DESIGN, ANALISYS AND VALIDATION OF SUPERVISORY CONTROL SYSTEM FOR VENTRICULAR ASSIST DEVICE

André César Martins Cavalheiro, andre.cavalheiro@usp.br
Diolino José dos Santos Filho, diolinos@usp.br
Paulo Eigi Miyagi, pemiyagi@usp.br
José Roberto Cardoso
Escola Politécnica da USP - Departamento de Eng. Mecatrônica e de Sistemas Mecânicos; Av. Prof. Mello Moraes, 2231, Cidade Universitária, São Paulo – SP.

Aron Andrade, aron@dantepazzanese.org.br
Eduardo Bock, eduardo_bock@yahoo.com.br
Jeison Fonseca, jfonseca@dantepazzanese.org.br
Institute Dante Pazzanese of Cardiology – IDPC – Departamento de Bioengenharia; Av. Dr. Dante Pazzanese, 500, Vila Mariana, São Paulo – SP.

Abstract. *Automation and control are important tools to deploy the interaction between rotary blood pumps (RBPs) and human circulatory system. This interaction is critical for the development of reliable physiological control systems of long-term RBPs. This paper discuss the design and implementation of an supervisory system that will be used to control Ventricular Assist Device (VAD) in cardiovascular system. Mathematical cardiovascular model and a mechanical cardiovascular simulator were used to analisys, test and validate the supervisory control. Tests were done at Institute Dante Pazzanese of Cardiology (IDPC) where is being developed an implantable of long-term centrifugal blood pump that will be able to help a sick human heart to maintain physiological blood flow and pressure. Therefore, improvement on device performance is important to get better level of interaction with patient's behavior or conditions. This work show a mechatronic application approach to this class of devices based on advanced techniques for control, instrumentation and automation to show the results of this devices make VAD control system dynamically, automatically and securely. To confirmed method effectiveness simulation with the interaction between rotary blood pumps and circulatory system are done. By using mathematical model and the physical simulator to simulate in vitro real circulatory properties, this study provides the bench-top test environment for long-term RBPs and their physiological controller.*

Keyword: *Ventricular Assist Device; Safety Instrumented System; Artificial Organs; Blood Pumps; Supervirory Control.*

1. INTRODUCTION

To helps a weakened heart, Ventricular Assist Device (VAD) may be used to auxiliary pump blood. That device is used in several situations like in cases when the patient waiting for heart transplantation or during the period of postoperative recovery. Its application can be performed definitive when the patient has no indication for heart transplantation because of immunological incompatibility, chronic infections, or advanced age. (Dinkhuysen *et al.*, 2007) (Andrade *et al.*, 1999). The VADs systems involve many research areas like electromechanical devices, computer technologies for data collection and data processing, decision making, human-machine interface, and sensing indicators such as blood pressure, blood flow, temperature Body and heart rate (Ohashi *et al.*, 1997). In this sense, automation can help to optimize the resources utilization and to improve devices performance. Thus, this work proposes a development of Ventricular Assist Device (VAD) to aid patient with heart failure to be able to have relatively normal life despite the disease. Figure 1 represents how the VAD interacts with the cardiovascular system.

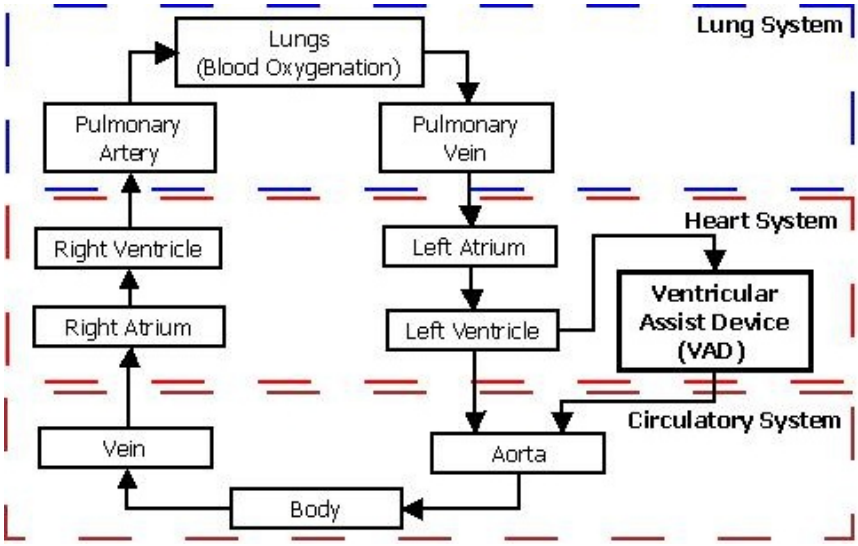

Figure 1 – VAD and cardiovascular system

Therefore this kind of system handles human lives, becomes necessary some precautions on the system project. Then the system shall demonstrate correct and accurate performance; otherwise, if the VAD fail during operation and there is no embedded system that enables the treatment of faults autonomously, serious risks to patient will be inevitable. The other point that must be considered is the patient comfort. Many VADs maintain constant blood flow regardless to patient daily needs (Fonseca *et al.*, 2008), ie, they help blood circulation and do not react properly to changes (Bock *et al.*, 2008). So, if VAD has no faults tolerance and no dynamic behavior according to the cardiovascular system performance serious limitation on results from this application may be observed. This work proposes application of a mechatronic approach based on advanced techniques for control, instrumentation and automation. These techniques allow treatment of fundamental limitations of current solutions. So, we propose a method for specifying a supervisory control system for a VAD that:

• Specify a logic for pump speed control, according to patient's dynamic behavior. Models based on Bayesian networks (BN) (Cooper and Herskovits, 1992) should be applied to diagnose patient's dynamic state, at every moment and to act in VAD control.

