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Study and development of a flow control system adapted to the physiological level for a ventricular assist device

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Abstract. Heart failure (HF) is a syndrome that makes the heart unable to pump blood at physiological levels. The most recommended treatment for a patient with advanced HF is heart transplantation, although this is limited by the number of donors. Alternatively, Ventricular Assist Devices (VADs) can be used clinically to mitigate this limitation. The rotary-type VAD is the most widely used today and is a device that requires improvement, since it can develop complications, such as thrombus formation and gastrointestinal bleeding, among other examples. The aim of this work is to develop flow control techniques adapted to the patient's physical demands, by analyzing the functioning of a clinically tested physiological controller for VADs, which is based on detecting the patient's physical activity levels by varying the heart rate to adjust the VAD flow and prevent side effects. The speed control module inspired by the evaluated controller was thoroughly implemented according to the literature studied in a computer environment using the Dev C++ and Google Colab programs. The performance results obtained were studied in detail. Changes in the patient's cardiac status were able to influence the speed control of the VAD pump.

Keywords. Heart failure, Ventricular Assist Device (VAD), Physiological control system.

Introduction. Heart failure (HF) is a clinical syndrome that affects 23 million people worldwide, with a 46% increase expected by 2030 (2). It is caused by structural or functional cardiac alterations that makes the heart unable to pump blood to the body at physiological levels, or only to do so under high filling pressures (4). Brazil is one of the countries with the highest mortality rate from HF, which represents the main cause of hospitalizations in the Sistema Único de Saúde (SUS) and generates a cost of approximately R$ 3 billion to the health service (2).

The most recommended treatment for HF in severe cases is heart transplantation, but the national demand is greater than the number of hearts donated (1). As an alternative, the use of Ventricular Assist Devices (VADs) may be indicated. These are blood pumps implanted next to the heart, whose motor is driven by a controller responsible for programming the device's settings (3). They work by providing support to the deficient ventricles, with the aim of maintaining organ perfusion, although this can be improved, as they have a direct impact on the patient's quality of life (7).

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One of the problems that makes it difficult to adapt to VAD is the inefficiency of the process of regulating the pump's blood flow according to the patient's physiological demand, as the adjustment can only be made during regular consultations with the doctor (9). The reduction in the device's preload sensitivity by at least three times compared to that of a healthy ventricle can also be mentioned, as this is caused by the pump operating at a constant speed and it increases the risk of possible venous suction or congestion (9).

Vollkron et al. (2005) developed a physiological control system for VADs that overcomes these limitations, based on the idea that automatic adaptation of pump output in response to changes in circulatory status can improve preload sensitivity and supply organ perfusion during exercise. As it is the only clinically tested physiological control system, this work was based on analyzing and reproducing the VAD pump speed adjustment module developed by him.

Main text. The project began with a study of the academic literature on control systems for VADs, adapted to the physiological demands of the patient. The article "Development of a Reliable Automatic Speed Control System for Rotatory Blood Pumps", by Vollkron et al. (2005), was the main one selected for study. The focus of the control system developed is to make the blood flow adaptable to the patient's venous return and physical activity, using only proven stable signals and sensors and with minimal need to determine specific parameters of the axial-type VAD.

To do this, the controller monitors venous return from the right ventricle and checks the maximum amount of blood that can be pumped from the left ventricle without causing side effects. Possible side effects are ventricular suction, pulmonary congestion, and blood reflux.The venous return is then compared with the level of perfusion required to establish the desired flow, based on the patient's heart rate. The heart rate, in turn, is constantly monitored using a hospital parametric meter, which is responsible for representing the heartbeat of the heart. Finally, the system seeks to give the blood flow a pulsatility, defined as the difference between the maximum and minimum value of blood flow in a cardiac cycle, at a target value of approximately 1.5 to 2.5 l/min and this value is called the P2P value.

The physiological controller can ascertain the effectiveness of changes in pump speed, energy consumption and pulsatility by integrating four interconnected functional blocks: Closed loop controller, Speed variation 1, Suction correction system and Speed variation 2. The interaction of these four units is shown in figure 1:

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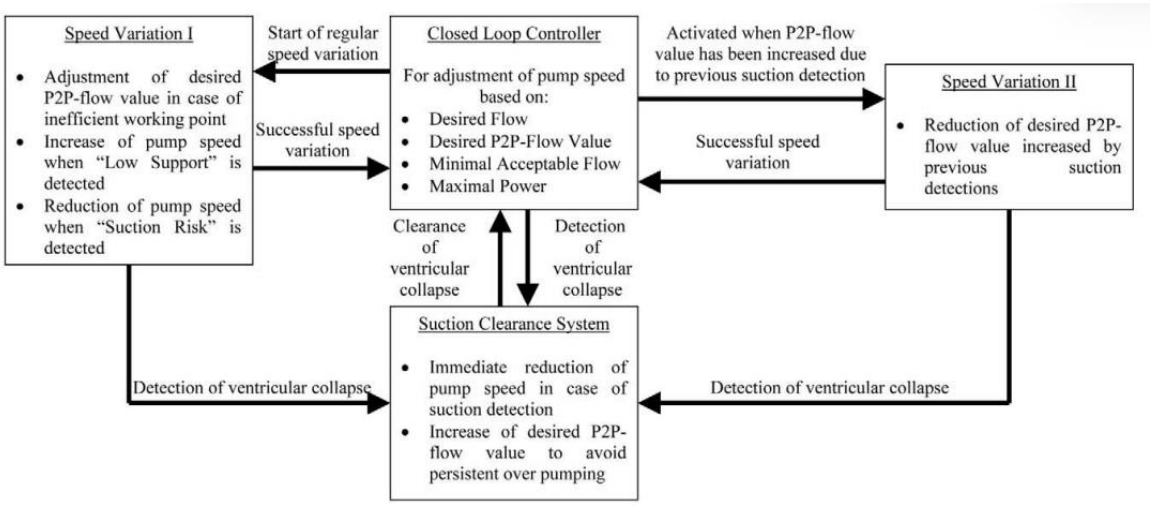
Figure 1 - Interaction of the four logic units of the physiological controller (Vollkron et al. (2005)).



