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In situ aortic root in vitro testing of the stented and stenless porcine aortic heart valves

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ABSTRACT

IN SITU AORTIC ROOT IN VITRO TESTING OF THE STENTED AND STENTLESS PORCINE AORTIC HEART VALVES

by
Sean Parker

Background - The stent, Delrin[®] support frame, for porcine heart valves has been blamed for reduced durability of these valves due to the additional stress caused by the relative stiffness of the stent. There is a tendency among surgeons to do away with the stent in the aortic position and use porcine stentless valves which are sewn directly in the aortic position after removing diseased valve. These stentless valves are extremely difficult to test and no appropriate holder has been designed for this purpose. New approach for in vitro testing of these valves has been developed at Shelhigh, Inc., Millburn, NJ. The stentless valves are sewn in real porcine heart; the aortic root is dissected out and the aortic root is connected to a holder then inserted in the Pulse Duplicator System.

This aortic root is kept fresh with antiseptic solutions but not fixed with glutaraldehyde since it can become stiffer than the natural aorta.

Method - In vitro hemodynamics, blood flow performance, of porcine bioprostheses were tested under physiological conditions using the pulse duplicator system. The system is comprised of a test chamber in which the porcine bioprosthesis is inserted, a pressure transducer, a flow probe, an amplifier pair, and real time software to analyze the fluid dynamics of stented and unstented porcine bioprostheses.

Thirteen Shelhigh Porcine valves were tested in the Pulse Duplicator System for this study which include 7 - 25mm valve, 4 stented and 3 stentless, and 6 - 23mm valves, 3 stented and 3 stentless.

Results - Preliminary results from testing three of each stented and stentless 23mm valves at a rate of approximately 90 Beats Per Minute (BPM) showed an average of a 6% increase in the Effective Orifice Area (EOA) of the Stentless bioprosthesis over the standard Stented bioprosthesis. The EOA ranged from a high of 2.41cm² for the 25mm stentless to a low of 2.18cm² for the 25mm stented bioprosthesis. The mean EOA for the stented bioprostheses was 1.94cm² and 2.06cm² for the stentless bioprostheses.

Conclusion - The series of tests which were performed using aortic roots and sizers to size the aortic root to implant the valve into the proper size root revealed that sizing the root is critical when trying to achieve a maximum Effective Orifice Area. Sizing of the stented valve implanted is not as critical due to the stent providing a predefined area for the valve, but then there is no means for the valve to distend at high flow rates. The stentless bioprosthesis is superior to the standard bioprosthesis in the sense there is no stress on the valve comparable to the stented bioprosthesis. At high flow rates the EOA of the stentless valve is not limited to the inside diameter of the valve because it is allowed to distend outward at times of high flow rates. Using stentless valves is of importance at times of high flow rates in order to eliminate the stenosis, the abnormal narrowing of the orifice, opening, in a heart valve, which is produced in stented valves.

**IN SITU AORTIC ROOT IN VITRO TESTING OF
THE STENTED AND STENTLESS
PORCINE AORTIC HEART VALVES**

**by
Sean Parker**

**A Thesis
Submitted to the Faculty of
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in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Biomedical Engineering**

Biomedical Engineering Committee

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APPROVAL PAGE

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CHAPTER 1

INTRODUCTION

1.1 Background Information

The stent, Delrin[®] support frame, for porcine heart valves has been blamed for reduced durability of these valves due to the additional stress caused by the relative stiffness of the stent. There is a tendency among surgeons to do away with the stent in the aortic position and to use instead porcine stentless valves which are sewn directly in the aortic position after removing the diseased valve. Because these valves have no stent they are extremely difficult to test in bench testing and no appropriate holder has been designed for this purpose. A new approach for in vitro testing of these valves has been developed at Shelhigh, Inc., Millburn, NJ. The stentless valves are sewn into a real porcine heart; then the aortic root is dissected out and the aortic root is connected to a holder which is then inserted in the Pulse Duplicator System (see section 4.2.1 for a description).

The purpose of this study was to compare the hemodynamic performance of 23mm diameter and 25mm diameter stented and stentless Shelhigh Porcine Bioprostheses implanted in an aortic root. These valves were evaluated for hydrodynamic performance during forward flow, at relatively large flow rates, and low and high pulse rates in a Pulse Duplicator System. In addition, this study was intended to determine sizing of the aortic annulus for implantation of the Shelhigh No-React[®] Unstented Porcine Aortic Xenograft in order to achieve an optimum Effective Orifice Area and at the same time to have a competent valve.

1.2 Objective

The specific objectives of the study were:

1. To obtain useful hydrodynamic information (transvalvular volumetric flow rate and pressure difference relations) from Shelhigh stented and stentless bioprostheses which were tested under conditions that simulate the dynamic flow behavior of the normal heart, using a pulse duplicator.
2. To compare the hydrodynamic performance of the stented bioprostheses to the stentless bioprostheses.
3. To evaluate whether undersizing or oversizing of the stentless valve by one or two sizes has any hemodynamic consequences.

The test instruments provide for excellent in-vitro testing. The Pulse Duplicator System provides a study of hydrodynamic performance and the functional performance of valves under simulated conditions of a natural heart.

CHAPTER 2

DESIGN

2.1 Stented Bioprosthesis

The Shelhigh stented porcine bioprosthesis, shown in figure 1, is an evolutionary third generation porcine heart valve prosthesis. This xenograft, tissue graft that is made from one animal species to another, is designed to provide improved hemodynamic function and increased durability and functional life when used in valve replacement surgery.

The aldehyde-stabilized tissue is fixed under “low pressure” to maintain natural collagen structure. The pericardial bias strip, a strip of pericardium sewn around the contour of the valve where the tissue is sutured to the Dacron® cloth, prevents possible valve leaflet abrasion which would result in a decrease in the functional life of the valve. A Dacron® covered acetal homopolymer stent, anatomically shaped for optimum fit in the host annulus, exhibits no sign of flexion fatigue or stent post deformation after complete in-vitro testing. Aortic valve models contain a sewing ring, implantation flange, that is positioned for supra-annular placement of the valve. Intraventricular profile, height of valve exposed in ventricle, of the mitral valve is minimized by the placement of the implantation flange¹.

2.2 Stentless Bioprosthesis

The Shelhigh stentless porcine bioprosthesis, shown in figure 2, is of revolutionary design. It has been constructed to resist distortion and to facilitate implantation. The stentless valve undergoes the same fixation process as the stented valve.

The Shelhigh stentless aortic valve can resist significant distortion. The two-suture-

lines implantation technique facilitates implantation. The valve is constructed from three separate porcine non-coronary cusps which are the smallest cusps of a porcine valve. They are joined together with a unique technique and then covered with pericardium. For implantation, all the sutures are threaded through the pericardial tissue flanges. The pericardial tissue flange is a strip of pericardium around the base of the valve used to facilitate implantation.

The valve is also designed to coapt (the coming together of the cusps) within certain limits even when the aorta dilates after coming off bypass (or when the pressure in the aorta rises)¹.

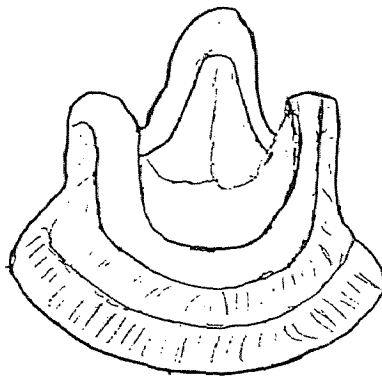


Figure 1. Drawing of Shelhigh stented porcine bioprosthesis.

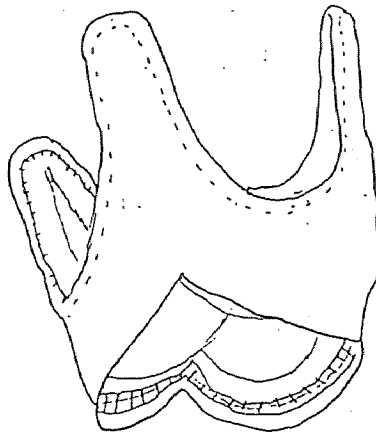


Figure 2. Drawing of Shelhigh stentless porcine bioprosthesis.

CHAPTER 3
FLUID DYNAMICS

3.1 Theoretical Analysis of the Flow through Prosthetic Heart Valves

The fluid dynamics of a prosthetic heart valve can be treated analogously to the dynamics of flow through an area reduction, and hence should be analyzed using the equations of motion of flow across an orifice².

An orifice is an aperture through which fluid passes and its thickness (in the direction of flow) is very small in comparison with its other dimensions³. In a sharp caged (rounded) orifice there is minimum contact with the fluid and consequently minimum “frictional” effects.

For steady, incompressible flow through an orifice (prosthetic valve) of cross-sectional area A_o , the pressure drop (mm Hg) between spatial points i and j is related to the volumetric flow rate Q(L/m) by the expression:

$$Q(L/m) = C_d A_o \sqrt{\frac{2(p_i - p_j)}{\rho}} \quad (1)$$

where C_d is the discharge coefficient (ratio of the actual discharge to the ideal discharge) and ρ is the density of the fluid.