• Specify a logic for safety interlock to prevent faults in VAD. We must diagnose the critical states by using BN and implement a diagnosis system by using Petri nets (PN). Once implemented the diagnosis control system, in parallel, should be implemented faults treatment according to specification of safety instrumented functions (SIFs) (Squillante *et al.*, 2010) (Pearl, 1988). These functions must be modeled in PN (Matsuno *et al.*, 2003) for generating the control algorithm for faults treatment.

• Check the mathematical model of supervisory control system according to its interaction with a model of human cardiovascular system (Mona *et al.*, 2010) (Sainte *et al.*, 2006) (Reed *et al.*, 2004).

So, supervisory control system can be implemented and specified for in vitro and in vivo testing in a consistent way.

2. TECHNOLOGIES APPLIED ON VAD CONTROLSYSTEMS DEVELOPMENT

The human body may presents dynamical behavior in which simultaneous evolution of continuous and discrete state variables occurs, ie, Continuous Variable System (CVS) behavior merges with Discrete Event System (DES) behavior (Pearl, 1988). Considering the requirement that VAD needs to perform control functions to adjust pump speed according to changes on cardiac frequency and needs to react against occurrence of critical faults, we proposed a hybrid supervisory control system (Cooper and Herskovits, 1992). Production Flow Schema (PFS) is a technique that can be used to model the set of activities that VAD can perform. The PFS is a bipartite graph composed of activity elements (action, execution), distributing elements (collect, accumulate and/or store information or items) and oriented arcs to connect the elements. Figure 2(a) shows the graphical representation of these elements.

Details of each activity modeled in PFS can be refined using Petri Net (PN) which are capable of representing dynamic behavior of device. As VAD has continuous variables, Hybrid Petri Nets (HPN) are necessary.

HPN model has been introduced as extension of discrete PN model been able to handle real numbers in continuous way and allowing us to express explicitly the relationship between continuous values and discrete values while keeping good characteristics of discrete PN soundly. In HPN model, two kinds of places and transitions are used: discrete/ continuous places and discrete/continuous transitions. A continuous place holds a nonnegative real number as content. A continuous transition fires continuously in the HPN model and its firing speed is given as function on model places. Figure 2(b) shows graphical notations of HPN elements (Matsuno *et al.*, 2003). The refinement of a model generated in PFS for a model in HPN is made based on the procedure adopted in Villani *et al.* (2006).

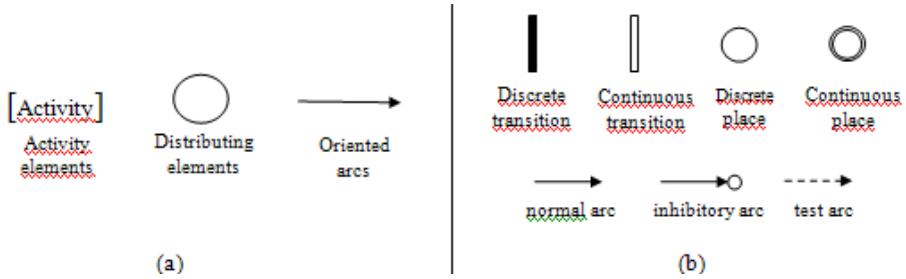

Figure 2 – (a) Production Flow Schema elements; (b) Basic elements of Hybrid Petri Net (Matsuno, 2003)

For modeling of diagnosis and treatment of critical faults, we are using the concept of Safety Instrumented System (SIS) and BN. According to Squillante *et al.* (2010) SIS is a layer of control in order to mitigate the risk or taking the process in a safe state. Definition of faults is made from the identification of Safety Instrumented Functions (SIF). In this way, a SIF describes a critical fault that should be diagnosed and treated by SIS. A SIS implements its SIFs through sensors and devices perform control by actuators. For each SIF a parameter called Safety Integrity Level (SIL) is defined. This parameter is a measurement of safety for components and/or systems. SIL reflects what end users can expect from a device and/or system in a safety function, and in case of fault, this occurs in a safety way. BNs provide formalism for reasoning about partial beliefs under uncertainty conditions. The propositions are as numerical parameters signifying the belief degree according to some evidence or knowledge. So, formally, BNs B = (G; Pr) are made up by a topological structure G and a set of parameters Pr that represents probabilistic relationship among their variables (Squillante *et al.*, 2010) (Pearl, 1988).