The unit that analyzes the heartbeat to detect possible ventricular suction is the Suction Correction System. It operates using an algorithm trained with 1,196 detection parameters and, if suction is detected, the unit modifies the pump's rotation speed and adjusts the P2P value to stop the suction.

The Speed Variation 1 block is responsible for adjusting the desired P2P flow, in case the current P2P flow is not meeting the patient's demand. It indicates a possible change in physical state (rest, movement or normal state). If low support has been detected by the Closed Loop Controller, the Speed Variation 1 unit increases the pump speed and, if the Suction Correction System detects a possible risk of suction, the pump speed is reduced.

Finally, the Speed Variation 2 unit only acts on the system when suction is detected. Its role is to determine when it is possible to decrease the pump's P2P flow value, due to the fact that when suction occurs it is increased by the Suction Correction System.

The Closed Loop Controller is the unit responsible for selecting the appropriate pump speed values based on flow proportional to heart frequency (Xflow), ideal flow pulsatility (XP2P), pump power (XPower) and minimum acceptable flow (XMinimumFlow). The closed-loop controller simulator was developed in the Dev C++ and Google Colab programming environments, in the C++ and Python languages respectively. The simulator will be presented in the flowchart below, with the appropriate access links in C++ (5) and Python (6).

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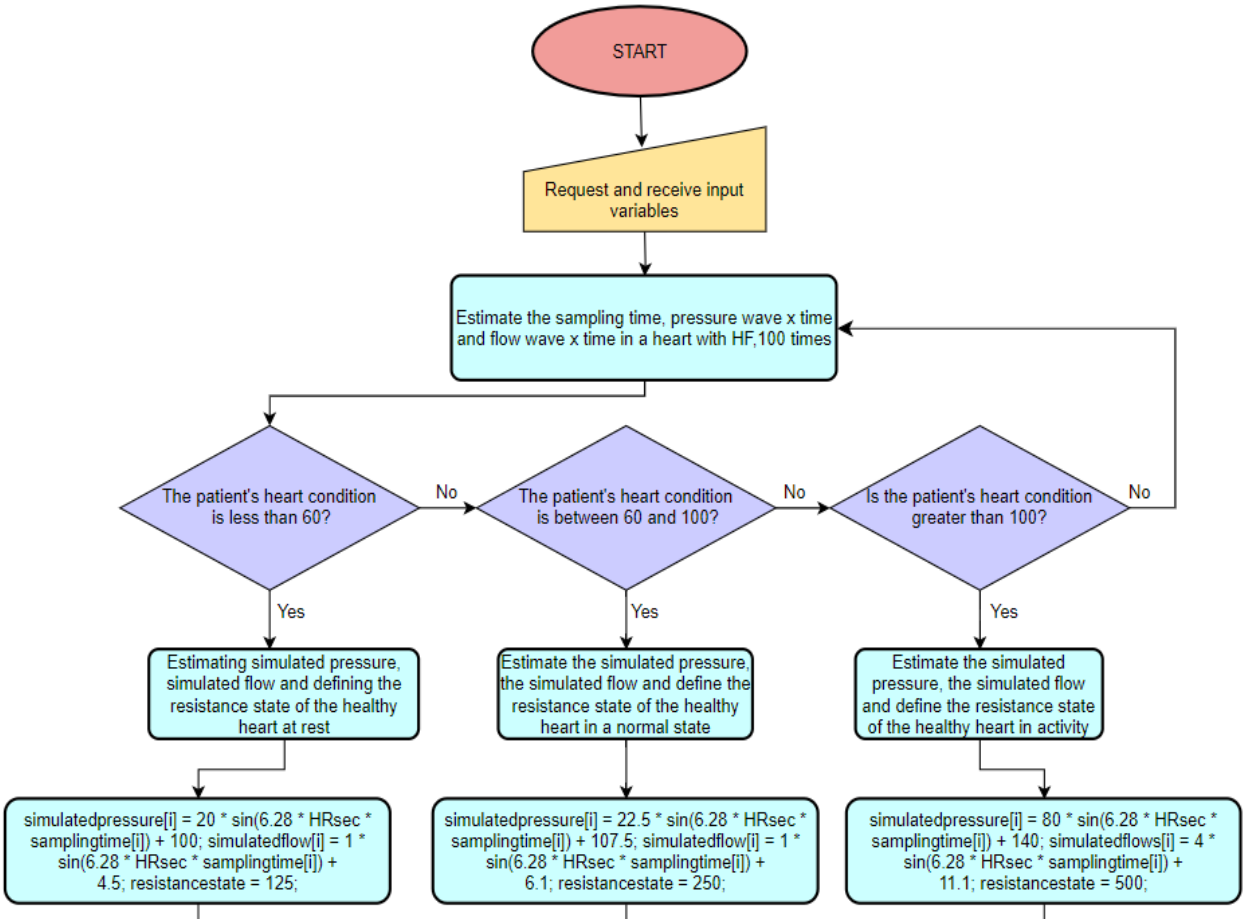
Figure 2 - Stage 1 of the developed simulator



Initially, the simulator requests the input variables, which are the patient's heart rate and blood flow value at rest and during exercise, the patient's cardiac status, blood flow status, maximum power, and desired P2P flow of the pump. It then estimates the sampling time for a reading of 100 intervals of a heartbeat, to facilitate visualization in the program interface.

Based on a sinusoidal function of the type:

$$F(t) = A * Sin\ (2* \boldsymbol{\pi} * f * t\ ) + B$$

Where F(t) is the heart pressure varying over the sampling time, A is the amplitude of the wave, π is the constant responsible for ensuring the visualization of a cycle, f is the frequency that the doctor initially entered, t is the sampling time and B is where the beat begins, the system estimates the variation in pressure and blood flow over time in a cardiac cycle of a heart with HF. The difference between the two waves lies in the values of A and B, which are determined according to real intervals of flow and pressure.