Rearrangement of eq. (1) gives:

$$P_i - P_j = \frac{\rho Q^2}{2C_d^2 A_o^2} \quad (2)$$

or

$$P_i - P_j = C_o Q^2 \quad (3)$$

where

$$C_o = \frac{\rho}{2C_d^2 A_o^2} \quad (4)$$

where C_o is the overall valve drag coefficient.

For steady flow through an orifice (prosthetic valve) of area A_o (cm^2),

$$\text{Orifice Area} = \frac{Q}{C_d K \sqrt{\Delta p}} \quad (5)$$

where Δp (mm Hg) = $p_i - p_j$, and K is a scale or a conversion factor. This expression constitutes the basis of Gorlin's Hydraulic formula⁴.

An "Effective Orifice Area" (EOA) can be defined by:

$$EOA(\text{cm}^2) = C_d A_o \quad (5)$$

or

$$EOA = \frac{Q}{K \sqrt{\Delta p}} \quad (6)$$

For time dependent flow across an orifice (prosthetic valve), the Bernoulli equation along a streamline between any two points i and j gives⁵:

$$\bar{p}_i(t) + 0.5v_i^2 = \bar{p}_j(t) + 0.5v_j^2 + \rho \int_j^i \frac{v}{r} da \quad (7)$$

where p' is the time dependent pressure and prime denotes an ideal quantity, since friction is neglected; and v is the velocity of flow. The last term in eq. (7) v/t represents the unsteady nature of the flow, and da is a length element along the streamline.

For one dimensional flow,

$$v = \frac{Q}{A} \quad (8)$$

where A is the cross-sectional area.

Therefore rearranging eq. (7) gives:

$$\bar{p}'_i - \bar{p}'_j = 0.5(v_j^2 - v_i^2) + \rho \frac{dQ}{dt} \int_i^j \frac{dx}{A} \quad (9)$$

In a real flow the actual pressure drop is larger than ideal due to frictional effects, therefore:

$$\bar{p}_i(t) - \bar{p}_j(t) = 0.5\rho \left(\frac{Q}{A_o C_d}\right)^2 + \rho \frac{dQ}{dt} \int_i^j \frac{dx}{A} \quad (10)$$

where $p(t)$ is the real time dependent pressure.

It is assumed that the values of C_d obtained from steady flow experiments are applicable to pulsatile flow at corresponding flow rates.

If L is the distance between the two pressure sampling points, then :

$$\int_i^j \frac{dx}{A} = \frac{L}{A} \quad (11)$$

where A is the average cross-sectional area between i and j .

Therefore:

$$\overline{p}_i(t) - \overline{p}_j(t) = C_o Q^2 + \rho \frac{dQ}{dt} \frac{L}{A} \quad (12)$$

or

$$\overline{p}_i(t) - \overline{p}_j(t) = RQ^2 + I \frac{dQ}{dt} \quad (13)$$

In eq. (13) the first term (RQ^2) on the right-hand-side is the resistive (dissipative) term and the second (I) is the inductive (inertial) term due to the acceleration of the fluid. Another term can be added to account for the frictional (viscous) losses (FQ).

$$\overline{p}_i(t) - \overline{p}_j(t) = RQ^2 + I \frac{dQ}{dt} + FQ \quad (14)$$

As can be seen in eq. (14), the pressure drop across a prosthetic valve is solely dependent upon valve flow characteristics and independent of the cardiovascular parameters. All three terms on the right-hand-side contribute to the pressure gradient in the natural valve. However the sum of all three terms in the normal valve is small. The majority of authors neglect this frictional term claiming that experience shows it to be small in comparison to the resistive term, for fluids with relatively minimal viscosity such as water or blood. The analysis which follows neglects this term. The temporal mean value of eq. (12) is:

$$\overline{\Delta p_{ij}(t)} = \overline{p_i - p_j} = \frac{1}{T} \int_0^T (p_i(t) - p_j(t)) dt \quad (15)$$

Where T is the period of integration (systolic, period of cardiac cycle during which the heart contracts, ejection for aortic valve substitute or diastolic, period between two contractions of the heart, when the muscle of the heart relaxes and allows the chambers to fill with blood, filling period for mitral valve substitute), i.e. the interval of forward flow from $Q=0$ to $Q=0$. From eq. (15) and eq. (12) in which the time average of the last term is zero, and where $\overline{Q^2}$ is the mean of the square of flow, then:

$$\overline{p_i - p_j} = C_o \overline{Q^2} \quad (16)$$

and

$$C_o = \frac{\overline{p_i - p_j}}{\overline{Q^2}} \quad (17)$$

The Gorlin formula tends to introduce large errors if the flow is not uniform in time (Equation 2), because it does not consider the following:

$$\overline{Q^2} \neq \overline{Q}^2$$

Where, $Q_{RMS} = \sqrt{\overline{Q^2}}$

and, $Q_{MEAN} = \overline{Q}$

also,

$$\overline{p_i - p_j} = (P_i - P_j)_{MEAN}$$

If the dissipative frictional term were not to be neglected, eq. (16) should be written:

$$(P_i - P_j)_{MEAN} = RQ_{RMS}^2 + FQ_{RMS} \quad (18)$$

In the event that the orifice area is incorrectly computed using eq. (6) then:

$$\text{Incorrect EOA} = \frac{Q_{MEAN}}{K\sqrt{(P_i - P_j)_{MEAN}}}$$

While the correct computation is:

$$\text{Correct EOA} = \frac{Q_{RMS}}{K\sqrt{(P_i - P_j)_{MEAN}}}$$

The incorrectly computed area will differ from the correct area by the factor:

$$\frac{EOA_i}{EOA_c} = \frac{Q_{MEAN}}{Q_{RMS}}$$

This factor is not constant but depends on the flow waveform, but the computed orifice area will always be erroneously small.

CHAPTER 4

IN VITRO HYDRODYNAMIC CHARACTERISTICS

4.1 The Goals

By using a pulse duplicator that simulates the left side of the heart and circulatory system, the present study intends to compare and contrast the fluid dynamics of stented and stentless heart valves under various flow rates.

The goal of this work is three fold:

- 1) To obtain useful hydrodynamic information from valves tested under conditions that simulate the dynamic flow behavior of the normal heart, using a pulse duplicator.
- 2) To evaluate the relative hydrodynamic performance of each of the bioprostheses used in this work.
- 3) To set up a standard hydrodynamic performance of the stentless bioprostheses.

4.2 Materials and Methods

4.2.1 The Pulse Duplicator

The pulse duplicator used in this study is shown schematically in figure 3. The Pulse Duplicator System simulates the left side of the heart. The test chamber (“left atrium” and “left ventricle”) consists of a rigid Plexiglas box, permitting an unobstructed view of the prosthesis from all aspects. The prosthesis is mounted in a rigid plate that separates atrium from ventricle via a retaining ring system permitting quick changes of test valves. Fluid leaves the ventricular chamber along a length of rigid Plexiglas tubing with an adjustable resistance and a parallel compliant chamber permitting adjustment of the load on the ventricle. Pulsatile flow is created by a positive displacement piston pump connected to the ventricular outflow by flexible bellows. Steady flow can be achieved through the test valve, with a pump and a series of reservoirs, as shown in figure 1. The stroke volume, volume pumped, is determined by the cylindrical piston of the pump being caused to move back and forth within the chamber. This stroke volume was set to approximately 75 milliliters and was held constant for the duration of the testing. All tests were performed using a 0.35% glutaraldehyde solution (formulated using physiological saline). The glutaraldehyde saline solution is used to maintain cleanliness of the system, as glutaraldehyde is an excellent sterilant, and the saline to allow for the electromagnetic flow probe to measure flow rates.

The fact that the ventricular outflow tract is rigid up to the flow probe ensures that the flow passing through the probe and the prosthesis are identical. Atrial and ventricular pressures were measured by a differential pressure transducer (Validyne DP-45) connected to the test chambers via stiff tubing. The pressure transducer was connected to a carrier amplifier and the flow meter was connected to a DC amplifier⁶.

4.2.1.1 Flow and Pressure Measurement: The flow meter used in this experiment was a square wave electromagnetic type (Carolina Medical Electronics, Inc., model FM501D, Winston Salem, NC). The flow probe associated with it contains an electromagnet which produces a magnetic field across the vessel. The probe operates on the principle of electromagnetic induction, by measuring the potential difference generated across the flow channel when a conducting fluid passes through a magnetic field. In general this technique provides an instrument of high sensitivity and adequate frequency response. The frequency used with the pulse duplicator was 30 Hz. The signal obtained by the induced voltage is preamplified and processed by the flowmeter. The transducers give accurate readings within a range of 5 milliliters/min to 19.99 liters/min.

The flow signal and pressure difference signal were then interfaced to a DC amplifier and a carrier amplifier. The two amplified signals were then routed from the amplifiers to a 16 channel analog-to-digital (A/D) convertor (Keithley Metrabyte) plugged into an expansion slot in the computer. The amplifier outputs in the range of -5 volts to +5 volts allow for maximum resolution in the analog-to-digital signal conversion. In addition, a pulse trigger in the form of a simple electrical circuit built in the pulse duplicator, was connected to a digital input channel of the A/D convertor. This trigger allowed for the data collection to begin at the correct time and also estimate the pulse rate.