Therefore, to develop a design for supervisory control system for VAD, according to the modeling techniques presented above, proposes a method for developing the VAD a supervisory system shown in Figure 3:

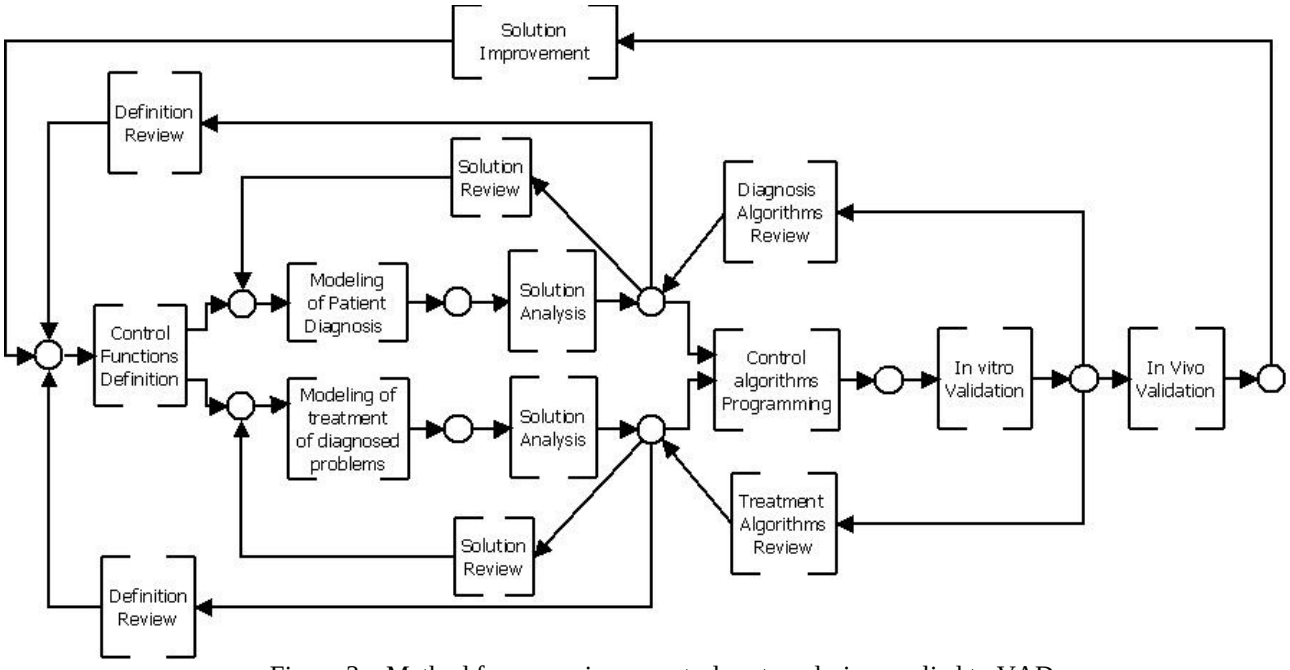

Figure 3 – Method for supervisory control system design applied to VAD;

The sequence proposed aims to organize the activities involved to develop control system design applied to VAD. So, these activities (represented by the elements of the activity model in the scheme proposed PFS) are presented briefly:

- Definition of control functions - A team of doctors and engineers defines the degree of autonomy of VAD control system. The team responsible control system development needs to select ideas that are possible to be implemented taking into account: sensors available, VAD performance characteristics and technological limitations. At this stage, a table with VAD control functions is specified.
- Modeling of Patient Diagnosis – Initially, diagnosis model involves development of a cause and effect matrix, which is basis for a BN. Then, this network can be converted into a HPN model.
- Modeling of treatment for diagnosed problems - From HAZOP (hazard and operability) (IEC, 1998) study the risk analysis report from VAD is obtained. Based on this information, we have the SIF, SIL and events (from sensors)

and actions (to actuators) for each SIF. Next, diagnostic model and corresponding SIFs are modeled in HPN for control system design.

- Solution Analysis – First, structural analysis of HPN model of diagnostic process is made. Next, it is checked if the HPN has no deadlock states (markings where no transition is enabled). For that, a simulator (Drath, 2004) can be used.
- Control algorithm programming - A Programmable Controller (PC) is an essential equipment for implementation of control systems. Consequently, standards have been set for this equipment allowing the reuse of existing software modules and ensuring high quality solutions, especially for conditions that require security methods for verification and validation. Thus, it is necessary to adopt following procedure: generation control program in programming language according to IEC 61131-3 (IEC, 2003), based on conversion of HPN models.
- In vitro validation for control algorithm - Control algorithms can be validated using mathematical model that simulates human cardiovascular system. The entire electrical equivalent of the model is shown in Figure 4. The electronic parameters are correlated to their mechanical parameters as follows: voltage (volt) is analogous to pressure (mmHg), capacitance (μF) to compliance (ml/Pa), resistance (kΩ) to resistance (1 Pa.s/ml), and inductance (μH) to inertance (1 Pa.s2/ml) (Mona *et al.*, 2010). The elements of each artery including one or two resistor, an inducer and a capacitor. Figure 4(a) belongs to the arteries with the radius of less than 0.2 cm and Figure 4(b) belongs to the rest of the arteries. The architecture used to validate VAD control with cardiovascular system presented in Figure 1. Next step is prototype implementation that can be validated by a simulator of cardiovascular system. Currently, the Institute Dante Pazzanese of Cardiology (IDPC) has a programmable mechanical simulator that performs in vitro testing and is able to simulate real situations that can occur in patient's behavior (Andrade *et al.*, 2008).