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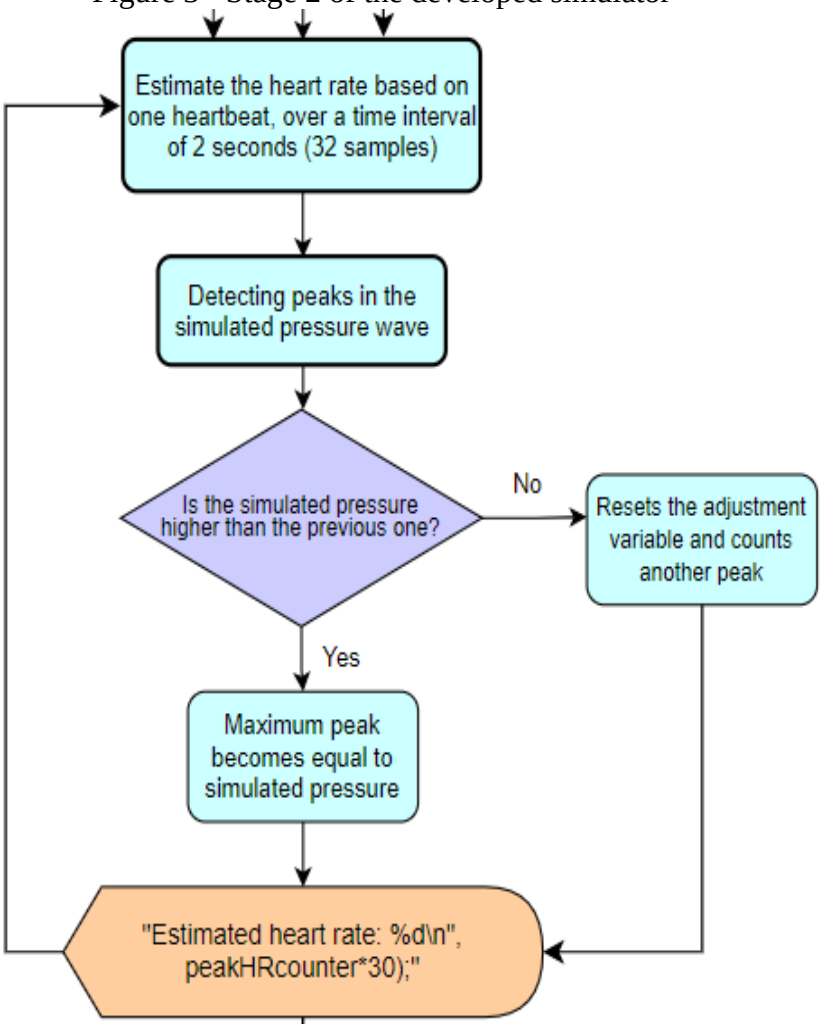
According to the patient's cardiac condition, the actual pressure and blood flow of a healthy heart is estimated using the sine function explained above, with A and B set based on actual flow and pressure values in a healthy heart. The patient's resistance is also set based on real values.

Figure 3 - Stage 2 of the developed simulator



Considering that there are patients with a heart rate of approximately 30 bpm and that this variation can be perfectly visualized in a 2-second interval in a cardiac cycle, it was stipulated that the patient's heart rate should be monitored every 2 seconds that means every 32 points of the 100 intervals defined in the sampling time. To determine the heart rate, the system then detects the maximum peaks of the pressure wave per time.

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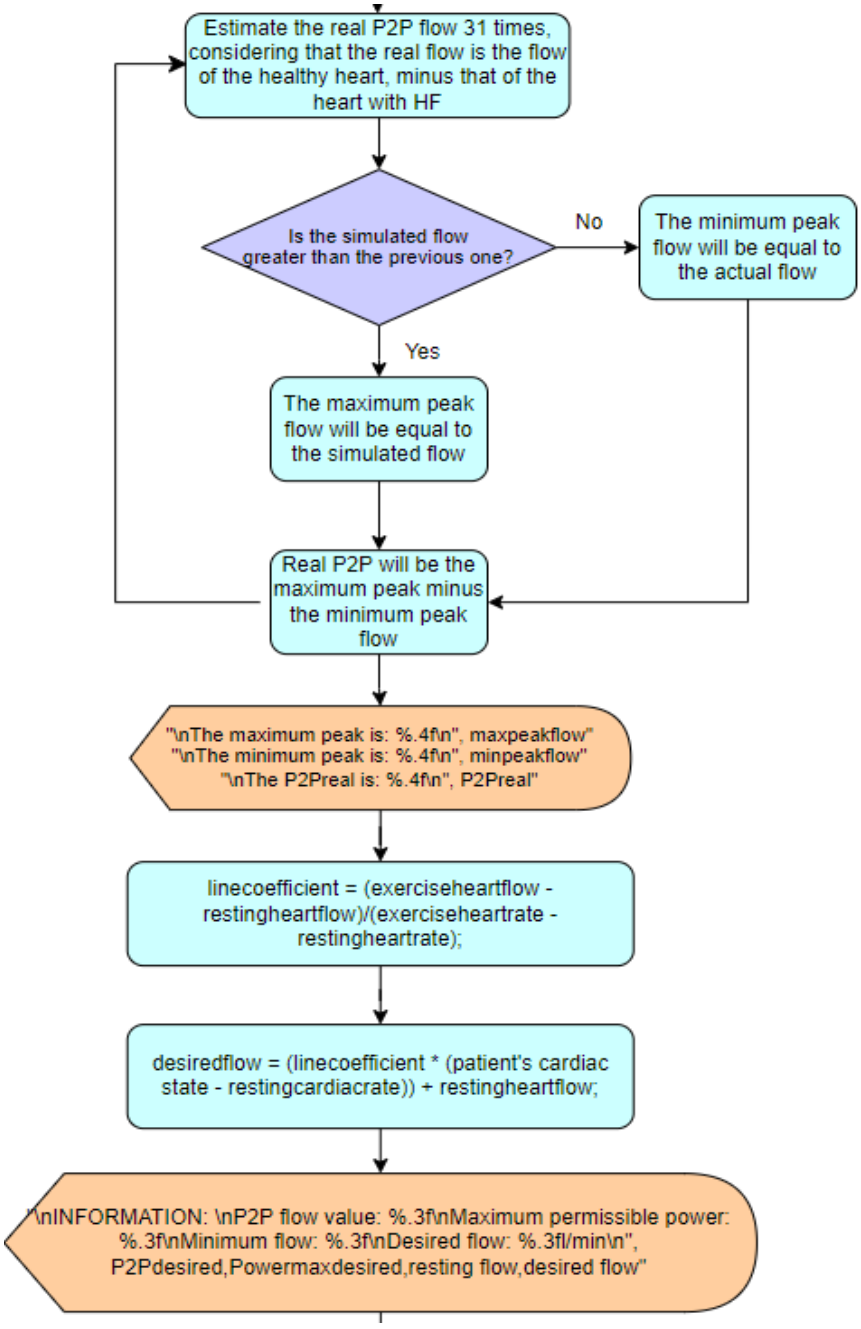
Figure 4 - Stage 3 of the developed simulator