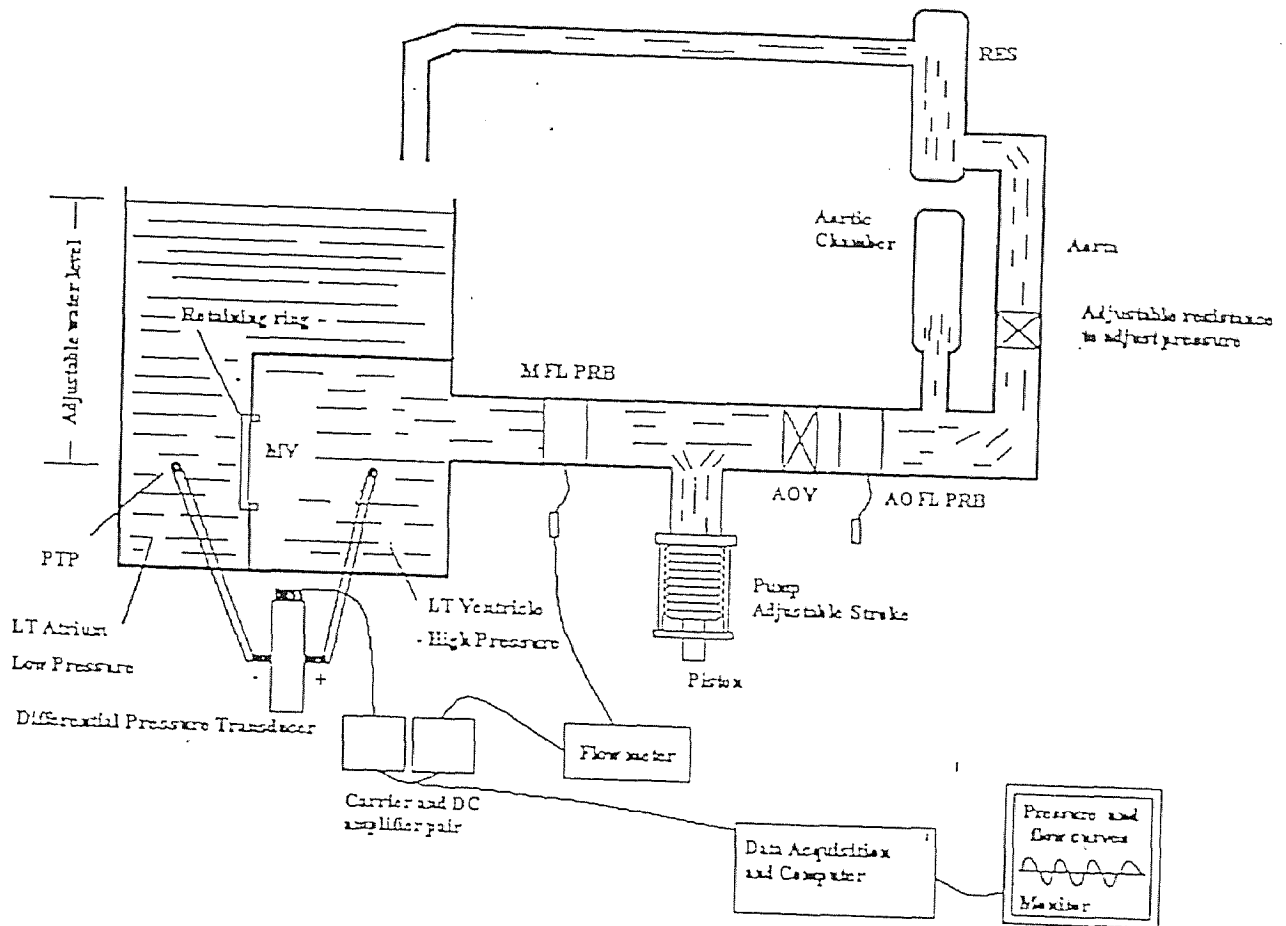


Figure 3. Diagram of the pulse duplicator. PTP = pressure transducer port; MFLPRB = mitral flow probe; MV = mitral valve; RES = reservoir; LT = left; AOV aortic valve; AOFLPRB = aortic flow probe.

4.2.1.2 Computer Software and Calibration: The software designed for these experiments made use of a visual programming language, HP VEE. A Keithley Metrabyte A/D convertor converts the analog signal to a digital signal to be processed by the software and computer. The above-described system constituted a flexible real-time data-acquisition set-up, where pulsatile flow and pressure-difference information could be immediately processed and graphically displayed on the high-resolution screen of the computer.

Using the software as indicated produces reliable and reproducible results. Calibration of the pressure transducer and flow meter is performed through the icon marked "Calibration". Information on calibration of the system is instructed to the user on the screen as they progress through the calibration cycle. Calibration of the system is performed once initially on start up and then on a periodic basis. Calibration of the pressure transducer is performed by opening both sides of the transducer to atmosphere and raising the "+" side of the transducer to a reference pressure of 1 cm of water; this value is then captured on the screen. The second step is to raise the manometer to a second reference pressure of 14 cm of water applied again to the "+" side and capture this value. The final step is to return the transducer to the pulse duplicator, the "+" side to the "atrium" side and the "-" side to the "ventricle" side of the pulse duplicator. This zero value is then captured on the screen. These three values are used as a reference for the software in calculating the measured pressures across the valves.

The flow meter was calibrated at the same frequency as the pressure transducer. A toggle switch in the flowmeter provided a 1-V signal on mean and pulsatile outputs to calibrate the external amplifier range (1V corresponded to a flow rate of 10 L/min). As with the pressure, the flow was calibrated for 0.1V, 1V and zero flow where these three values

were captured and used as a reference to determine the flow rates. Each analog signal was digitized at a rate of 1500 samples per second using the A/D convertor.

The pulse rate was calculated through a subroutine devised for this purpose, by using an on-board high resolution counter, by processing binary data coming from the digital input channel to which the pulse trigger was routed.

With flow rate, pressure difference, and pulse rate-data available, all other pertinent parameters (stroke or positive volume, negative or backflow volume, regurgitation fraction, cardiac output, effective orifice area, discharge coefficient, and performance index) were immediately calculated within the program. These parameters are defined in Section 4.2.3 Data Calculation and Statistical Analysis. These values, together with the corresponding flow and pressure waveform curve at every run, were automatically stored in specific files, displayed on the screen and, if desired, printed. It was possible to recall runs at a later date for analysis and/or printing.

4.2.2 Bioprostheses Tested

Thirteen Shelhigh Porcine valves were tested in the pulse duplicator system for this study which include 7 -25mm valves, 4 stented and 3 stentless , and 6 -23mm, 3 stented and 3 stentless. At least three complete runs of each size and each type (stented or stentless) valve were performed.

4.2.3 Data Calculation and Statistical Analysis

The hydrodynamic characteristics of the bioprostheses were analyzed by mean pressure drop as a function of root mean square (rms) pulsatile flow rate. Value: of 1) mean pressure difference in millimeters of mercury, and 2) root mean square pulsatile flow rate in liters/min were internally calculated by the data-acquisition software for every run in the pulse duplicator system. In addition, the following parameters were also internally calculated for each run: 3) rate (beats/min) in BPM, 4) stroke (positive forward) volume in milliliters, 5) negative (back flow) volume in milliliters, 6) regurgitation fraction calculated as the percent regurgitation flow (percent ratio of the negative volume to the positive volume), 7) Effective Orifice Area (EOA) in square centimeters, 8) Discharge Coefficient (C_d), and 9) Performance Index (PI).

An effective orifice area (EOA), in square centimeters, based on a modification of the Gorlin formula was calculated ignoring the discharge coefficient ($C_d = 1$).

Two different estimates of EOA were calculated as:

$$EOA_{RMS}(cm^2) = \frac{Q_{RMS}(L/m)}{51.6 \Delta p_{MEAN} (mm Hg)} \quad \text{and,} \quad EOA_{MEAN} = \frac{Q_{MEAN}}{51.6 \Delta p_{MEAN}}$$

where 51.6 is a constant conversion factor, which includes the gravitational constant and the conversion of pressure units (millimeters of mercury to centimeters of water).

A discharge coefficient (C_d) was calculated using the formula:

$$C_d = \frac{\text{EOA}}{\text{Measured Internal Orifice Area}}$$

A performance index (PI) was calculated according to the formula:

$$\text{PI} = \frac{\text{EOA}}{\text{Measured External Mounting Area}}$$

All data were statistically treated as being drawn from a normally distributed population, with p less than 0.05 being considered significant. Difference between EOA of Stented and Stentless valves of the same size were identified using Student's t -test⁷.

4.3 Protocol

Every bioprosthesis to be tested was evaluated according to the following protocol, using 0.35% glutaraldehyde solution at room temperature as the testing fluid. Viscous effects were assumed to be negligible.

Pulse Duplicator

In-vitro hemodynamic tests were performed on each valve with a constant stroke volume and pulse rates of 60, 70, 80, 90, 100, 110, 120 beats per minute, with a range of error of ± 5 beats per minute.

4.4 Results

4.4.1 Pulse Duplicator Testing

Figure 4 shows EOA vs Cardiac Output for Shelhigh Porcine Stented and Stentless Bioprostheses, 23mm mounting size, tested on the Pulse Duplicator system at the pulse rates indicated in the protocol.