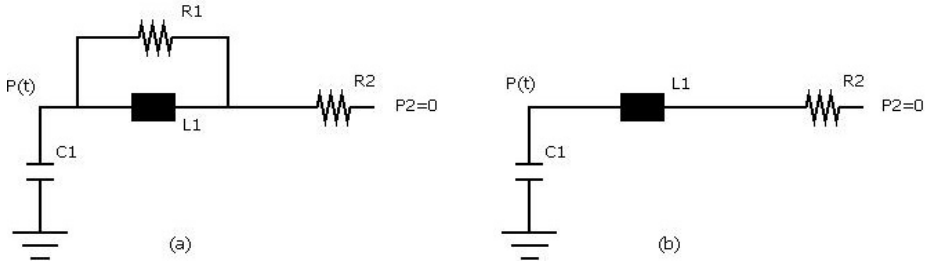

Figure 4 – (a) Electronic elements equivalents arteries with radius less 0.2 cm (b) others arteries.

- In vivo validation for control algorithm - After simulation and in vitro validation of control algorithm, VAD is ready for in vivo tests in calves (Andrade *et al.*, 1999).

Applying this set of procedures, is definition of a method for supervisory control system design is possible and capable to provide changes in VAD rotation speed, according to changes in cardiac frequency of patient, and can improve security and quality of life for patient who needs this type of device.

3. DISCUSSION OF RESULTS AND METHOD CONTRIBUTION

The project of the control system of VAD according to the procedure previously considers:: (i) critical faults from HAZOP study for VAD, (ii) BN for diagnosis and decision, (iii) definition of Safety Instrumented Functions (SIF) using HPN and (iv) modeling of supervisory control system considering discrete and continuous variables of VAD. The result is the logical ordering of supervisory control system functions that are shown in Figure 3 based on PFS formalism (Figure 5). To implement this control system for VAD at IDPC is proposed the architecture according to Figure 6.

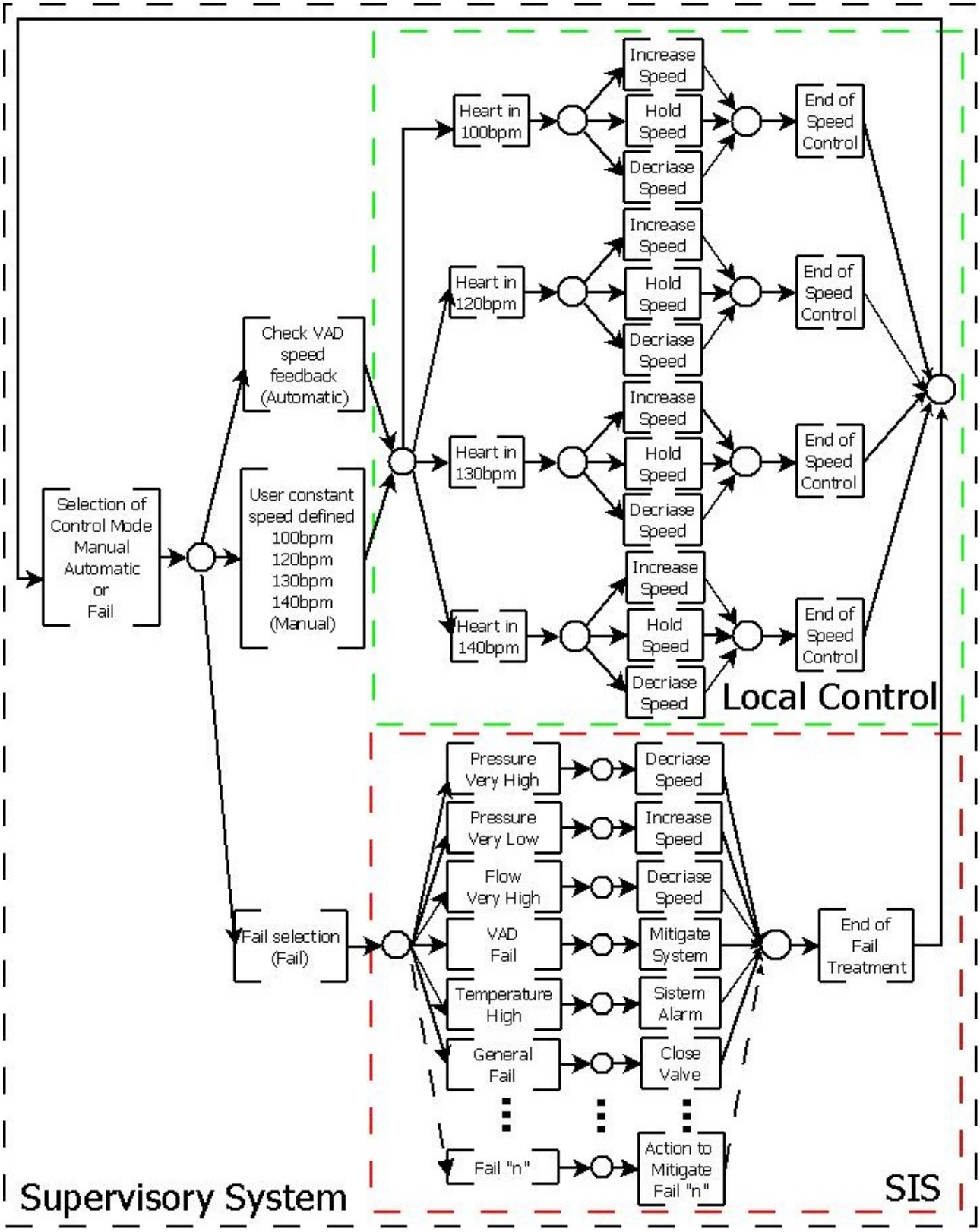

Figure 5 – PFS model to VAD supervisory control system.

