. The increase in people's life expectancy is notorious and this fact is due to research conducted daily around the world to develop new medicines, new instruments and new techniques in order to provide people with a healthy life.

In recent decades, cardiovascular disease (CVD), specifically ischemic heart disease (IHD), has become the leading cause of death in the world, accounting for 16.17% of all deaths worldwide, according to data from IHME (Institute for Health Metrics and Evaluation) (2019). It is worth noting that these diseases arise due to the accumulation of fat in the arteries, called arteriosclerosis, causing a decrease in the blood flow that passes through the heart.

Treatment for arteriosclerosis consists in removing the fat plates that are trapped in the walls of the arteries and healing the lesions that remain in place. This can be achieved through surgery, catheterism, laser angioplasty and through the use of some medicines and physical activity. Another way to remedy this problem is through coronary angioplasty or percutaneous intervention with the stent implant, providing an improvement in quality of life, and increasing survival of patients affected by arteriosclerosis. (Bavry *et al.*, 2006; Mehta *et al.*, 2005).

Coronary stents are tubular structures made of metal in the form of a mesh that have the property of expanding, shaping the vessel, in areas subjected to balloon angioplasty (Araújo et al., 1996). According to Vasconcelos (2010), an average of 140,000 coronary interventions are carried out using stents in Brazil per year. However, even presenting itself as such an important advent for modern medicine and with great development in recent years, in Brazil, the first stent manufactured entirely in the national territory came to the market only in 2009.

Therefore, it is important that the manufacturers of these devices have the mastery of the technique for testing on them in order to ensure that they behave as expected throughout their lifetime, thus reducing the number of failures.

Thus, the present work sought, based on Standard ASTM 2477-7, to develop an experimental pulsed flow bench with the aim of performing tests on Stents, simulating the conditions to which this device will be subjected when inserted into the human body.

2. MATERIALS AND METHODS

The flow diagram illustrated in Figure 1 schematizes the methodology used in the project and its respective steps.

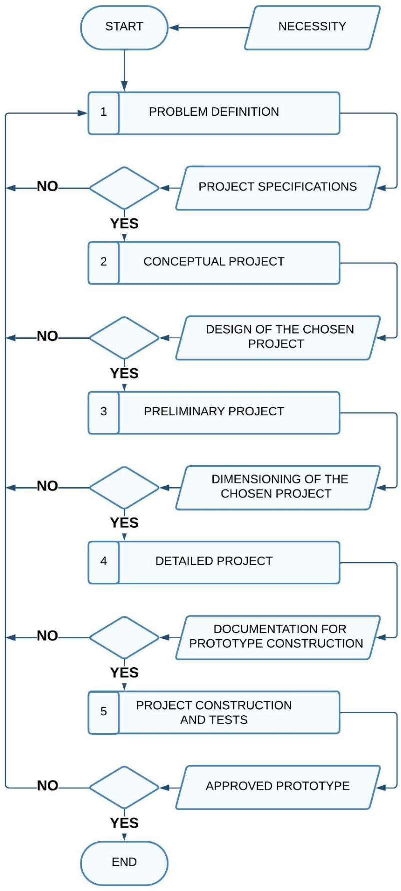

Figure 1. Fluxogram of adopted project methodology.

From this, it is noted that the execution of the project was divided into five stages, from the definition of the problem. Thus, the Information Project was initially carried out in order to know the procedure, to conduct a survey of the limitations, equipment and materials necessary for the development of the prototype, a bibliographic survey was conducted in journals and specialized books seeking information regarding the requirements and specifications of the design of the device to be developed, from the works of TRUANT, R. (2007), TSAI, W (2010), GUPTA, R. et al. (2007) and GUZMAN, J. and al. (2007).

The second stage in the development of the system was the Conceptual and Preliminary Project, where the requirements and specifications raised in the Information Project were taken and the operation concept of the pulsed flow system to be developed, with its main subsystems, as illustrated in Figure 2, was elaborated.

