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Development and Calibration of a Portable Controller for Adjustable Pulmonary Artery Shunt

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Abstract

Control of Pulmonary Blood Flow (PBF) in newborn babies remains challenging after surgery for congenital heart disorders. According to multi-institutional data, the mortality after this complex surgery is 15%-20%. A leading cause of high mortality is the difficulty in maintaining balance between blood flowing into the body and the lungs. Control of flow can be improved with medical therapies that have unwanted side effects. As such, a mechanical blood flow control device is preferable. A Personal Computer (PC) based system is used at present that has issues of size and portability. Design and calibration of a smaller, portable version of the controller is desired and a 90% smaller controller is presented in this paper. Experimental results show that the controller can vary flow rate from 100% (fully open switch) to 20% (fully closed switch). A consistent flow rate is obtained using such a controller with minimal deviations from the desired flow (as low as 0.36%). This very specialized heart disorder condition occurs in about 1000 patients annually. As such, commercial companies find little motivation for investment and the obligation lies on non-profit institutions to take up such an initiative.

Keywords: Pulmonary Blood Flow, Flow Controller, Calibration

1 Introduction

Control of Pulmonary Blood Flow (PBF) remains problematic after neo-natal palliation of Single Ventricle Palliation (SVP). According to multi-institutional data, mortality after complex single ventricle corrective surgery is 15% - 20%. A leading cause of high mortality is the difficulty in maintaining the balance between the pulmonary and systemic circuits. Imbalance can be altered by medical therapies (such as by changing ventilator settings or by using medications). However, these medical therapies are inexact and could not lower the mortality below 15% - 20%. In addition, these drugs often cause serious unwanted secondary effects. As such, a mechanical control of blood flow is developed through an artery shunt.

At present, it is achieved by means of an electromechanical system controlled from a Personal Computer (PC) running a commercial application program (LabVIEW). This process to control blood flow is carried out for about 48 hours. It is intended that the device be controlled by a standalone, miniaturized, and portable device that can be easily carried and operated by clinicians.

Authors were motivated by recent work of a new perfusion system for off-pump coronary artery bypass grafting. The reported system is small and simple in comparison with other coronary perfusion systems. However, its use is limited to off-pump coronary artery bypass grafting (OPCABG) and cannot be used for PBF after neo-natal palliation.

Another reported device (AbioCorTM) is implantable and can be used for replacement of heart system. However, its use is restricted to patients under normal activity and can not be used under surgical conditions.

Yet another study examined the effects of the pulmonary blood flow ratio on systemic oxygen availability in neonates with hypoplastic left heart syndrome [9]. An equation was derived that related the key variables of cardiac output, pulmonary venous oxygen saturation and the pulmonary blood flow ratio to systemic oxygen availability. This analysis provided a theoretic basis for balancing both the pulmonary and systemic circulation but did not provide any suggestion for a device implementing this balance.

A device was reported that provides precise control of flow in Vivo. Authors suggested that for a completely implantable device, a stepper motor, battery, and wireless control mechanism could be placed underneath the abdominal fascia in a sealed box, similar to a pacemaker implantation. This served as the basis of our work. As such our approach to achieve mechanical flow control and balance using a compact device is quite relevant to implantation.

This paper presents the development of the desired controller and its performance evaluation. In section II, development of hardware is presented. Software required to drive the hardware is discussed in section III.

Test bed used to calibrate and to evaluate performance of the controller is presented in section IV. Results and analysis are contained in section V. Performance comparison with respect to a reported device is presented in section VI. The paper ends with Discussion and conclusion in section VII.

2 Hardware Development

The electromechanical system controlling the blood flow consists of an assembly of a stepper motor, torque transmission screw, and a plunger as shown in Figure 1.

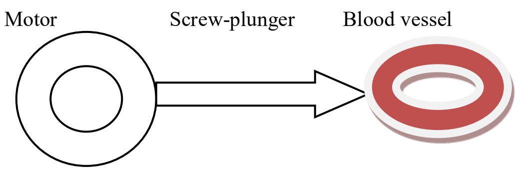

Fig. 1. Stepper Motor, Screw-plunger, and the Blood vessel

When the motor rotates, the screw also rotates. This in turn linearly displaces the plunger. The plunger compresses or releases the blood vessel to control the flow.