In an interval of 32 points, defined in the previous step, the patient's real blood flow is calculated by subtracting the blood flow of a healthy heart from that of one with HF. After this, the system simulates real P2P flow by detecting the maximum and minimum peaks of real blood flow and subtracting the 2 values. Then, using equations 1/2, the desired flow within the VAD is stipulated.

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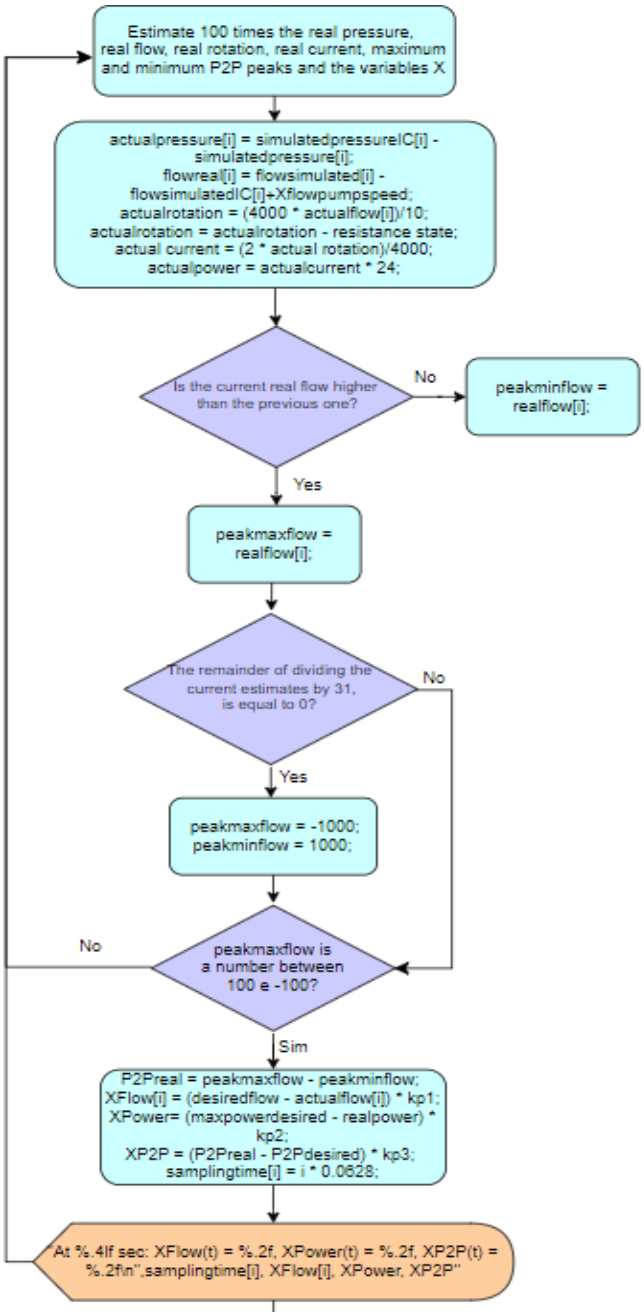
$$Line\ Coefficient = \frac{(heart\ flow\ during\ exercise\ - heart\ flow\ at\ rest)}{(heart\ rate\ during\ exercise - heart\ rate\ at\ rest)} \quad 1$$

$$Desired\ blood\ flow = (line\ coefficient\ *\ (patient's\ heart\ condition\ - resting\ heart\ rate)) + resting\ heart\ flow \quad 2$$

Figure 5 - Stage 4 of the developed simulator.



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The next step is to determine the patient's actual pressure by subtracting the pressure of a healthy heart from that of a heart with HF. The actual blood flow is summed with the variation in pump speed flow, for control power reasons, and the actual speed of the VAD pump is defined initially on the basis of equation 3 and subsequently on the basis of equation 4.

$$Actual\ rotation = \frac{(4000 * actual\ flow)}{100} \quad 3$$

$$Actual\ rotation\ = (Actual\ rotation\ -\ patient's\ resistance\ state) \quad 4$$

The values 4000 and 10 come from a known relationship between rotation per minute and liters of blood passing through the pump. The actual current of the VAD is defined using equation 5 and the actual power using equation 6, also based on known relationships between rotation, current and power.

$$Actual\ current\ = \frac{(2 * Actual\ rotation)}{4000} \quad 5$$

$$Actual\ power\ = Actual\ current\ * 24 \quad 6$$

The maximum and minimum peaks of the P2P Flow wave are detected and the subtraction of the maximum peak from the minimum refers to the patient's actual P2P Flow. Following the schematic of the Vollkron et al controller, shown in figure 6, the Xflow, Xpot and XP2P values are established.