According to this work proposal, each activity of model presented at PFS of Figure 5 is represented by a place on HPNs, and the marks can represent local and global states of VAD control system. Transitions are synchronized with human body reactions through adequate sensors. Oriented arcs can define the sequence for control functions processing. Therefore, we apply obtain VAD control algorithm based on proposed method in the proposal control architecture as show in Figure 6.

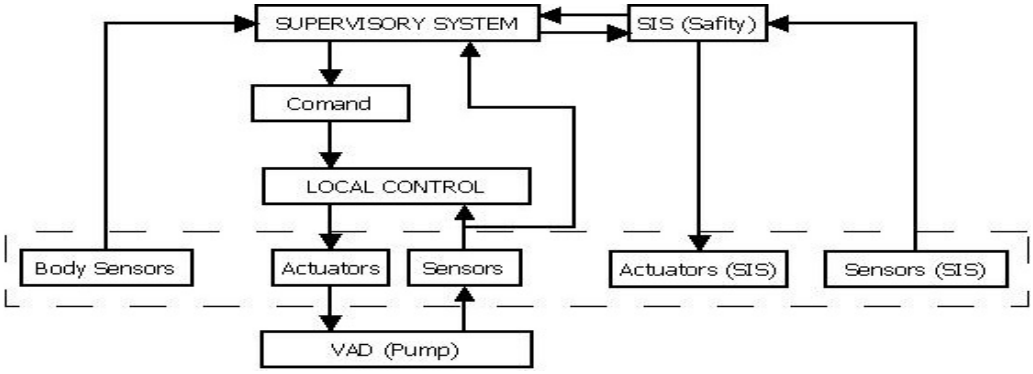

Figure 6 – Control architecture proposed.

Therefore, the control system proposed can improve VAD and can fit patient needs providing a security level and a better patient quality of life and longer survival. Supervisory system can also assist in diagnosis and in interventions to maintain VAD functions.

4. TESTS, ANALISYS AND VALIDATION OF SUPERVISORY CONTROL SYSTEM

A pump blood device should be submitted to extensive testing in vitro before any in vivo study (Yi *et al.*, 2004). Several in vitro tests have been executed to verify the performance of the VAD under different operating conditions. A mathematical model to test was developed to simulate the human circulatory system considering some behavioral characteristics (Mona *et al.*, 2010) (Cavalheiro *et al.*, 2010). The characteristics considered on simulation were a reaction curve of the blood pump and a circuit simulating the oscillation of the patient's heart rate (Bock *et al.*, 2010). This simulation environment was proposed in this paper to analyze the control algorithm conduct generated from the proposed model of the supervisory system of VAD (Figure 5) implemented in the control architecture proposed (Figure 6). The heart rate oscillations on the simulation are make to verify if the control algorithm work properly, changing the blood pump speed appropriately for each case simulated. The reaction curve of the pump implanted in the human body was used to verify that the control system could stabilize the conditions of the cardiovascular system in which the pump will be deployed. This test system was developed at Department of Bioengineering, Institute of Cardiology Dante Pazzaneze to evaluate the VAD under development. Performance tests of the pump control were performed by elevating the heart rate and reaction time constant of the system defined by the mathematical model of the pump inserted into the human body (Bock *et al.*, 2010). We generated several reaction curves for different heart rates to analyze how the control system should operate in VAD Variable Frequency (VF), i.e. automatic control mode. As can be seen in the Figure 7 the system responded as the control model proposed. The red trace shows the heart rates were adjusted in increments starting from 10 beats per minute to 50 beats per minute and reaching a maximum frequency of 180 beats per minute meeting the specifications of the proposed model. The blue trace shows the output of control system changing and controlling the blood pump rotation (0 – 3000 RPM). The green trace shows the blood flow (0 – 5 LPM), considering the pump mathematical model (Bock *et al.*, 2010). In Figure 8 have more detail about automatic speed control, reacting to maintain constant blood flow to the proposed set-poin, regardless of pump load changes.