An embedded microcontroller and a motor driver are needed to rotate the stepper motor precisely according to the setting of an input rotary switch. The rotary switch has twenty four positions indicating twenty four different blood flow levels as indicated in Figure 2.

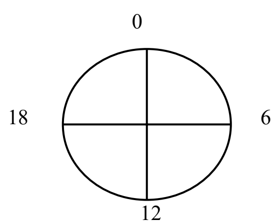

Fig. 2. Different Positions of Rotary Switch

There are two possible directions of movement of the rotary switch: Clockwise (CW) and Counter Clockwise (CCW). Microcontroller detects the direction of movement of the rotary switch by reading two signals S1 and S2 that comes from the rotary switch. It also counts the number of such movements in each direction. Detection is defined as follows:

If (S1 = = 1 followed by S2 = = 0) then direction = CW,
If (S1 = =0 followed by S2 = = 1) then direction = CCW,
The number of net movements, M = (# of detected CW direction) – (# of detected CCW direction)

A positive value of M indicates a net CW movement whereas a negative value indicates a net CCW movement. The magnitude of M indicates the number of steps it has moved.

Based on detected direction of movement and the number of steps of the rotary switch, the microcontroller generates the direction (clockwise or counterclockwise) signal and the required clock pulses to feed the motor driver. Motor driver, in turn, generates all the required phase signals for the stepper motor. Figure 3 shows the overall set-up of the proposed controller. The microcontroller is connected to a stepper motor driver. The motor driver, in turn, is connected to the stepper motor that attaches to the torque transmission screw and the plunger. The microcontroller sends the necessary clock pulses as well as the direction signal to the driver. From the clock pulses and the direction signal, the driver generates excitation signals to different phase coils of stepper motor in sequence. This rotates the stepper motor the required number of steps in the desired direction.
Rotary Switch

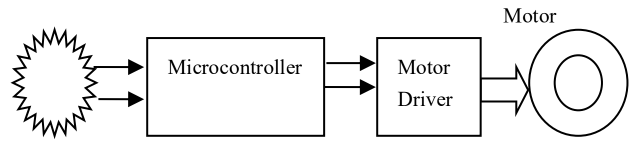

Fig. 3. Overall Schematic set-up of the Blood Flow Controller

Speed of rotation is controlled by the number of pulses generated per second by the microcontroller. Calculation of the number of pulses needed for different linear displacement is discussed in the following section. The actual hardware set-up of microcontroller, motor driver, and the screw plunger is shown in Figure 4. The dimension of the controller board is 7.62 × 5.08 × 2.54 cm.

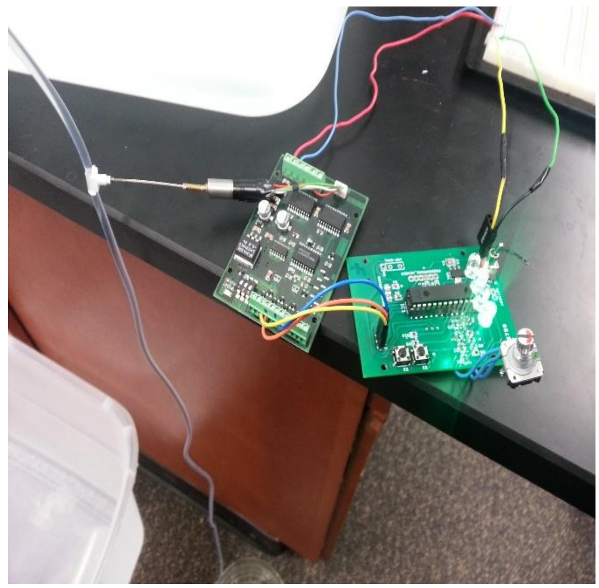

Fig. 4. The Actual Hardware Set-up

3 Software Development

The next step is to develop software for this device. The software should work in conjunction with the hardware to control pulmonary blood flow under surgical conditions in accordance with good standard practice.