Figure 6 - Schematic of the closed-loop controller (Vollkron et al. (2005)).

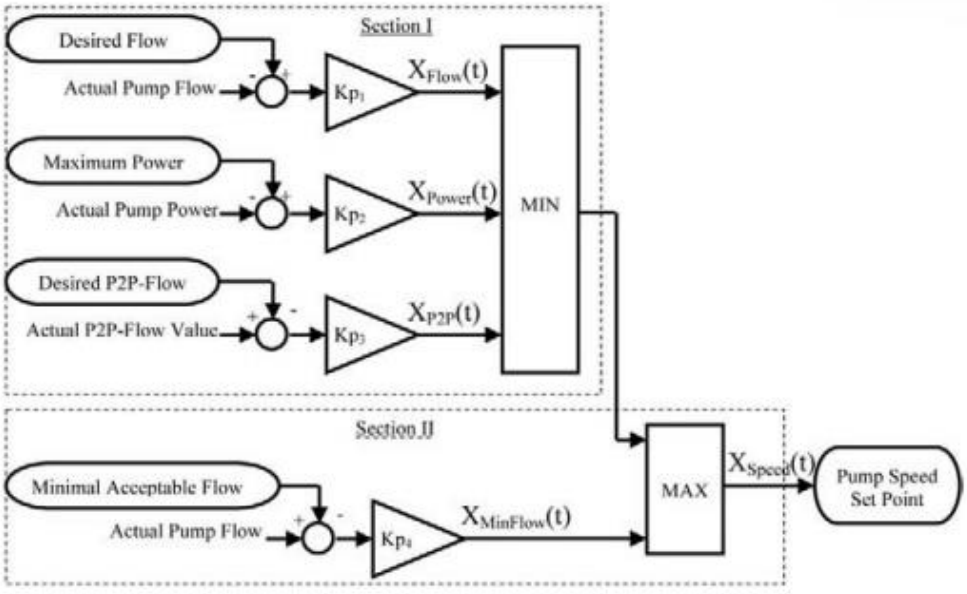

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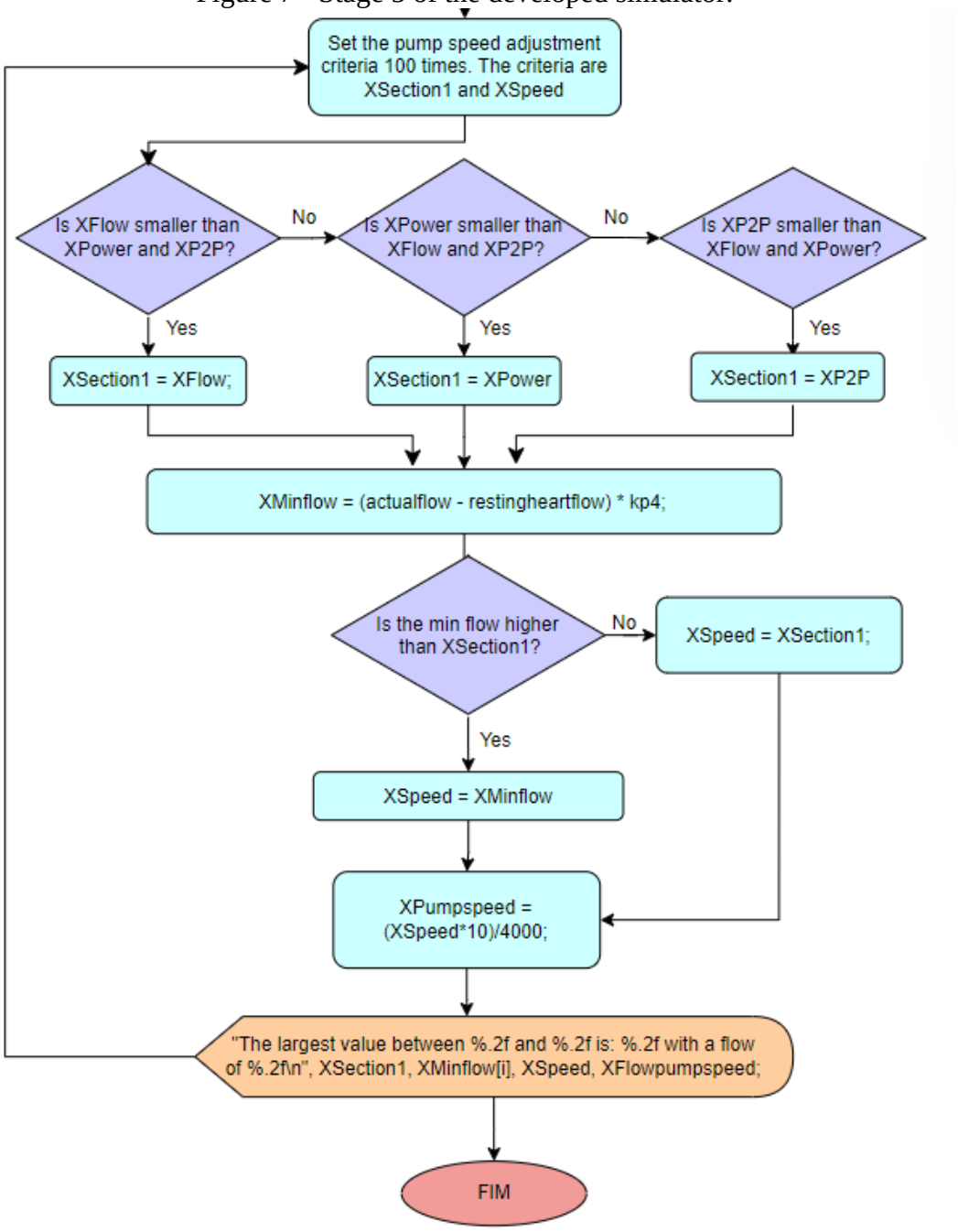
Figure 7 - Stage 5 of the developed simulator.