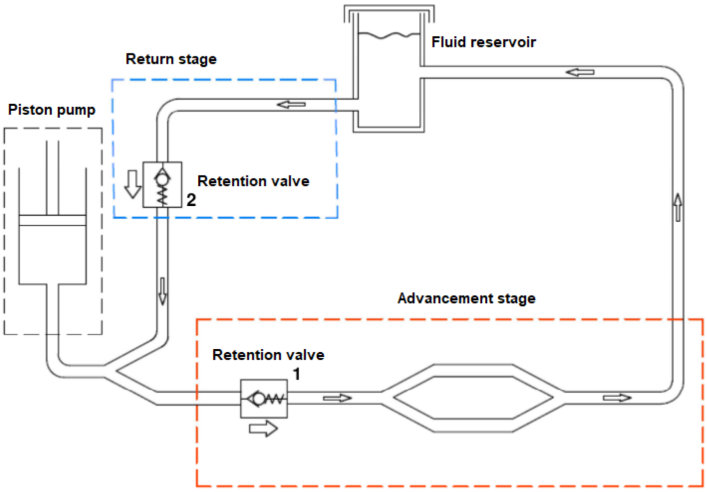

Figure 2. Pulse pumping system.

As in the heart cycle, this is a closed grid system, consisting of two stages, one of advance and another of return. Each heart cycle has two phases: diastole, the time during which the heart muscle relaxes, and systole, a period during which it contracts. (SILVERTHORN, 2017). In view of this, the systole is simulated when the piston embolism moves forward, and the fluid circulates forward, in the advanced stage, from the piston plunger to the fluid reservoir. The diastole is simulated when the piston moves backwards, and the fluid circulates backward, in the return stage, from the liquid reservoir to the piston pump.

During the advanced stage, the pressure on the piston plunger is higher due to the mass of the fluid in the reservoir. In this stage, the fluid is conducted, from the inner chamber of the piston, through the pipes passing through retention valve 1, to the reservoir. The retention valve 2 closes at this stage, allowing the fluid to return to the reservoir only by the forward connection.

During the return stage, the pressure in the piston plunger is lower and the fluid is conducted, from the reservoir, through the pipes passing through the retention valve 2 to the inner chamber of the piston. Valve 1 closes at this stage, allowing the fluid to return to the reservoir only by the return connection.

With all this scope, the pulsed flow bench was developed over a chassis, where all other subsystems were coupled. Thus, so that the system did not suffer any damage or vibrate during the tests, a rigid, lightweight structure was used that allowed regulation, as shown in Figure 3.

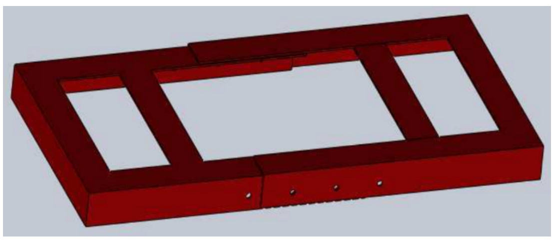

Figure 3. Structural Subsystems of the Bench.

The pulsatile flow generator of the bench was obtained from the development of a connecting rod crank system that turns the rotating movement of the engine into alternative rectilinear movements. For the manufacture of this system, ABNT 1020 steel was used, as well as bronze bushings at the joint points. The use of phosphorous bronze is justified because in these joint points continuous rotational movements and constant friction between the joint pin are produced.

The alternative linear movement of the system originates in a continuous current electric motor that transmits the rotation movement to the eccentric-rod set that turns it into alternative rectilinear motion. The engine rotation is variable and controlled by means of a potentiometer, this function allows during the tests, to change the number of cycles per minute. The engine chosen was the micro planetary gearbox with motor - 107-KR2, with a vacuum rotation of 112 rpm and a torque of 15.6 kgf·cm.

Figure 4 presents the assembly of these elements in an exploded view.

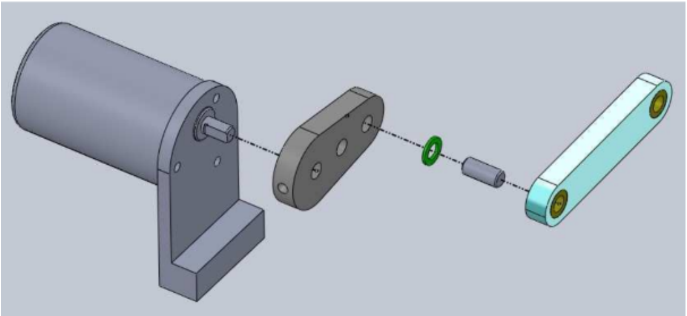

Figure 4. Exploded view of the eccentric-rod assembly.

To ensure that the fluid circulation goes all the way in a single direction and without high pressures at certain points of the system, the pipes were scaled out from the piston with a diameter of 16 mm to a diameter of 5 mm at the test points.