The software running on the microcontroller detects the direction of rotation as well as the position (number of steps) of the rotary switch. Direction of rotation is detected by following the sequence of occurrence of two signals generated from the rotary switch as explained in previous section. First signal changes before the second for clockwise rotation (CW) of the switch whereas the second signal changes before the first for counterclockwise rotation (CCW) of the switch. The change in number of positions is detected by counting the occurrences of such sequences. The final position of the switch is computed by algebraically summing up the sequences. However, there are bounces in mechanical contacts of the switch when they change position. As such, the switch is de-bounced with appropriate delay to detect a genuine change in position.

Based on the detected position, the software calculates and generates the necessary signals for the stepper motor driver to rotate the screw (clockwise or counter clockwise). This rotation in turn displaces the plunger and presses (or releases) the blood vessel to achieve desired blood flow. The simplified software flow diagram is depicted in Figure 5.

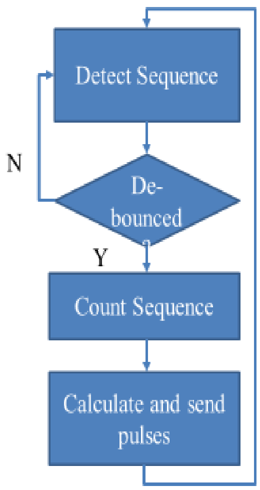

Fig. 5. The Software Flow Diagram

Calculation of the number of pulses needed for a specific linear displacement proceeds as follows. The motor needs 18 steps to complete one revolution and one clock pulse is needed for each step. The planetary gear ratio for the screw is 16:1. As such, 18 × 16 clock pulses are needed for one revolution of the screw.

The required linear displacement per step of the rotary switch is 0.1 mm. So, linear displacement d achieved in Sr number of steps is 0.1 × Sr (Sr represents number of steps steps of rotary switch),

d = 0.1 × Sr, where Sr is the number of steps of rotary switch.

The pitch (linear displacement per revolution) of the screw is known to be 0.454 mm. The number of screw revolutions needed to achieve displacement d is (Sr × 0.1) ÷ 0.454 = 0.22 Sr.

The required number of motor revolutions needed for this displacement is obtained by multiplying it with 16 (planetary gear ratio). This value is multiplied by 18 to obtain the required number of clock pulses. So, the total number of pulses needed to achieve displacement d is 0.22 Sr × 16 ×18.

Empirical formula for calculating the number of pulses Np is,

Np = (d ÷ p) × r × n, where d = required linear displacement, p = pitch of screw, r = gear ratio, n = number of pulses needed for one revolution.

So, Np = Kp × d, where Kp = (r × n) ÷ p

Since r, n, and p are constants, Kp is also constant. As such, Np is linearly related to displacement d. The relationship between the number of clock pulses Np and the linear displacement d (in mm) is shown in Figure 6.

These pulses are generated by the microcontroller and applied to the motor driver as the clock. The width of these pulses will determine the frequency of this clock and controls how fast the motor will rotate. We have chosen 500ms width of the high-time of these pulses with 50% duty-cycle resulting in 1 Hz clock signal.

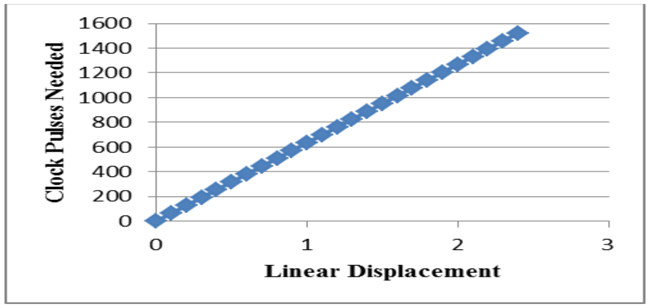

Fig. 6. Number of Pulses Needed for each Possible Linear Distance

The microcontroller code was developed in C/C++ using the compiler (Integrated Programming Environment, IPE) from Microchip Inc. The code was downloaded into the microcontroller using Maxloader programmer and its utility.

4 Test-bed for Calibration

The first step taken in designing the experiment for calibration and performance evaluation was to recreate the prior experiment. As such, it was decided to develop experiment with the materials readily available. Authors were able to obtain a graduated cylinder and an Intra-Venous (IV) tube and IV bag. Designing the experiment without an efficient way to pump water was a challenge.