Figure 5 shows EOA vs Cardiac Output for Shelhigh Porcine Stented and Stentless Bioprostheses, 25mm mounting size, tested on the Pulse Duplicator system at the pulse rates indicated in the protocol.

Figure 4 shows EOA vs Cardiac Output for Shelhigh Porcine Stented and Stentless Bioprostheses, 25mm mounting size, tested on the Pulse Duplicator system at the pulse rates indicated in the protocol.

Table 1 shows a statistical analysis using a two sample Student t-test of the EOA for 23 and 25mm stented and stentless bioprostheses.

Table 2 shows the Effective Orifice Area of the Shelhigh Porcine Stented and Stentless Bioprostheses, 23mm, and 25mm mounting size, tested on the Pulse Duplicator system at the pulse rates indicated in the protocol.

Tables 3 - 9 present the cardiac output (heart rate x stroke volume), flow rates (measured flow during diastole), pressure (not representative of physiologic system) and EOA and leakage volume percentage* for each valves tested at rates specified in the protocol ('23' and '25' represent 23 and 25mm stented valves respectively and 'S23' and 'S25' represent 23 and 25 mm stentless valves respectively).

*This is not factual, there is no leakage during valve closure.

4.4.2 Effective Orifice Areas

In this study, effective orifice area (EOA) has been computed for each bioprosthesis using essentially the Gorlin formula with a discharge coefficient of 1². Table 1 shows the statistical analyses (t-test) of the differences in the EOA for stented and stentless valves of the same size. The stented and stentless valves of the same size provide significantly different EOAs. For all rates tested as specified in the protocol, the 25mm stentless valve provided an average EOA of 2.41 cm² while the 25mm stented valve provided an EOA of 2.18 cm². The 23mm stentless valve provided an average EOA of 2.13 cm² while the 25mm stented valve provided an EOA of 1.91 cm². There is an obvious and statistically significant tendency of EOA to increase as with the stentless bioprostheses as shown in figure 4 and 5. The significance was based on the calculation of the p value for the size 23 and 25mm stented and stentless bioprostheses. A p-value of 0.039 and 0.037 was calculated for the 23 and 25mm bioprostheses respectively.

Test data sheets for each test run of each valve which include pertinent information such as stroke volume, cardiac output, flow rates, pressure gradients, regurgitant fraction, EOA, performance index and additional information are listed in appendix I.

Table 1. Two-sample student's t-test for 23 and 25mm stented and stentless bioprostheses. P value < 0.05 for a one tail t-test is considered significant.

t-Test: Two-Sample Assuming Unequal Variances

	23mm Bioprostheses		25mm Bioprostheses	
	<i>Stented</i>	<i>Stentless</i>	<i>Stented</i>	<i>Stentless</i>
Mean EOA (cm ²)	1.91	2.13	2.18	2.41
Variance	0.06	0.03	0.04	0.05
Observations	7	7	7	7
Hypothesized Mean Difference	0		0	
df	11		12	
t Stat	-1.9376		-1.9471	
P(T<=t) one-tail	0.039		0.038	
t Critical one-tail	1.80		1.78	

Table 2. Overall Effective Orifice Area (EOA) and p-value using a one-tail Student's t-test of 23 and 25 mm stented (model 100) and stentless (model 2000) aortic valves mounted in aortic root and tested using the Pulse duplicator system at rates of 60, 70, 80, 90, 100, 110, and 120 BPM.

Size	Effective Orifice Area (EOA) (sq. cm)		p-value one-tail
	Stented	Unstented	
23	1.91	2.13	.039
25	2.18	2.41	.037

A statistical analysis was performed using a one-tail Student's t-test to determine the p-value in which a p-value of less than .05 is considered statistically significant. A p-value of 0.039 and 0.037 was obtained for the 23 and 25 mm valves respectively showing the EOA between stented and stentless valve are statistically significant.

Table 3
Pulse Rate: 60 BPM

Run #	CO (L/m)	Flow RMS (L/m)	Flow mean (L/m)	Pressure mean (mm Hg)	EOA (sq. cm)	Leakage Volume (percent)*	Size (mm)
1	4.65	11.41	7.67	7.07	1.39	5.31	23
2	4.87	11.94	8.06	5.68	1.62	4.31	
3	4.47	10.49	7.21	4.63	1.57	2.93	
4	-----	-----	-----	-----	-----	-----	
mean	4.66	11.28	7.65	5.79	1.53	4.18	
σ_x	0.16	0.60	0.35	1.00	0.10	0.98	
5	5.03	11.09	7.64	3.18	2.01	2.43	25
6	4.76	11.16	7.60	7.16	1.35	2.48	
7	4.75	11.55	7.77	3.90	1.89	4.04	
8	4.26	10.79	7.17	2.94	2.03	5.10	
mean	4.70	11.15	7.55	4.30	1.82	3.51	
σ_x	0.28	0.27	0.23	1.69	0.28	1.12	
9	4.60	10.56	7.44	3.15	1.92	5.72	S23
10	4.78	10.11	7.09	2.90	1.92	4.88	
11	4.71	10.74	7.41	3.44	1.87	2.73	
12	-----	-----	-----	-----	-----	-----	
mean	4.70	10.47	7.31	3.16	1.90	4.44	
σ_x	0.07	0.27	0.16	0.22	0.02	1.26	
13	4.22	10.60	7.11	2.84	2.03	7.57	S25
14	5.27	12.14	8.44	3.68	2.04	3.09	
15	4.40	10.58	7.23	2.67	2.09	6.82	
16	-----	-----	-----	-----	-----	-----	
mean	4.63	11.11	7.59	3.06	2.05	5.83	
σ_x	0.46	0.73	0.60	0.44	0.03	1.96	

Table 4
Pulse Rate: 70 BPM

Run #	CO (L/m)	Flow RMS (L/m)	Flow mean (L/m)	Pressure mean (mm Hg)	EOA (sq. cm)	Leakage Volume (percent)*	Size (mm)
1	5.28	13.00	8.69	7.08	1.58	5.02	23
2	5.41	12.97	8.76	5.60	1.77	3.87	
3	5.55	12.36	8.63	5.79	1.66	2.58	
4	-----	-----	-----	-----	-----	-----	
mean	5.41	12.78	8.69	6.16	1.67	3.82	
σ_x	0.11	0.29	0.05	0.66	0.08	1.00	
5	5.50	13.01	8.74	5.18	1.85	2.08	25
6	5.72	13.94	9.26	5.37	1.94	2.31	
7	5.88	13.83	9.26	4.48	2.11	4.80	
8	5.50	13.69	9.08	4.24	2.15	6.93	
mean	5.65	13.62	9.09	4.82	2.01	4.03	
σ_x	0.16	0.36	0.21	0.47	0.12	1.99	
9	5.52	13.14	9.00	4.71	1.96	3.90	S23
10	4.90	12.12	8.11	3.86	1.99	4.08	
11	5.43	12.25	8.36	4.30	1.91	2.39	
12	-----	-----	-----	-----	-----	-----	
mean	5.28	12.50	8.49	4.29	1.95	3.46	
σ_x	0.27	0.45	0.37	0.35	0.03	0.76	
13	5.34	13.65	9.08	4.08	2.18	10.57	S25
14	5.85	13.83	9.35	4.32	2.15	4.56	
15	5.10	12.62	8.42	3.54	2.17	5.56	
16	-----	-----	-----	-----	-----	-----	
mean	5.43	13.37	8.95	3.98	2.17	6.90	
σ_x	0.31	0.53	0.39	0.33	0.01	2.63	

Table 5
Pulse Rate: 80 BPM

Run #	CO (L/m)	Flow RMS (L/m)	Flow mean (L/m)	Pressure mean (mm Hg)	EOA (sq. cm)	Leakage Volume (percent)*	Size (mm)
1	6.01	14.40	9.65	6.61	1.81	0.02	23
2	6.49	15.42	10.37	6.85	1.90	3.72	
3	6.56	14.96	10.27	6.51	1.89	1.74	
4	-----	-----	-----	-----	-----	-----	
mean	6.35	14.93	10.10	6.66	1.87	1.83	
σ_x	0.24	0.42	0.32	0.14	0.04	1.51	
5	6.17	14.86	9.86	4.58	2.24	4.18	25
6	6.07	14.82	9.85	8.25	1.67	2.59	
7	6.27	15.57	10.29	5.25	2.19	5.55	
8	6.41	16.56	10.91	5.35	2.31	1.82	
mean	6.23	15.45	10.23	5.86	2.10	3.54	
σ_x	0.13	0.71	0.43	1.41	0.25	1.44	
9	6.74	15.24	10.71	5.59	2.08	0.01	S23
10	5.96	14.40	9.64	4.89	2.10	1.17	
11	6.38	14.13	9.68	5.16	2.01	2.35	
12	-----	-----	-----	-----	-----	-----	
mean	6.36	14.59	10.01	5.21	2.06	1.18	
σ_x	0.32	0.47	0.50	0.29	0.04	0.96	
13	6.16	16.32	10.65	4.78	2.41	13.03	S25
14	6.82	17.25	11.44	5.32	2.42	6.55	
15	6.17	15.92	10.48	4.64	2.39	4.39	
16	-----	-----	-----	-----	-----	-----	
mean	6.38	16.50	10.86	4.91	2.41	7.99	
σ_x	0.31	0.56	0.42	0.29	0.01	3.67	