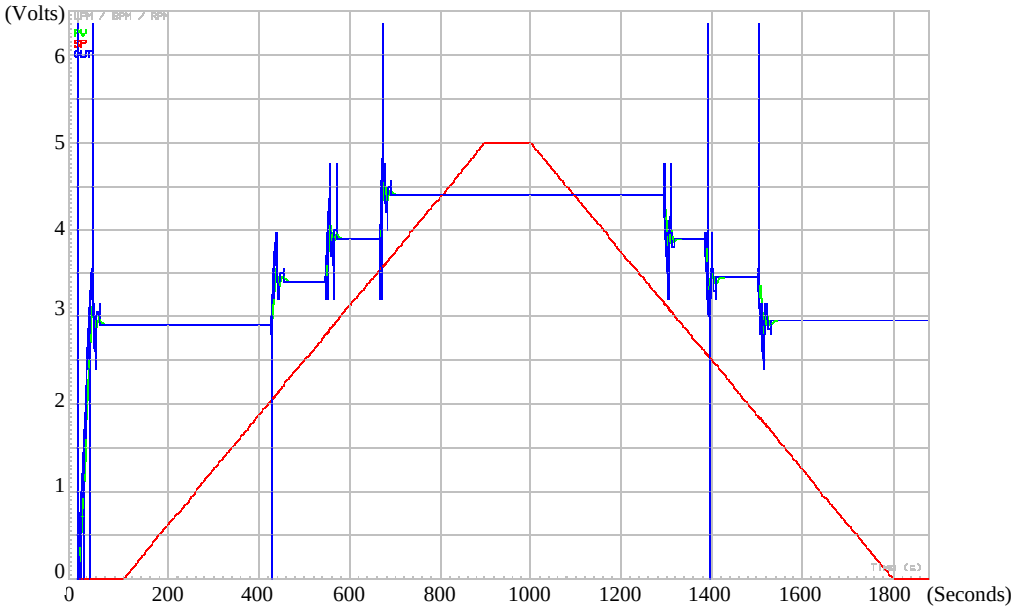

Figure 7 – Change of speed set-point following the changes of heart beats

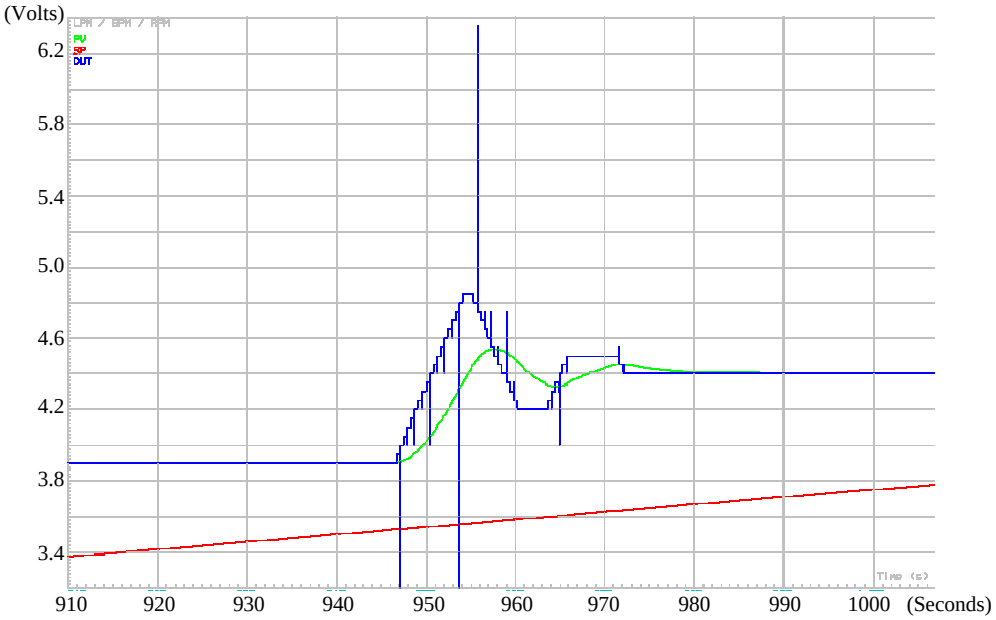

Figure 8 – Pump load changes and reaction of automatic speed control

It was also the operation of the VAD in Fixed Frequency (FF), i.e. manual operation mode. It is show in the Figure 9 where the control following values: 100 bpm (a), 120 bpm (b), 130 bpm (c) and 140 bpm (d) as determined by the control model proposed. In this case, it was observed that regardless of changes in heart rate the output of pump speed remained constant as provided in the proposed model.

At last, tests were performed on the failure mode, where the SIS has acted in various situations by changing the output to certain values that were provided to maintain patient safety. For this test was considered four situations that are represented in Figure 10: (a) the output speed control on 100% of speed capacity; (b) the output seep control on minimum speed capacity only to guarantee that there is not reflux in the blood pump; (c) square wave that may be used for example to a cardiovascular resuscitation; (d) a triangular wave that may be used for example to clearing system. The purpose of these graphs is to show that the SIS, when requested, has priority over any mode of control of the VAD and that SIS can generate any form of output necessary to preserve the patient's life, independent of VAD or patient situation.