When considering ways of creating a constant flow of water, authors decided that the best way would be to create a siphon through the IV tube from a reservoir. With a large enough reservoir, a near constant flow of water could be achieved with a minimal amount of refilling. The reservoir would drain through the IV tube, down to a secondary graduated reservoir, allowing the flow of water to be nearly constant. The arrangement is shown in Figure 7.

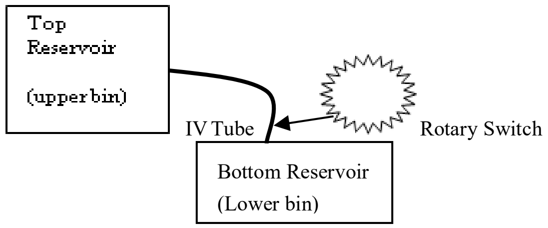

Fig. 7. Schematic Set-up of the Test Bed

Also, this water can be used for easy refilling without changing the overall volume of the water. The IV tube was taped to inner edge of a clear plastic reservoir bin with extra care taken to ensure that the tube was not compressed. The tube's lower end was placed directly at the lowest point of the source bin (top reservoir). This bin would then be noted as the upper bin placed at a higher elevation (the table) and be used to create potential energy for siphon. The second plastic bin (bottom reservoir) would be placed at a lower elevation (the floor) to catch the water that would be running down the tube. The difference in effective height between the two reservoirs was 91cm. The upper reservoir was filled with 10 gallons (38 liters) of water. Water was then siphoned through the IV tube using a small amount of suction and then let flow into the lower reservoir. Testing was done by quickly moving the IV tube into the graduated reservoir and measuring the time it takes to reach 1 liter of water in the graduated reservoir. Water that was left in the lower reservoir during this test was then immediately poured back into the upper reservoir so that the water level would remain almost constant throughout, and thus, gave us better overall measurements. The actual placement of the reservoirs is shown in Figure 8.

Fig. 8. The Actual Placement of the Reservoirs

During the experiment the blood flow controller device (screw-plunger with grip) was attached to the IV tube. While testing, the rotary switch was set at each of 24 different positions for different flow-data acquisition. Experiment consisted of seven different sessions. Two of these sessions were "forward runs" which means that we started the device at rotary switch position 0 and worked way clockwise up to position 24 taking measurement at each position. Two sessions were "reverse runs" which meant that we started the device at switch position 24 and then moving a step down counter-clockwise until the device was fully open (switch position 0). A flow measurement was taken at each position.

Two more sessions were set for "extended runs" to ensure that the device maintains a constant flow over a longer time. In this run, water would flow for 15 minutes (for a particular rotary switch position), taking a measurement, waiting for 15 more minutes, taking a second measurement and then moving 4 positions upwards and repeating this process. This was done due to time constraints (as taking a measurement like this at each point would have taken many days and would have extended our work for weeks). The last run was a forward run with top reservoir at a different height. This new position for the reservoir was much lower (than it was earlier) which translated to a "low pressure run". The low pressure run was carried out at an effective height of 53cm.

5 Results and Analysis

After collecting the flow data, authors were able to obtain different flow rate curves. Figure 9 shows the flow rates at different positions of the rotary switch with various testing procedures. Forward run represents clockwise movement of the rotary switch. Reverse run represents counterclockwise movement of the rotary switch. Extended run represents measuring the flow rate at a particular rotary switch setting for extended period of time (15 minutes).