Table 6
Pulse Rate: 90 BPM

Run #	CO (L/m)	Flow RMS (L/m)	Flow mean (L/m)	Pressure mean (mm Hg)	EOA (sq. cm)	Leakage Volume (percent)*	Size (mm)
1	6.46	15.46	10.35	6.93	1.90	0.01	23
2	7.15	16.32	11.12	6.88	2.01	3.22	
3	7.64	16.48	11.51	7.75	1.91	2.39	
4	-----	-----	-----	-----	-----	-----	
mean	7.08	16.09	10.99	7.19	1.94	1.87	
σ_x	0.48	0.45	0.48	0.40	0.05	1.36	
5	7.79	16.83	11.65	5.13	2.40	4.20	25
6	6.86	15.99	10.76	5.97	2.11	5.39	
7	7.11	16.61	11.29	5.23	2.35	6.03	
8	7.13	17.19	11.65	5.56	2.36	0.03	
mean	7.22	16.66	11.34	5.47	2.31	3.91	
σ_x	0.34	0.44	0.36	0.33	0.11	2.34	
9	7.37	15.72	11.14	5.80	2.11	1.76	S23
10	6.72	15.44	10.53	5.28	2.17	3.21	
11	7.33	16.05	10.89	5.59	2.19	2.17	
12	-----	-----	-----	-----	-----	-----	
mean	7.14	15.74	10.85	5.56	2.16	2.38	
σ_x	0.30	0.25	0.25	0.21	0.03	0.61	
13	6.96	17.97	11.91	5.48	2.48	12.63	S25
14	8.05	17.82	12.32	5.48	2.46	6.19	
15	6.48	16.78	11.11	4.89	2.45	8.78	
16	-----	-----	-----	-----	-----	-----	
mean	7.16	17.52	11.78	5.28	2.46	9.20	
σ_x	0.66	0.53	0.50	0.28	0.01	2.65	

Table 7
Pulse Rate: 100 BPM

Run #	CO (L/m)	Flow RMS (L/m)	Flow mean (L/m)	Pressure mean (mm Hg)	EOA (sq. cm)	Leakage Volume (percent)*	Size (mm)
1	7.36	16.19	11.01	6.73	2.02	0.01	23
2	7.82	16.66	11.50	6.42	2.12	4.00	
3	8.40	17.56	12.20	7.90	2.02	2.10	
4	-----	-----	-----	-----	-----	-----	
mean	7.86	16.80	11.57	7.02	2.05	2.04	
σ_x	0.43	0.57	0.49	0.64	0.05	1.63	
5	7.98	16.84	11.73	6.74	2.10	4.95	25
6	7.95	16.95	11.77	6.24	2.19	2.67	
7	8.02	16.98	11.83	5.50	2.34	4.81	
8	7.75	17.90	12.24	5.72	2.42	6.91	
mean	7.93	17.17	11.89	6.05	2.26	4.84	
σ_x	0.10	0.43	0.20	0.48	0.13	1.50	
9	8.12	16.86	11.94	6.07	2.21	4.56	S23
10	7.78	16.40	11.44	5.57	2.24	4.19	
11	8.01	17.37	11.85	6.04	2.28	2.75	
12	-----	-----	-----	-----	-----	-----	
mean	7.97	16.88	11.74	5.89	2.24	3.83	
σ_x	0.14	0.40	0.22	0.23	0.03	0.78	
13	7.70	18.75	12.58	5.71	2.53	9.47	S25
14	8.80	18.68	13.02	5.66	2.54	5.30	
15	7.83	18.43	12.39	5.29	2.59	7.32	
16	-----	-----	-----	-----	-----	-----	
mean	8.11	18.62	12.66	5.55	2.55	7.36	
σ_x	0.49	0.14	0.26	0.19	0.03	1.70	

Table 8
Pulse Rate: 110 BPM

Run #	CO (L/m)	Flow RMS (L/m)	Flow mean (L/m)	Pressure mean (mm Hg)	EOA (sq. cm)	Leakage Volume (percent)*	Size (mm)
1	7.96	17.36	7.14	7.14	2.10	0.03	23
2	8.74	18.19	12.53	6.76	2.26	1.41	
3	8.83	18.03	12.62	7.72	2.10	1.21	
4	-----	-----	-----	-----	-----	-----	
mean	8.51	17.86	10.76	7.21	2.15	0.88	
σ_x	0.39	0.36	2.56	0.39	0.08	0.61	
5	8.98	18.74	12.98	5.85	2.50	2.88	25
6	8.54	18.08	12.45	6.34	2.32	3.85	
7	8.75	18.11	12.61	5.88	2.41	4.57	
8	8.54	19.35	13.16	6.54	2.44	0.02	
mean	8.70	18.57	12.80	6.15	2.42	2.83	
σ_x	0.18	0.52	0.28	0.30	0.07	1.73	
9	8.56	17.89	12.52	6.56	2.26	2.51	S23
10	8.04	17.46	11.98	5.93	2.31	3.17	
11	8.31	17.18	11.95	6.04	2.26	3.16	
12	-----	-----	-----	-----	-----	-----	
mean	8.30	17.51	12.15	6.18	2.28	2.95	
σ_x	0.21	0.29	0.26	0.27	0.02	0.31	
13	8.33	19.86	13.27	6.07	2.60	7.50	S25
14	9.43	20.05	13.88	6.39	2.56	4.60	
15	8.79	19.83	13.44	5.99	2.62	4.23	
16	-----	-----	-----	-----	-----	-----	
mean	8.85	19.91	13.53	6.15	2.59	5.44	
σ_x	0.45	0.10	0.26	0.17	0.02	1.46	

Table 9
Pulse Rate: 120 BPM

Run #	CO (L/m)	Flow RMS (L/m)	Flow mean (L/m)	Pressure mean (mm Hg)	EOA (sq. cm)	Leakage Volume (percent)*	Size (mm)
1	8.85	19.50	13.23	8.49	2.16	0.00	23
2	9.81	19.88	13.95	8.05	2.26	2.82	
3	9.47	19.15	13.44	8.14	2.17	2.78	
4	-----	-----	-----	-----	-----	-----	
mean	9.38	19.51	13.54	8.23	2.20	1.87	
σ_x	0.40	0.30	0.30	0.19	0.05	1.32	
5	9.38	19.44	13.48	6.38	2.49	3.59	
6	9.40	19.39	13.45	6.91	2.38	3.02	
7	9.67	19.80	13.81	6.66	2.48	3.98	
8	9.35	20.56	14.09	9.65	2.14	4.30	
mean	9.45	19.80	13.71	7.40	2.37	3.72	
σ_x	0.13	0.47	0.26	1.31	0.14	0.48	
9	9.09	18.94	13.22	6.97	2.32	4.95	S23
10	8.98	19.05	13.06	6.59	2.40	4.05	
11	9.51	19.33	13.44	6.80	2.39	2.40	
12	-----	-----	-----	-----	-----	-----	
mean	9.19	19.11	13.24	6.79	2.37	3.80	
σ_x	0.23	0.16	0.16	0.16	0.04	1.06	
13	9.37	22.04	14.78	7.04	2.68	8.76	S25
14	10.11	21.32	14.80	6.99	2.61	4.44	
15	9.49	21.81	14.73	6.74	2.71	3.98	
16	-----	-----	-----	-----	-----	-----	
mean	9.66	21.72	14.77	6.92	2.67	5.73	
σ_x	0.32	0.30	0.03	0.13	0.04	2.15	

Tables 3-9

* This leakage volume is an artifact; it is due to the fact that the disks which were used to mount the aortic root in the pulse duplicator were not sealing completely because no glue was used. This "leakage" is due to fluid leaking around the annulus of the aortic root, but not due to leakage of the valves themselves. There was no real variation in leakage percent among the valves which were mounted in different size roots. This "leakage" is therefore not due to coaption, the coming together of the cusps, of the valve and thus it is not regurgitation. Regurgitation of a valve is the backflow of blood through the valve while the valve is in the closed position. To confirm the nature of the leakage, a test was performed using a dye to actually see the leakage of fluid around the annulus due to the imperfect connection of the disks used to hold the aortic root that were not sealing fully.