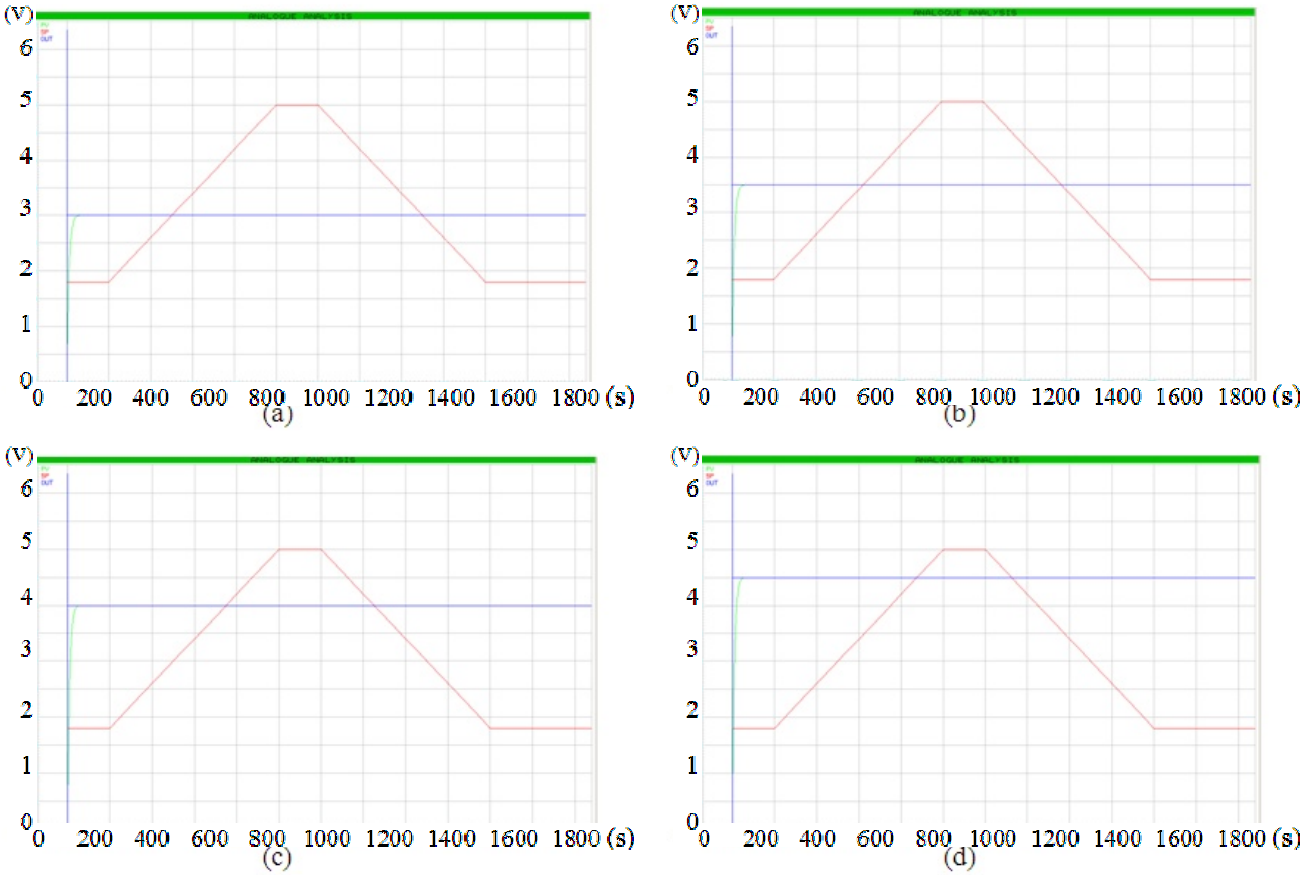

Figure 9 – VAD control system operating in fixed frequency. (a) 100 bpm, (b) 120 bpm, (c) 130 bpm and (d) 140 bpm.