According to ASTM 2477-7, for tests on stents the temperature of the fluid must be 37°C ± 2°C, and fluid pressures during tests must be between 80 and 160 mmHg. Subsequently, temperature sensors (B-class platinum thermal resistance) and pressure sensors were used to monitor these data, as well as a system for counting the number of motor cycles. It is worth noting that all the sensors on the bench were calibrated.

Figure 5 shows the design location of the sensors.

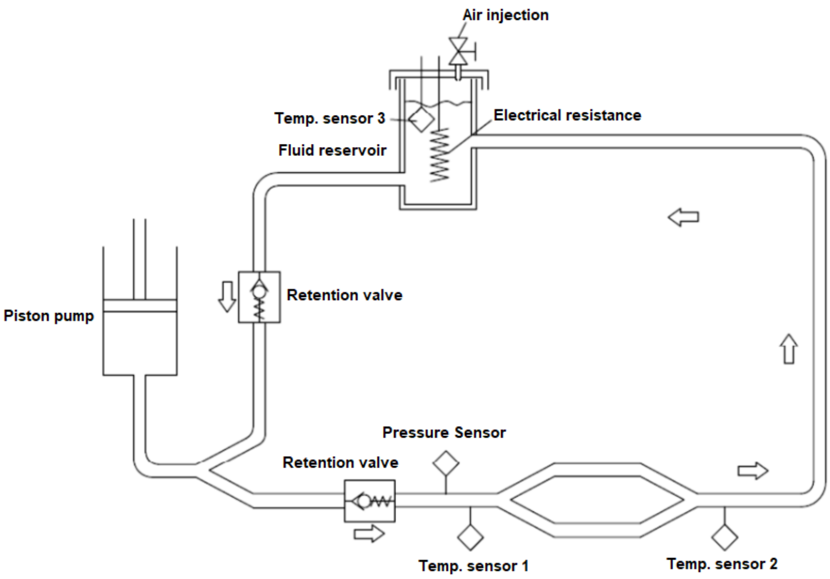

Figure 5. Location of sensors.

The entire monitoring system, illustrated in Figure 6, was developed to enable data control through a software called MaC, in C++ programming language. The software communicates with the bench control system via Raspberry via a local LAN network, allowing remote monitoring in a virtual environment.

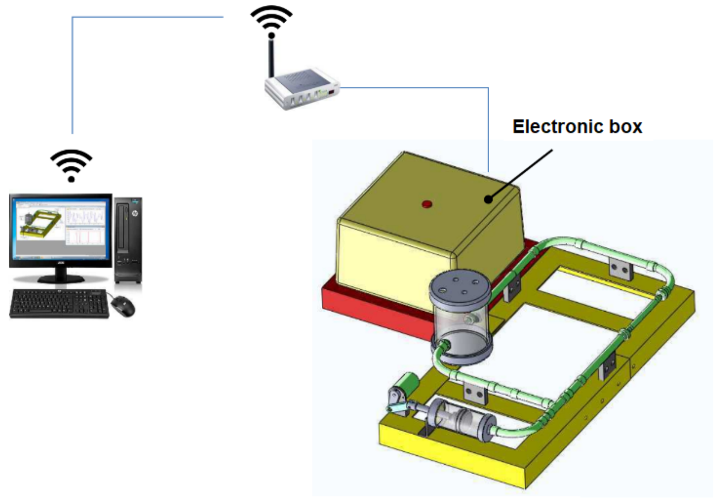

Figure 6. Communication between the bench and the monitoring software.

3. RESULTS AND DISCUSSIONS

Figure 7 shows the charts of pressure, temperature and beats per minute that are obtained from the values read on the sensors installed on the bench.