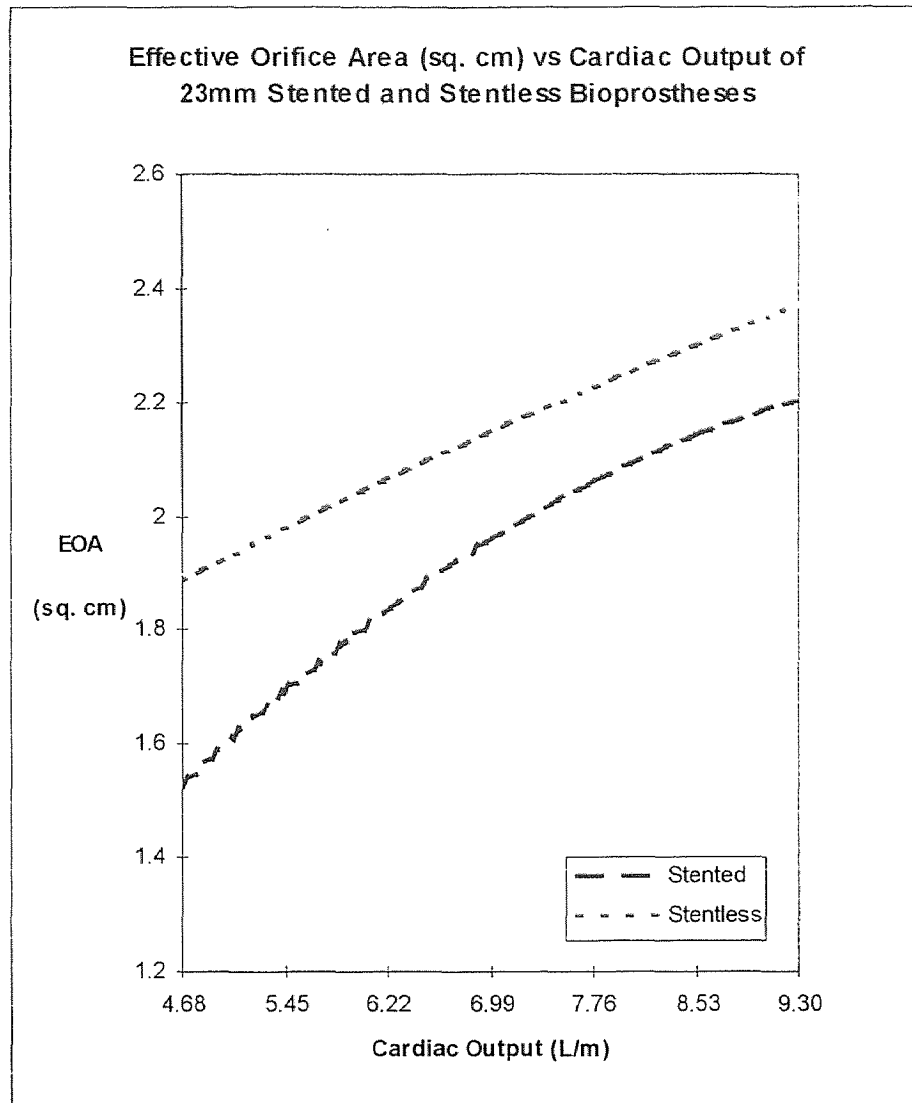


Figure 4. Effective Orifice Area vs Cardiac Output of 23mm Stented and Stentless Bioprostheses

Graph of EOA vs Cardiac Output for the 23mm stented and stentless bioprosthesis shows a somewhat parallel trend of a statistically significant higher EOA for the stentless bioprostheses for all cardiac outputs than the stented bioprostheses.

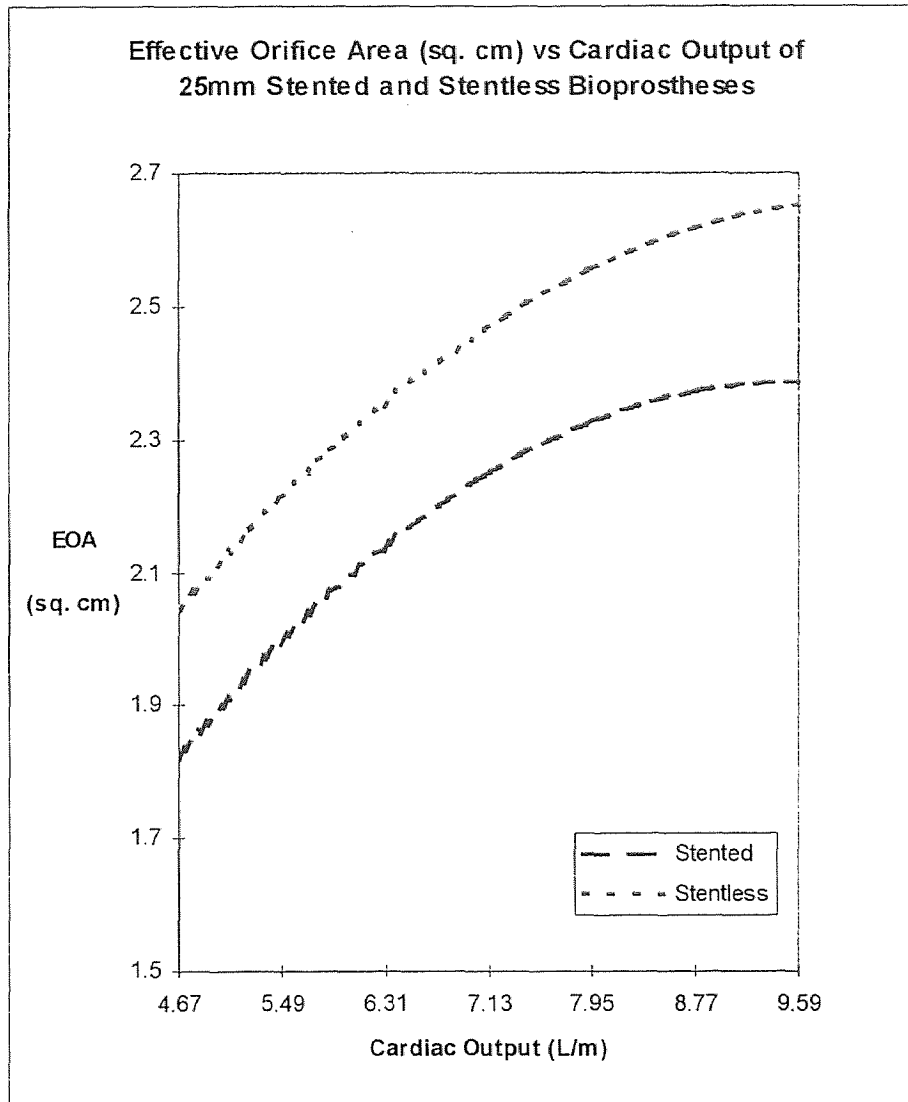


Figure 5. Effective Orifice Area vs Cardiac Output of 25mm Stented and Stentless Bioprostheses

Graph of EOA vs Cardiac Output for the 25mm stented and stentless bioprosthesis shows a somewhat parallel trend of a statistically significant higher EOA for the stentless bioprostheses for all cardiac outputs than the stented bioprostheses.

CHAPTER 5

CLINICAL DATA

Data of the Shelhigh Stentless Porcine Bioprosthesis implanted clinically shows that smaller size valves can have a better Effective Orifice Area than larger valves. The Effective Orifice Area was calculated using 2-D Echo on a total of 97 implanted valves, 52 stentless valves and 45 stented valves implanted by Prof. Infantes at Virgen Macarena Hospital - Seville Spain. Data shows that the stentless valve had an overall higher EOA than the Stented valve. The Effective Orifice Area ranged from 1.20 to 2.32cm² with stentless valves and 1.06 to 2.28cm² with stented valves, sizes 21 and 29 mm respectively. This clinical data agrees with the data obtained from in vitro testing of stented and stentless valves. In vitro testing showed a higher EOA in the stentless valve than in the stented valve. Table 10 shows number of stentless and stented valves of different sizes implanted as well as the average EOA for each size⁸.

Table 10. Clinical Data from Virgen-Macarena Hospital-Seville Spain. Comparative Effective Orifice Area calculated by 2-D Echo.

Size	Stentless Valves (O'Brien-Angell)			Stented Valves (Angell-Duran)		
	No. of implants	EOA (sq. cm)	s.d. (sq. cm)	No. of implants	EOA (sq. cm)	s.d. (sq. cm)
21mm	2	1.20	0.4	8	1.06	0.02
23mm	18	2.07	0.7	17	1.50	0.4
25mm	11	1.45	0.5	10	1.48	0.2
27mm	11	2.41	0.7	6	1.73	0.4
29mm	10	2.32	1.0	4	2.28	0.9

CHAPTER 6

DISCUSSION

The Effective Orifice Area of the Shelhigh Porcine Stented and Stentless Bioprosthesis determined by the pulse duplicator averaged for all rates and valves tested for each of the two sizes, demonstrates the Shelhigh stentless valve has a statistically significant higher EOA than the stented bioprostheses. The Shelhigh stentless 23mm valve with an average EOA of 2.13 cm² at an average Cardiac Output of 6.7 L/M is 11% higher than Shelhigh stented valves, a value which is statistically significant. A P value of 0.039 was obtained using a one tailed t-test, where a P value less than 0.05 is considered to be statistically significant. Also statistically significant are the Shelhigh 25mm stentless valves with an average EOA of 2.41 cm² as compared to the Shelhigh 25 mm stented valves with an EOA of 2.18 cm². The 25mm Shelhigh stentless valve has a 10% higher EOA than the stented Shelhigh valve. A P value of 0.037 was obtained using a one tailed t-test which is considered significant.

Comparison of clinical data of 97 clinically implanted valves, stented and stentless, using 2-D echocardiogram revealed that the average Effective Orifice Area of the stentless valve is higher than stented valves. It was found that the average Effective Orifice Area of the stentless valve was higher in all but one size valve, the 25mm stentless valve. The average EOA for the 25mm valves implanted was 1.45 cm² and 1.48 cm², stentless and stented valves respectively. The cause of the 0.03 cm² lower EOA in the stentless valve than the stented valve may be contributed to the sizing of the stentless valves during implantation. Due to the lack of a fixed orifice in the stentless valve, oversizing of the valve during implantation can cause relative stenosis and the EOA to be reduced to that of stented valves or less.