According to the diagram in figure 6, the system regulates the speed of the VAD pump by selecting the lowest value between Xflow, XP2P and Xpower, according to section 1, and then selects the highest value between the selected value and the minimum flow, which is the difference between the actual flow and the flow of the heart at rest, multiplied by an experimentally defined gain.

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Results and Discussion. After studying and analyzing the control system proposed by Vollkron et al., it emerged that the speed control of the VAD pump is based on the integration of four interconnected functional blocks: Closed loop controller, Suction correction system, Speed variation 1 and Speed variation 2.

The closed-loop controller is the unit responsible for controlling the VAD's quality (Xflow and Xpower) and safety (XP2P and XMinimumFlow) variables. The quality variables ensure that the VAD delivers a blood flow proportional to the patient's physiological demand, operating at the power needed to recover the weakened heart. The safety variables, meanwhile, ensure that the patient's life is not at risk with the implanted VAD, by acting against the occurrence of any suctions or blood reflux.

XP2P is the variable responsible for indicating the occurrence of possible ventricular suction, since its value depends on the pulsatility of the implanted patient's blood flow. Pulsatility, in turn, is given by the difference between the maximum and minimum values read for blood flow and, therefore, if it results in 0 it means that all the blood that was in the ventricle is flowing into the VAD and ventricular suction is occurring.

From the moment the P2P value is 0, the system detects suction and XP2P results in a negative value, remembering that it is given by the difference between the actual P2P and the desired P2P. Therefore, as shown in figure 6, XP2P is quantified with a value lower than that of XFlow, Xpower and higher than that of XMinimumFlow to be chosen as a criterion for adjusting the pump speed and correcting suction. This situation can be better observed in figure 8, obtained from a simulation of the controller.

The figure shows the variables used to adjust the VAD's speed control (XFlow, Xpower, XP2P and XMinimumFlow), the speed chosen (Xspeed) and the pump's output blood flow (Flow) resulting from the new speed selected, over a time interval of 6.28 seconds, which corresponds to one cardiac cycle, equivalent to 2 * π radians. The variables not selected are shown in dashed lines.

XMinimumFlow represents the sum of the minimum acceptable flow and the actual pump flow and its main function is to indicate the occurrence of blood reflux. This is because a high minimum flow value indicates that there is little blood being sent to the VAD and that it is therefore being refluxed into the heart due to the low resistance created in the pump. If its value is higher than XFlow, Xpower and XP2P, it is chosen as the speed adjustment criterion, as showed in figure 9.

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Figure 8 - Suction protection graph

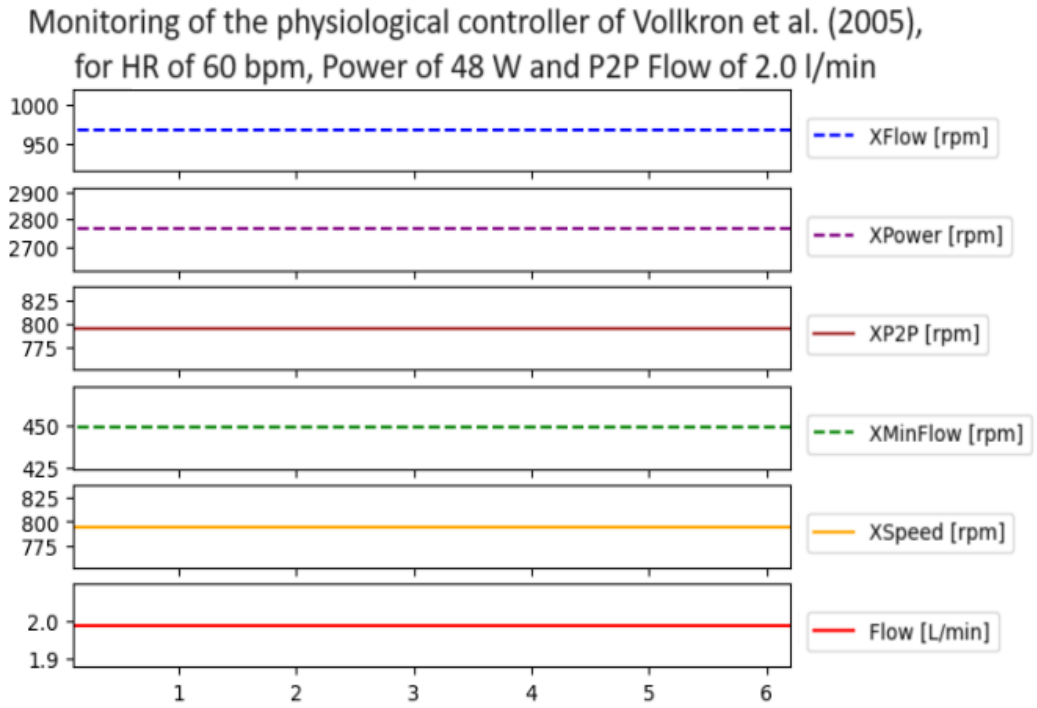

Figure 9 - Blood reflux protection graph.