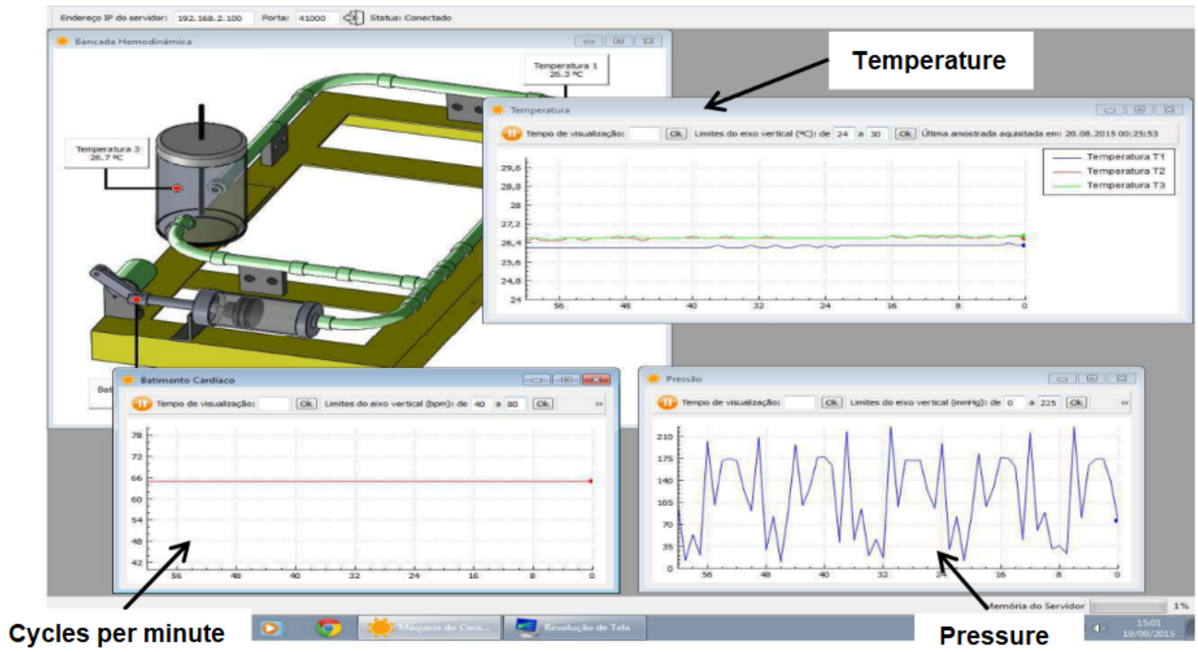

Figure 7. Monitoring software with graphics.

With the experimental bench and monitoring system properly constructed, general tests in the system were carried out in order to assess the behavior of the mechanical system as a whole, the fluid flow in the pipes and in the reservoir, as well as to evaluate the monitoring and data acquisition system, with the following parameters:

- Fluid: Water at ambient temperature
- Reservoir: Open – depressed system
- Test time: 15 minutes in each cycle
- Cycles per minute: 50 and 60 bpm

During the tests, the bench showed satisfactory behavior throughout the test with a uniform rotation of the engine without significant variations in the number of cycles, as well as without abnormal heating.

Figure 8 shows the cycle of 50 beats per minute that during most of the trial varied between 50 and 52 bpm, but it is understood that at some points there was a greater variation (49 e 54 bpm).

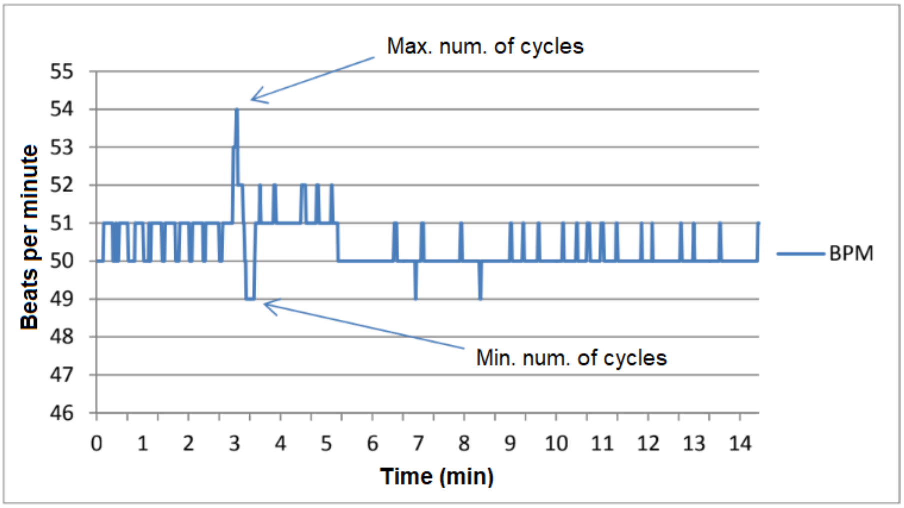

Figure 8. Beats per minute cycle graph (50 bpm).

The results obtained for a 60 bpm cycle are shown in Figure 9. It is noted that the experiment varied between 59 and 60 bpm during the first 9 minutes, however, similar to what occurred for the 50 bpm cycle, there was a greater variation (58 and 61 bpm) at some points of the trial. Variations in the 50 bpm and 60 bpm cycles occurred due to the instability of the laser responsible for the movement reading of the pulse generator. Such uncertainty was resolved after adjustments in the fixation of the pulse reader.