This study in general demonstrates that the Shelhigh stentless bioprosthesis has a much higher EOA throughout the entire spectrum of flow rates tested than the stented bioprosthesis. This shows stented bioprostheses produce some degree of obstruction to flow due to the semi-rigid stent, thus not allowing for the valve to distend fully at times of high flow rates. The stentless valve, since there is no stent the valve is prone to distend at high flow rates.

The design of the stented bioprosthesis has some limiting factors, mainly the fixed orifice. Thus the area available for flow has certain limits. Furthermore, the muscle shelf on the right cusp causes additional potential for stenosis. The Shelhigh unstented porcine aortic xenograft composite will not only increase the hemodynamic efficiency to an optimum level, but it will reduce the stress on the commissures. This “mechanical” advantage is known to increase the durability of porcine valves. The flow of a composite valve is optimized due to the design of the valve. This valve, the Shelhigh No-React[®] unstented aortic xenograft is a composite of three porcine aortic valves which have been preserved by a low pressure aldehyde fixation process. The non coronary leaflets from each of three aldehyde fixed porcine aortic heart valves are dissected, matched and sutured together with cardiovascular suture, then covered with pericardium. The resulting composite unstented valve has an optimum orifice area due to the absence of the septal shelf found on the right coronary leaflet of the natural porcine aortic valve.

The regurgitant fraction of the valves in some instances appeared higher than others due to the manner in which the discs that are placed around the aortic annulus are used in the mounting of the aortic root in the PDS. This process results in imperfect sealing because no glue is used. These discs may also not have been the proper size, thereby allowing fluid to

leak back through the discs giving results of high regurgitation. Most of the “leakage” is recorded as a closing volume. This volume is recorded as “regurgitant” because of the volume needed to close the valve and even after the valve is closed the soft cusps continue to move backward. The real regurgitation fraction after the valve is closed is practically zero. A small amount of fluid might leak around the mounting ring, since it is very difficult to prevent this leak in a pulse duplicator.

Sizing of the stentless valves became an important factor during this study. The 23mm valve was implanted and tested in different size roots which include, 23, 25 and 27mm roots. The 25mm valve was implanted and tested in size 25, and 29mm root. This was performed to compare the results of implanting the same size stentless valve in different size aorta. The reason for this type of testing is to examine the effects of surgeons oversizing or undersizing valves during implantation and the effects of remodeling which takes place after surgery. During surgery, sizing of the aortic root while the patient is on bypass may be slightly smaller than it would be after the patient is taken off bypass due to the systolic pressure expanding the aorta. The following was the approach used to undersize the valve by one size, an aortic root sized to be 25mm using selected sizers with an outer diameter equivalent to the stated valve size was used for the implantation of a 23mm stentless valve. Hemodynamics improved slightly; however the valve still appeared to have less than perfect hemodynamics based on the data obtained and visual inspection of the valve in the aortic root. Additional testing was done in which a stentless valve was implanted into a root two sizes larger than the valve. Previously it had been thought that implanting a valve in a larger root would cause serious regurgitation and inflict a substantial amount of stress on the valve; however there was no sign of stress on the valve. All three cusps were symmetrical and

during testing the valve opened and closed very well. Results of testing showed no significant regurgitation and an EOA higher than a stented valve of the same size. Results indicate that even with the dilatation of the aorta after surgery, implanting a stentless valve in an aortic root one size larger, hemodynamics will be improved over the stented valve. It is apparent from this study that the Shelhigh stentless valve model 2000, can resist dilatation up to 2 sizes higher. It is probably better to undersize the valve during implantation as the EOA will be higher when compared to an oversized valve still no significant regurgitation could be measured. This is due to the relatively higher coaptation area of the cusps, as well as the maintenance of the physical integrity of the valve due to the pericardial tissue covering the valve.

CHAPTER 7

CONCLUSION

The Shelhigh No-React® Unstented Porcine Aortic Xenograft found to have an excellent hemodynamic properties superior to the stented valves. A statistical analysis showed stentless valves have a significantly higher EOA than stented valves of the same size. The valve can be undersized and still produce excellent hemodynamic properties better than that of a stented.

The in-vitro hemodynamic studies were confirmed by clinical comparative findings that hemodynamic advantages of the stentless valve is not always evident; smaller size valves can have better hemodynamics than larger valves.

One of the most significant problems of the stentless valve is its propensity for less than ideal coaption of the cusps leading to high incidence of aortic regurgitation murmur. Regurgitation murmur can be a sign of reduced durability. This study shows that the Shelhigh No-React® stentless valve covered with pericardium, even if implanted in larger aortic root can resist distention or distortion and continue to be competent. Oversizing appears to cause relative stenosis and the EOA can be reduced significantly. We conclude that the pericardial cuff gives the valve certain design integrity and more resistance to distortion and dilatation. Oversizing is not necessary to assure a good coaption. Undersizing can be desirable and might achieve higher effective orifice areas. This ability to adapt to different size aortic roots is important when the aorta distends with changes in systolic pressure. Based on the research of stentless valves it is recommended that surgeons use one size smaller than measured.

APPENDIX A
TEST DATA SHEETS

SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 159 Valve Type: **SHELHIGH** Serial No. **S1069** Valve size: **23 mm** Mitral Posi
 Operator: E. Sean Parker

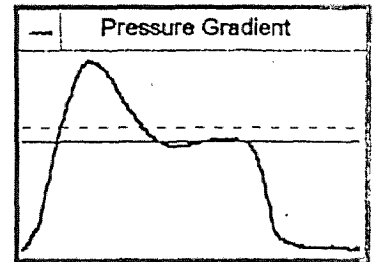
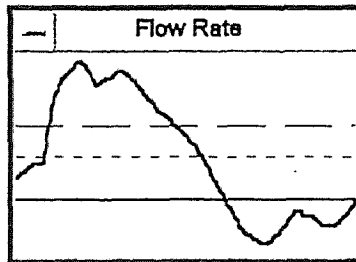
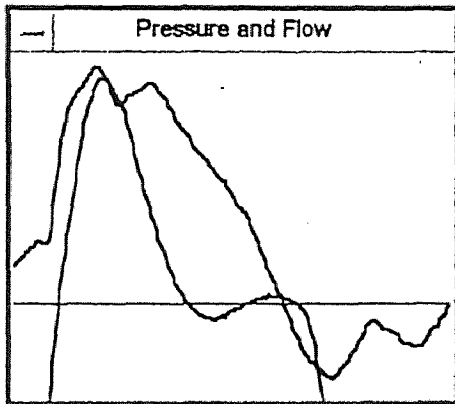
System Parameters: Heart Rate: 61.22 bpm
 Stroke Volume: 75.21 ml
 Cardiac Output: 4.60 L/m
 Duration of valve cycle: 0.98 sec.
 Forward Flow Phase: 0.60 sec. 61.44 %

Measured Flow (L/m): RMS: 10.56 L/m
 Mean: 7.44 L/m
 Peak: 12.43 L/m

Measured Pressures (mm Hg): Mean: 3.15 mm Hg
 Peak Pressure: 11.80 mm Hg
 Pressure at max flow: 11.62 mm Hg

Valve Parameters Closing Volume: 8.71 ml, 11.59 %
 Leakage Volume: 4.30 ml, 5.72 %
 Regurgitant Fraction: 17.30 %

Effective Orifice Area (sq cm.): Peak: 2.26 Discharge Coefficient: 0.612
 Mean: 1.35 Performance Index: 0.463
 RMS: 1.92 Efficiency Index: 0.383



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 160 Valve Type: **SHELHIGH** Serial No. **S1069** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

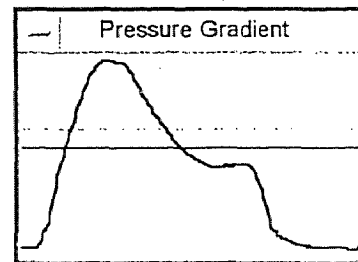
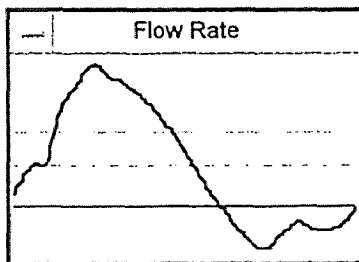
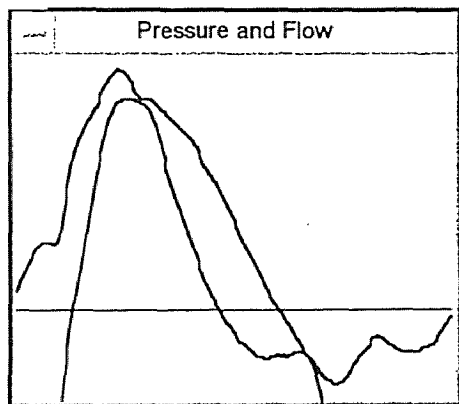
System Parameters: Heart Rate: 75.38 bpm
 Stroke Volume: 73.23 ml
 Cardiac Output: 5.52 L/m
 Duration of valve cycle: 0.80 sec.
 Forward Flow Phase: 0.48 sec. 60.71 %