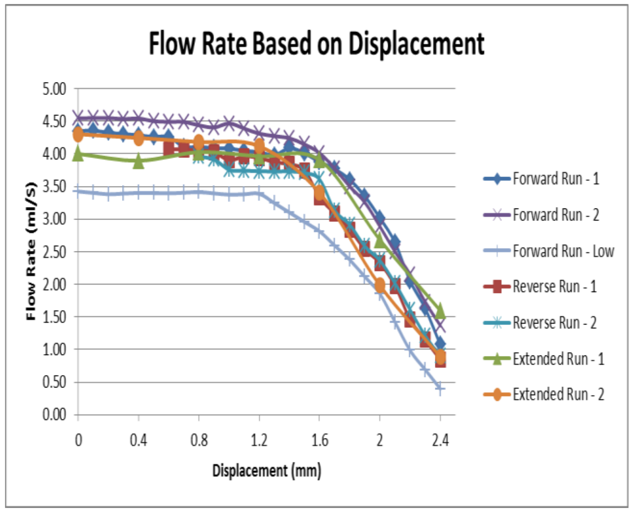

Fig. 9. Absolute Flow Rate vs Linear Displacement of Screw

As seen in Figure 9, all the curves follow a similar pattern which means that the device is relatively predictable. Main difference in the overall flow rate can be associated with variation of pressure.

The next step in analyzing the data is to normalize the curves to account for any variance in pressure between each run. This is shown in Figure 10.

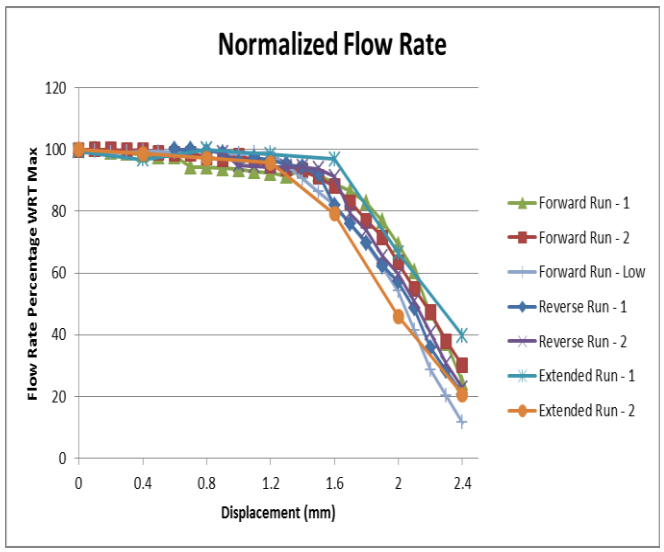

Fig. 10. Normalized Flow Rate vs Linear Displacement of Screw

This figure was drawn by plotting all the values in a set as percentages of the highest value in that data set. For example, the maximum flow rate for forward – low pressure run is 3.4 ml/s. Each of the flow rate values on this curve is divided by this maximum value (then multiplied by 100) to obtain its normalized value.

In Figure 10, one can see the reduction in the spread of data. While the curves were separate from each other in the previous figure, the curves mostly overlap in this figure. Even the curve representing low pressure run mostly overlaps with others. The difference in flow rate only amplifies as it progresses to the higher displacements. The reason for this pattern is detailed later in discussion section.

The final step is to calculate the average of the normalized values and determine the standard deviation. For example, average of all the normalized flow rates for different runs at displacement of 1.2 mm is about 94%. This is shown in Figure 11. It shows the average normalized values of flow rates at different displacements. This gives us a curve that could be used as a specification for the final product. Standard deviation at each displacement point is also shown in this figure. As seen from Figure 11, the curve stays mostly smooth throughout. The standard deviation is 0.36% at position 0 and reaches a maximum value of 9.36% at position 24 (2.4 mm displacement). Also, it is clearly visible that the deviation begins to increase significantly around position 16.

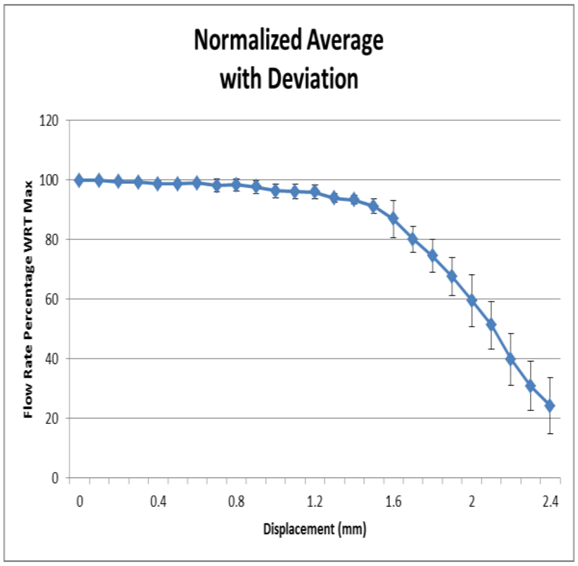

Fig. 11. Average Normalized Flow Rate vs Linear Displacement of Screw (with standard deviation)

Although we obtained different flow rates for different positions of the rotary switch, the change in flow rate from one position to the next is not uniform. This is shown in Figure 12.