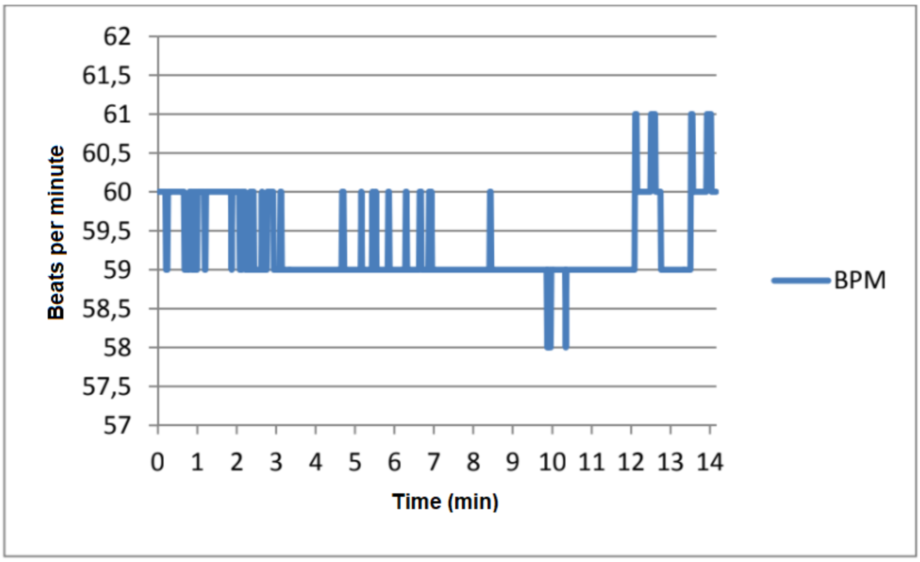

Figure 9. Beats per minute cycle graph (60 bpm).

Figures 10a and 10b show the behavior of the fluid pressure during the test at 50 and 60 bpm, respectively. In both cases, the behavior is acyclic, with pressures ranging from 0 to 220 mmHg. This is due to two factors: the first is the fact that the reservoir is open, with no initial pressure in the fluid. Therefore, there is a force exerted by atmospheric pressure on the water column, causing an oscillation in the fluid pressure. The second is that during the return movement of the piston, a vacuum is generated in the pipe, causing the pressure oscillation to increase. This vacuum can be eliminated by sealing the reservoir and setting an initial pressure.

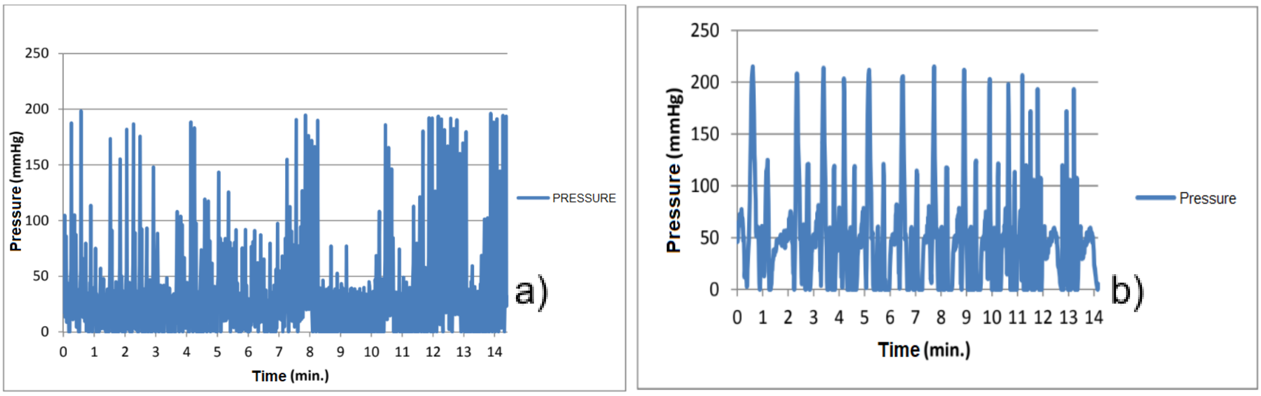

Figure 10. Graph of fluid pressure for a) 50 bpm and b) 60 bpm.

Figure 11 shows the temperature variation during the test with the reservoir open and the system depressurized. The T1 and T2 sensors are positioned before and after the place where the test body should be inserted. The temperature variation observed on sensor 1 was between 23.9 °C and 24.3 °C. T2 had a variation between 24.2 °C and 24.5 °C.