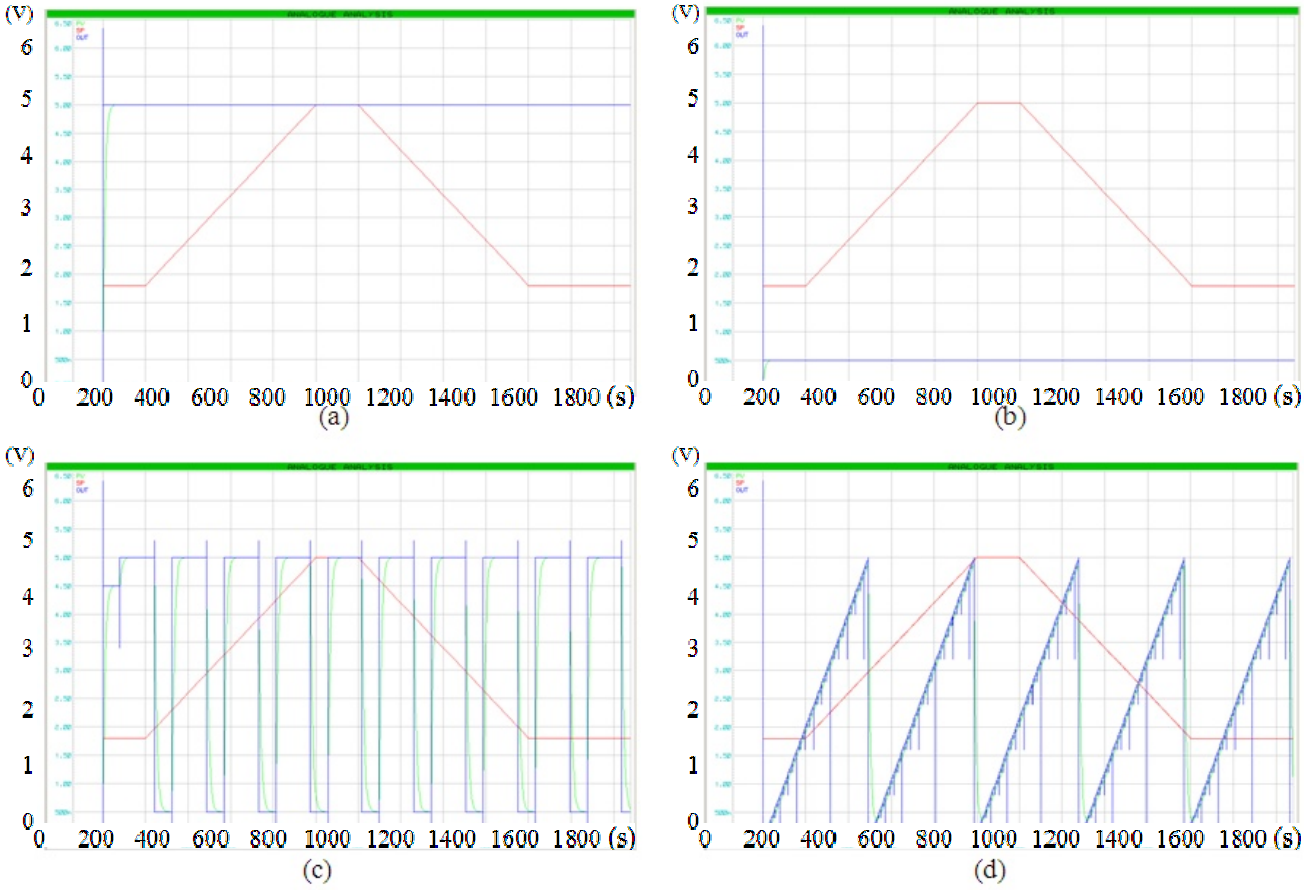

Figure 10 – VAD control system operating in Safety Mode. (a) maximum output speed; (b) minimum output speed; (c) square wave output speed; (d) a triangular wave output speed.

5. COMMENTS AND RESULTS

The performance of the supervisory control of the VAD have been evaluated by monitoring the oscillation of heart rate and blood flow in the human body for the analysis and validation of the supervisory system. These variables were generated oscillations in the cardiovascular system due to an increase and a decrease in the heartbeat of a patient. Figure 7 shows the results. With the VAD operating at variable frequency, the increase in cardiac output caused by increased heart rate shows that the VAD has a high sensitivity to the oscillation can be observed the change in speed at four predetermined levels in the model. With the VAD operating at a fixed frequency on heart rate range was changed from 50 to 180 bpm and control remained with the constant output until the end of the graphics card behaves as a conventional VAD. Thus we see that in both situations the VAD behaved as expected and cardiac output was not significantly affected indicating that the device can generate an effective aid to the cardiovascular system. The Figure 10 show the system operating in safety mode. The safety mode is controlled by the SIS and has priority over any other mode of operation. In this case were tested four hypothetical situations showing that the SIS must act in different ways to control the speed of blood pump. During the simulation tests, it is shown that the performance of the VAD is satisfactory, being able to help the heart to maintain blood flow in acceptable levels.

Important information was obtained from the in vitro tests using the mathematical model of the pump and making the changes in frequency of the cardiovascular system using the simulator. Thus, there was an adequate response to variations caused the VAD. With the VAD can help the heart maintain an adequate blood flow to the next step, following the proposed method is to test bench using a physical simulator of the cardiovascular system. This will make it possible to predict whether the VAD will assist the weakened heart to regain its function as a pump. There is a tendency to make the correction of the VAD pump speed if there is a change of load on the cardiovascular system, i.e. the VAD system controlled a constant rate independent of the rotation of the pump working in a synchronized demand for a natural heart; these confirmations will probably be confirmed at the time they made tests using the physical simulator to validate the model that will prepare it for the next stage of the proposed method (Figure 3) that is the *in vivo* test system.

6. CONCLUSIONS

The VAD under development at IDPC presents difficulties concerning blood flow adjustment according to patient state: there is no device supervisory control that could adjust the blood pump speed based on patient needs and there is no treatment of VAD faults that can help patient's safety.

With a control system automatic and dynamic is possible that VAD adjust patient needs, providing a higher quality of life and enabling a patient survival. The supervisory system can also assist in diagnosis and possible interventions that doctors need to VAD control. Thus, VAD system may be adapted to the patient needs, keeping security and provides risks reduction. Therefore, VAD supervisory control system proposed offers advantages compared to currents VADs control systems.

This study contributes to have a customized VAD considering the patient's illness and different metabolism. Moreover, Safety Instrumented System concept is essential to provide risk reduction that might interfere in VAD functioning and in patient's life.

6.1 Future works

About the method to obtain VAD control architecture:

- Make research about a most efficient method for setting requirements to improve control system autonomy, concerning items complexity to determine the control and security system and to optimize process to obtain supervisory system.

About sensors and actuators used:

- Work to improve sensors to make them less invasive and allow to provide signals with higher quality and precision;
- Work to improve the dynamic pump features to improve system efficiency.
- Add block valves to VAD applying new technologies and using biomaterials.

7. ACKNOWLEDGEMENTS

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