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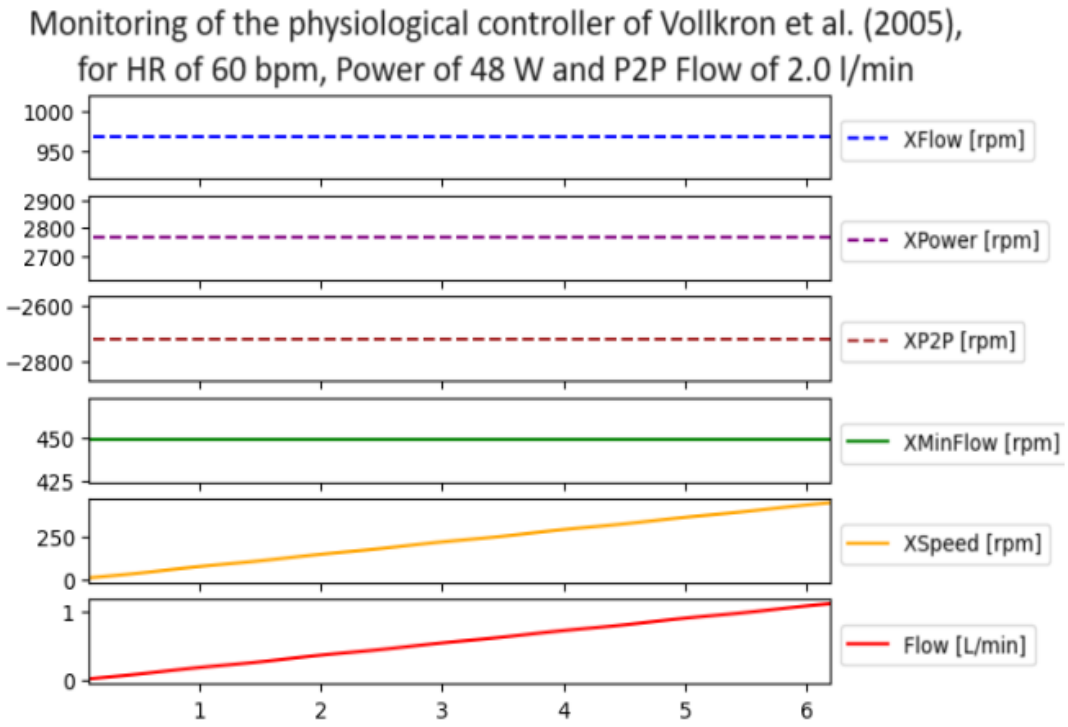

There are situations, such as the one shown in figure 10, in which the correction to prevent ventricular suction causes blood reflux. In these cases, the controller chooses to avoid blood reflux, and the behavior of the Xvelocity and Flow lines shows the dynamic nature of the Closed Loop Controller.

Figure 10 - Suction and reflux protection graph

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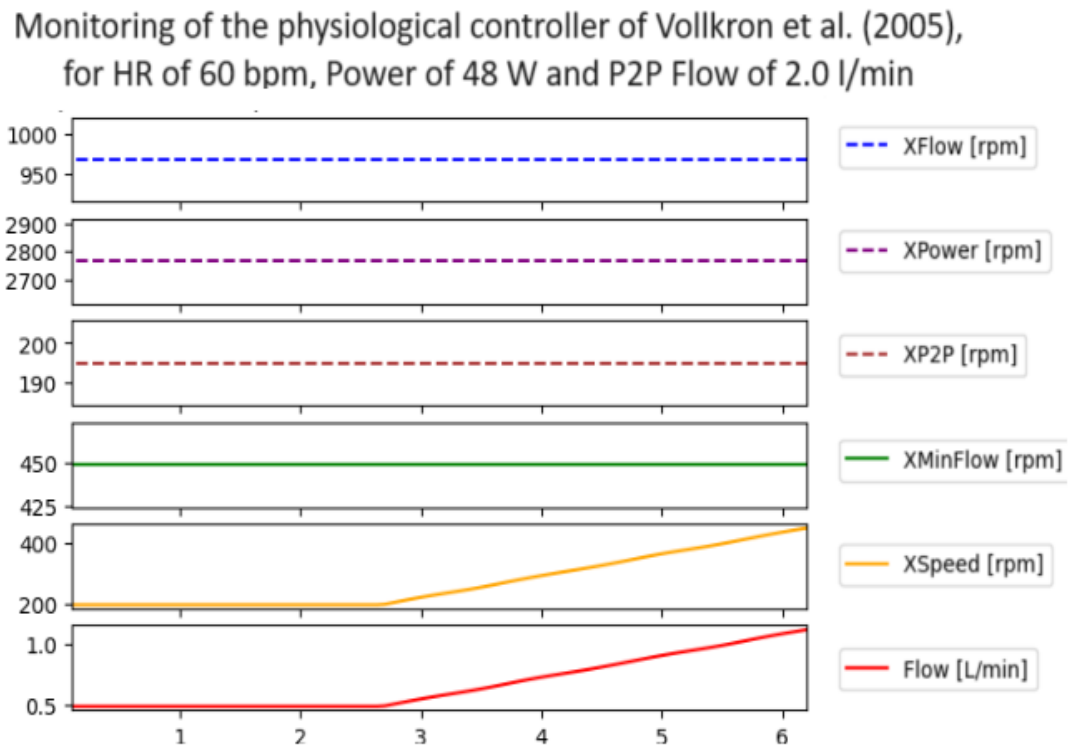

When no ventricular suction or reflux is detected, the XFlow and Xpower variables are chosen as the speed adjustment criteria, since they control the ideal blood flow, according to the patient's physiological demand, and the best operating power for the heart to recover, respectively, contributing to a better adaptation of the patient to the device.

Figure 11 illustrates a situation in which the occurrence of blood suction or reflux is not indicated and the XFlow variable is selected as the pump speed adjustment criterion, because the VAD's blood flow is not proportional to the patient's physiological demand in the cardiac cycle under analysis.

Figure 12 represents a situation in which no blood suction and reflux was detected and Xpower was chosen as the criterion for adjusting the pump speed. This indicates that the VAD support is inadequate for recovery of the weakened heart in the cardiac cycle analyzed.

Figure 11 - VAD quality graph.