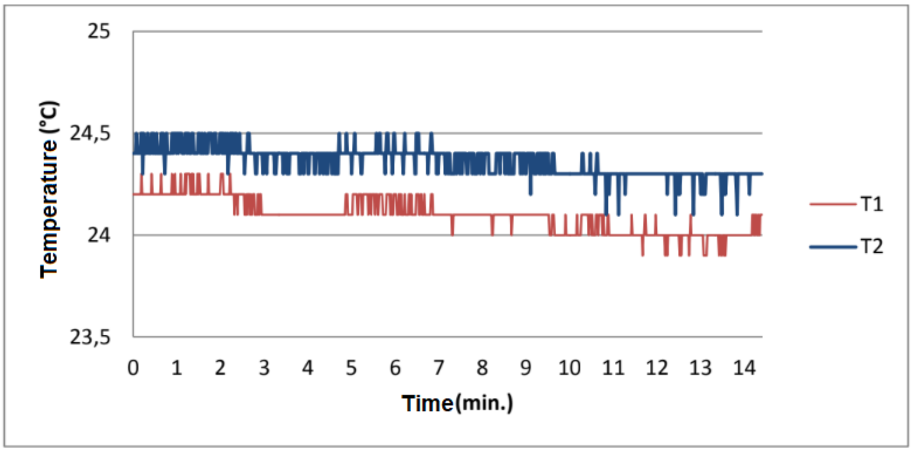

Figure 11. Graph of fluid temperatures (T1 and T2) for 50 bpm.

In the cycle of 60 beats per minute, illustrated in Figure 12, T1 showed variations between 27.1 ºC and 27.4 ºC. While the temperature sensor 2 showed a variation between 27.3 ºC and 27.7 ºC.

Considering that the accuracy of the instruments is 0.6 °C, it can be said that the values obtained for the temperatures are within the precision tolerance. This finding validates the temperature sensors and their application on the bench.

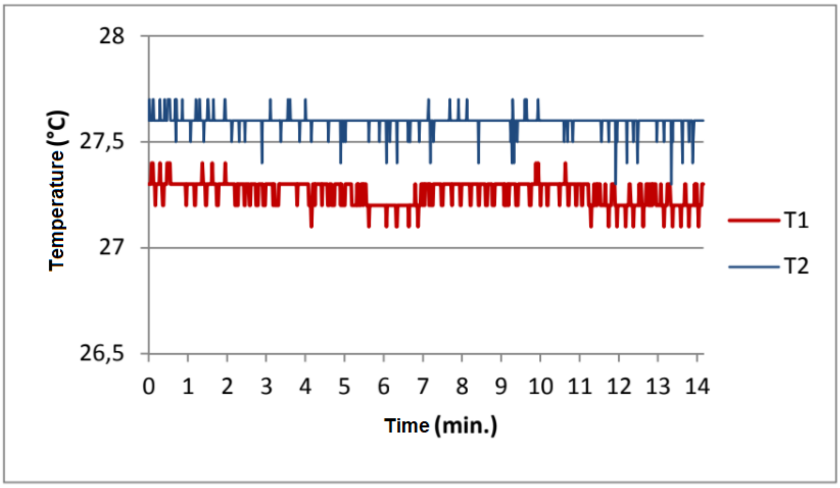

Figure 12. Graph of fluid temperatures (T1 and T2) for 60 bpm.

4. CONCLUSION

Based on the results obtained, we can conclude that:

It was possible to develop a low-cost experimental pulsed flow bench with control of pressure, temperature and beats per minute, presenting all the technical data and specifications, with a didactic and easy-to-operate interface. In addition, the bench can be configured for various other test situations making only small adjustments, such as using continuous flow by just replacing the pulse generator with a continuous generation system.

The monitoring software was able to collect pressure, temperature and cycle data per minute, allowing simultaneous graphics to be generated for the operation of the bench, and can be monitored remotely via the Internet at locations far from the testing.

Finally, it was possible to simulate empty pulsatile cycles (without proof body) with pressure variations between 0 mmHg to 220 mmHg in 15 minutes of testing. The behavior of the number of cycles per minute was satisfactory, showing, on average, variations of 2 bpm over 15 minutes of testing. During the test, on the experimental bench developed, the heating system worked properly with variations of up to 4 °C.

5. ACKNOWLEDGEMENTS

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7. RESPONSIBILITY NOTICE