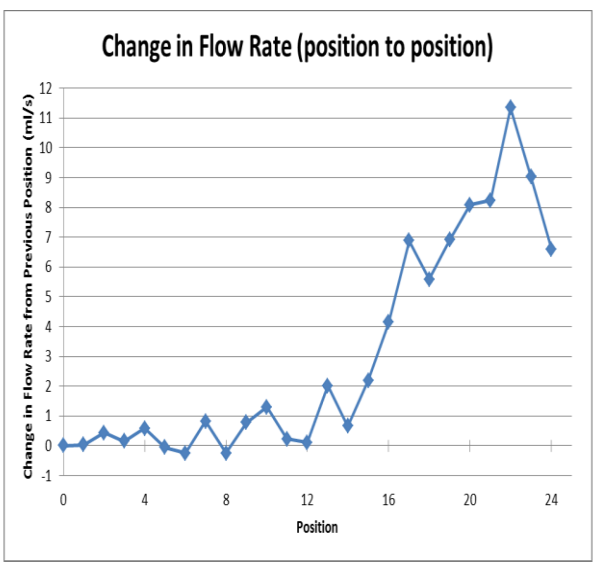

Fig. 12. Change in Flow-rate from one Position to the Next of the Switch

In this graph, at position 1, the change in flow rate represents the change in flow between position 0 and position 1 of rotary switch. It appears that the flow rate changes minimally at lower switch positions (between positions 0 and 5). However, it is significantly higher beyond position 14.

6 Performance Comparison with a Reported Device

Experimental results were reported from a Personal Computer (PC) based blood flow controller. The controller is reported to be controlled by commercial software running on a PC. The experiment was conducted on blood vessels of piglets of different sizes. The flow rate measured at different linear displacements of the screw is reported to be the same for displacements smaller than 1mm. In our case, the flow rates measured are the same for displacements smaller than 1.2 mm. This little variation is natural as we experimented with IV tube carrying water (instead of blood vessel carrying blood as reported in the paper). Also, the paper reports that the flow rate falls off beyond that point (1mm) with additional linear displacement of the screw. We also observed the same trend beyond the displacement of 1.2 mm as shown in Figures 9 and 10. Moreover, the normalized flow rate has a standard deviation of 1.34% to 8.05% as reported in the paper [10]. In our case, the normalized flow rate has a standard deviation of 0.36% to 9.36%. This also shows similarity of the results. However, our device has the ease of operation by controlling the blood flow using a standalone rotary switch as compared to commercial software running on a PC. Clinicians prefer such standalone, portable control over PC based control.

7 Discussion and Conclusion

A portable blood flow controller has been developed that controls the flow in pulmonary artery shunt under surgical conditions. A 90% smaller controller is presented in this paper. Microcontroller based hardware board has been fabricated with a rotary switch that interfaces with a stepper motor driver. The stepper motor connected to the motor driver is coupled to a screw that moves forward and backward to compress or release the blood vessel. The controller is tested and calibrated in a simulated test bench of IV tubes carrying water. Results show that the controller responds consistently to the changes of input rotary switch positions. The flow at a particular setting of the rotary switch is similar when approaching the setting both from clockwise or counter-clockwise directions. Laboratory testing serves to support the original conclusion that an adjustable and portable pulmonary artery shunt can predictably change the flow rate. It is possible to predict the flow rate for all positions (with less than10% error).