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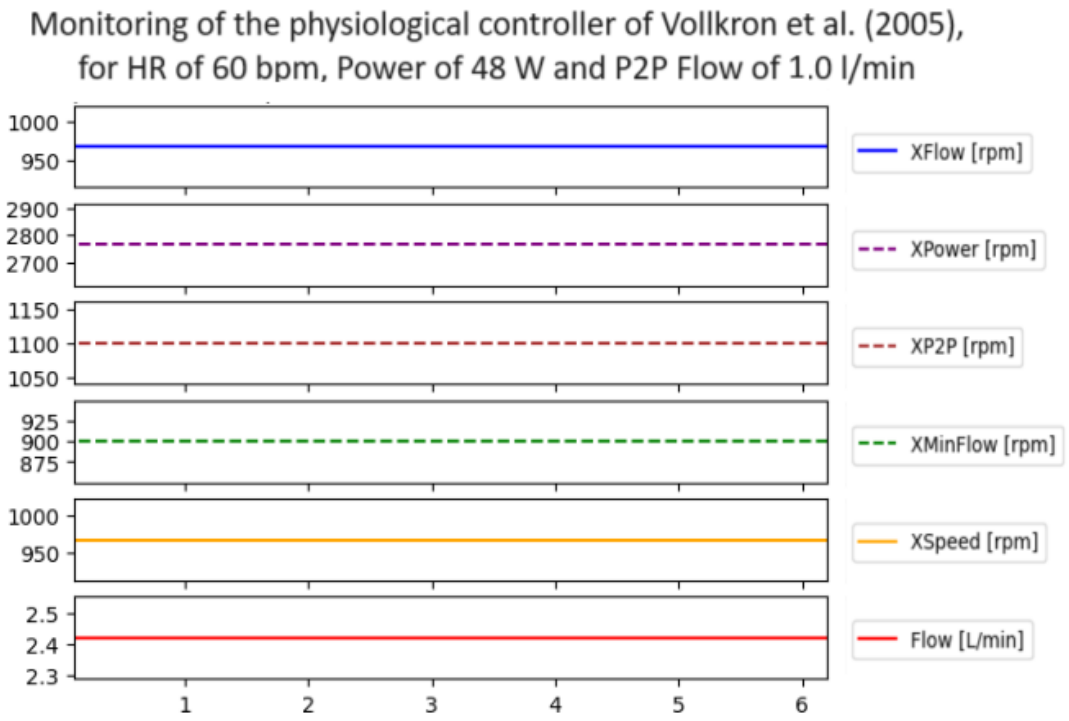
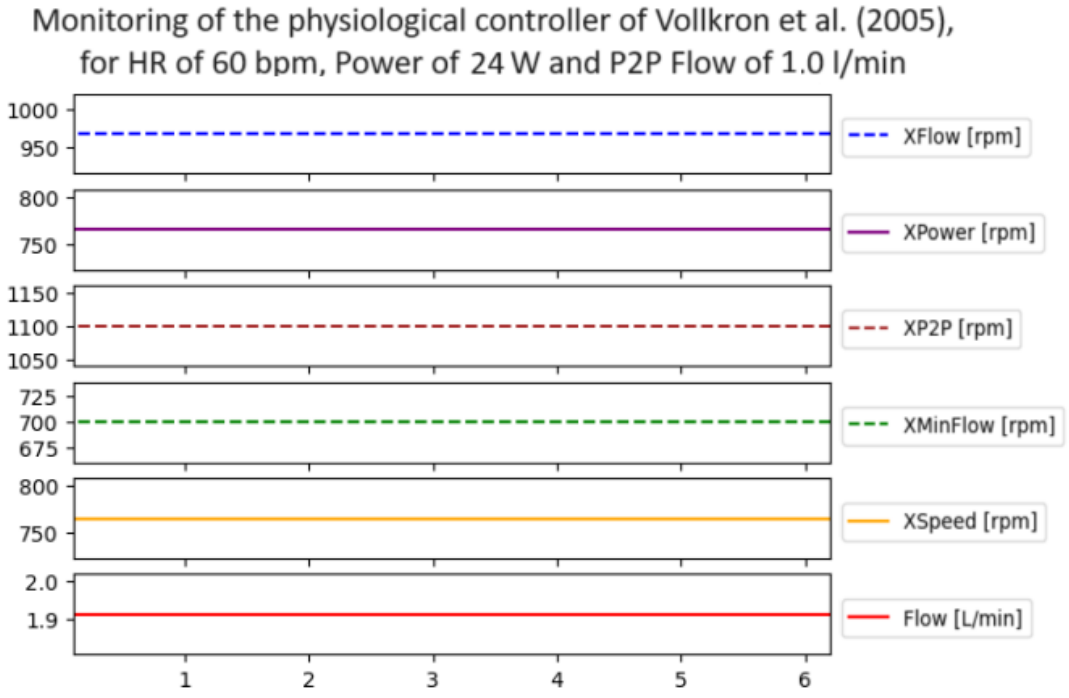


Figure 12 - VAD quality graph.



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Conclusion. The development of this work led to the conclusion that the VAD is a device that needs improvement, given that it directly influences the quality of life of the implanted patient. One way of improving adaptation is to include a physiological control system that meets cardiac demand at different levels of activity. The proposed adapted flow control system by Vollkron et al. proved to be an interesting solution, as it was clinically tested and proved capable of mitigating not only the physiological limitations of the device, but also the risk of suction occurring. This result is due to the development of a mechanism to increase the heart's preload sensitivity, giving pulsatility to the blood flow. The Vollkron et al. controller is made up of four interconnected units, which operate together for the device to function fully. The main unit in this work was the "Closed Loop Controller", simulated in a computer environment using C++ and Python. Simulation results were obtained and showed the influence of changes in the patient's cardiac status on the speed adjustment variables of the VAD pump in a cardiac cycle. In the future, the aim is to incorporate the developed controller into a controller and carry out practical operational tests. As the controller was developed using open source code, it serves as a basis for study and acts as a reference for proposing and developing other physiological controllers.

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