Improved hardware such as the rotary switch can easily reduce this percentage error. It should be noted that The simulated test was partially complete. We were able to test the change in flow rate under constant flow conditions. This is not true for the real operation of a heart where pressure as well as flow rate change constantly. Through the use of an IV pump or dialysis machine authors believe it is possible to simulate a heart more accurately. Improved tube could avoid significant change in flow rate after position 16. Current tube compresses more after a threshold position of 16. Also, we used water as our test fluid. Water does not have the same viscosity and density as that of blood. Glycerin could be a good surrogate for blood in a testing environment. We propose that further tests be carried out to show that this controller is indeed feasible and usable.

References

Riordan C.J.Locher J.P. Jr,Santmore W.P., et al: Monitoring Systemic Venous Oxygen Saturationsin the Hypoplastic Left Heart Syndrome. Ann Thorac Surg 63:835-837, 1997.

Tweddel J.S., Hoffman G.M., Mussatto K.A. et al:Improved Survival of Patients Undergoing Palliationof Hypoplastic Left Heart Syndrome: Lessons Learned from 115 Consecutive Patients. US National Library of Medicine, Circulation 106: 1-82-1-89, 2002.

Jacobs J.P., Jacobs M.L.Lacour-Gayet F.G., et al: Stratification of Complexity improves the Utility and Accuracy of Outcomes Analysis in a Multi-institutional Congenital Heart Surgery Database: Application of the Risk Adjustment in Congenital Heart Surgery (RACHS-1) and Aristotle Systems in the Society of Thorasic Surgeons (STS) Congenital Heart Surgery Database. Pediatr Cardiol 30: 1117-1130, 2009.

O'Brien S.M., Clarke D.R., Jacobs J.P., et al: An Empirically based Tool for Analyzing Mortality Associated with Congenital Heart Surgery. J Thorac Cardiovasc Surg 138:1139-1153, 2009

Ohye R.G., Sleeper L.A., Mahony L. et al: Comparison of Shunt Typesin the Norwood Procedure for Single-ventricle Lesions. N Engl J Med 362: 1980-1992, 2010.

Di Filippo S., Lai Y., Manrique A., et al: Intensive Care Course after Stage 1 Norwood Procedure: Are there Early Predictors of Failure? Intens Care Med 33:111-119, 2007.

Yoshinao Koshida, Go Watanabe, Tamotsu Yasuda, Shigeyuki Tomita, Shinichi Kadoya, and Taro Kanamori, Portable Coronary Active Perfusion System for Off-Pump Coronary Artery Bypass Grafting, The Society of Thoracic Surgeons, Published by Elsevier Inc, 2006, 81:706–11

U.S. FOOD AND DRUG ADMINISTRATION, AbioCoriTM - Implantable Replacement Heart System: PATIENT AND FAMILY GUIDE, Approval Date: September 5, 2006.
https://www.accessdata.fda.gov/cdrh_docs/pdf4/H040006C.pdf. (August 15, 2018).

Barnea O1, Austin EH, Richman B, Santamore WP., Balancing the Circulation: Theoretic Optimization of Pulmonary / Systemic Flow Ratio in Hypoplastic Left Heart Syndrome, J. Am. Coll Cardiol. 1994 Nov 1;24 (5):1376-81.

Douglas, William I.; Moore, Karabeth B.; Resig, Phillip P†; Mohiuddin, M Waqar, The Adjustable Systemic-Pulmonary Artery Shunt Provides Precise Control of Flow In Vivo, ASAIO Journal: January-February 2010 - Volume 56 - Issue 1 - p 73-76.

Stepper Motor DRIVER Constant Voltage Mode USER MANUAL. Faulhaber, n.d. Retrieved May 13, 2014, from http://www.micromo.com/manuals/pdf/geraetehandbuch/ad_vx_mxx/EN_7000_15008.pdf>.

Integrated Programming Environment (IPE) User's Guide. (2013, January 1). Retrieved May 13, 2014, from http://ww1.microchip.com/downloads/en/DeviceDoc/50002227A.pdf

MaxLoader User's Guide. (n.d.). . Retrieved May 13, 2014, from https://www.jameco.com/Jameco/Products/ProdDS/2110158.pd

Mohiuddin W. M., Resig P. P., Sexton W. K., Douglas I. W.: Two-Day Control of Pulmonary Blood Flow with an Adjustable Systemic-Pulmonary Artery Shunt. J of American Soc of Art Int Organ, May-June, 2011.