Measured Flow (L/m): RMS: 13.14 L/m
 Mean: 9.00 L/m
 Peak: 16.13 L/m

Measured Pressures (mm Hg): Mean: 4.71 mm Hg
 Peak Pressure: 14.17 mm Hg
 Pressure at max flow: 14.00 mm Hg

Valve Parameters Closing Volume: 11.40 ml, 15.57 %
 Leakage Volume: 2.86 ml, 3.90 %
 Regurgitant Fraction: 19.48 %

Effective Orifice Area (sq cm.): Peak: 2.40 Discharge Coefficient: 0.622
 Mean: 1.34 Performance Index: 0.471
 RMS: 1.96 Efficiency Index: 0.379



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 161 Valve Type: **SHELHIGH** Serial No. **S1069** Valve size: **23 mm** Mitral Position:
 Operator: E. Sean Parker

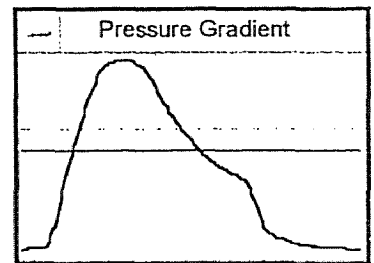
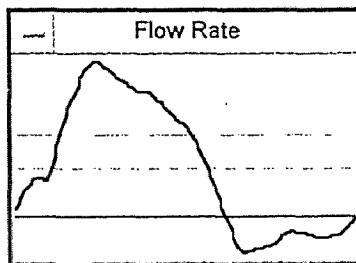
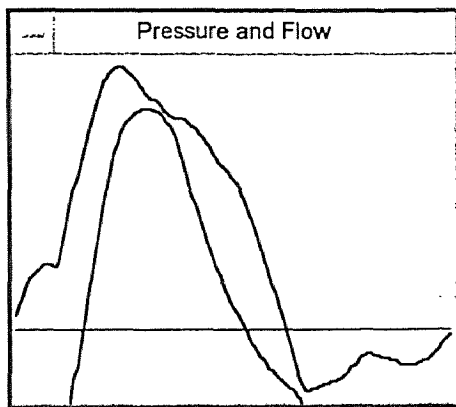
System Parameters: Heart Rate: 84.75 bpm
 Stroke Volume: 79.54 ml
 Cardiac Output: 6.74 L/m
 Duration of valve cycle: 0.71 sec.
 Forward Flow Phase: 0.44 sec. 62.21 %

Measured Flow (L/m): RMS: 15.24 L/m
 Mean: 10.71 L/m
 Peak: 18.39 L/m

Measured Pressures (mm Hg): Mean: 5.59 mm Hg
 Peak Pressure: 15.37 mm Hg
 Pressure at max flow: 13.67 mm Hg

Valve Parameters Closing Volume: 11.11 ml, 13.96 %
 Leakage Volume: 0.01 ml, 0.01 %
 Regurgitant Fraction: 13.98 %

Effective Orifice Area (sq cm.): Peak: 2.51 Discharge Coefficient: 0.663
 Mean: 1.46 Performance Index: 0.501
 RMS: **2.08** Efficiency Index: 0.431



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 162 Valve Type: **SHELHIGH** Serial No. **S1069** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

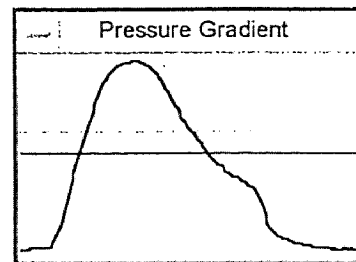
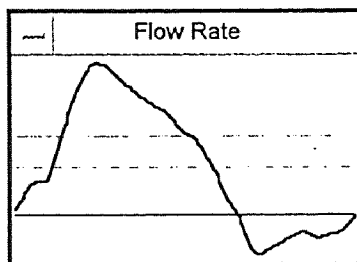
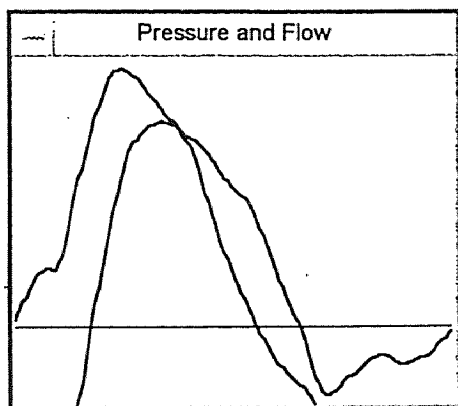
System Parameters: Heart Rate: 92.59 bpm
 Stroke Volume: 79.64 ml
 Cardiac Output: 7.37 L/m
 Duration of valve cycle: 0.65 sec.
 Forward Flow Phase: 0.42 sec. 65.41 %

Measured Flow (L/m): RMS: 15.72 L/m
 Mean: 11.14 L/m
 Peak: 20.22 L/m

Measured Pressures (mm Hg): Mean: 5.80 mm Hg
 Peak Pressure: 16.07 mm Hg
 Pressure at max flow: 11.45 mm Hg

Valve Parameters Closing Volume: 9.56 ml, 12.01 %
 Leakage Volume: 1.40 ml, 1.76 %
 Regurgitant Fraction: 13.77 %

Effective Orifice Area (sq cm.): Peak: 2.71 Discharge Coefficient: 0.671
 Mean: 1.49 Performance Index: 0.507
 RMS: 2.11 Efficiency Index: 0.438



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 163 Valve Type: **SHELHIGH** Serial No. **S1069** Valve size: **23 mm** Mitral Positic
 Operator: E. Sean Parker

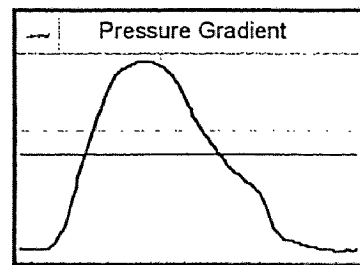
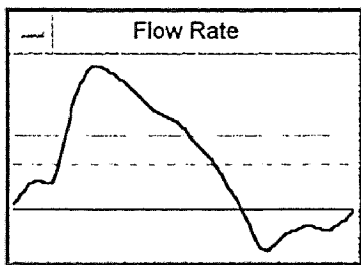
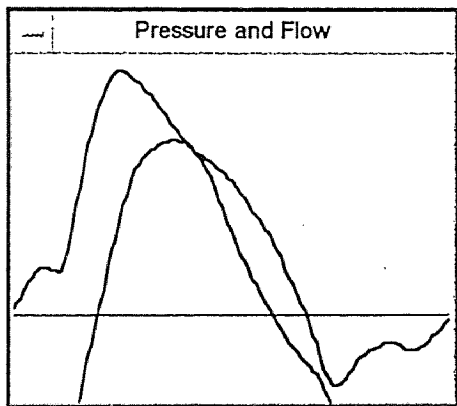
System Parameters: Heart Rate: 102.04 bpm
 Stroke Volume: 79.61 ml
 Cardiac Output: 8.12 L/m
 Duration of valve cycle: 0.59 sec.
 Forward Flow Phase: 0.39 sec. 67.12 %

Measured Flow (L/m): RMS: 16.86 L/m
 Mean: 11.94 L/m
 Peak: 22.65 L/m

Measured Pressures (mm Hg): Mean: 6.07 mm Hg
 Peak Pressure: 16.25 mm Hg
 Pressure at max flow: 10.25 mm Hg

Valve Parameters Closing Volume: 7.55 ml, 9.48 %
 Leakage Volume: 3.63 ml, 4.56 %
 Regurgitant Fraction: 14.04 %

Effective Orifice Area (sq cm.): Peak: 2.97 Discharge Coefficient: 0.703
 Mean: 1.57 Performance Index: 0.532
 RMS: 2.21 Efficiency Index: 0.457



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 164 Valve Type: **SHELHIGH** Serial No. **S1069** Valve size: **23 mm** Mitral Positic:
 Operator: E. Sean Parker

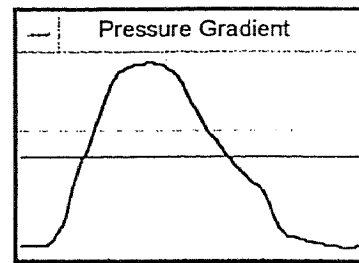
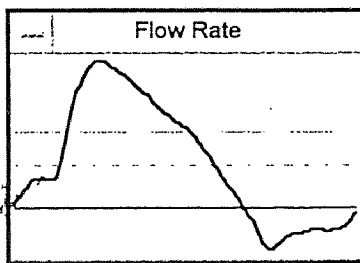
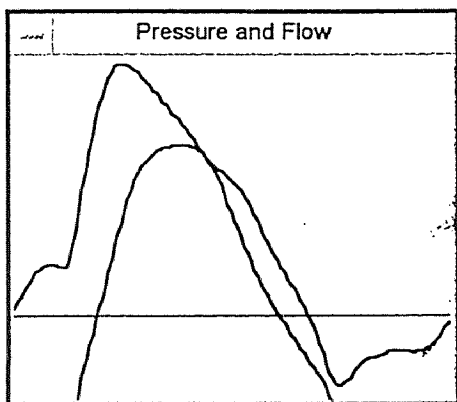
System Parameters: Heart Rate: 111.11 bpm
 Stroke Volume: 77.06 ml
 Cardiac Output: 8.56 L/m
 Duration of valve cycle: 0.54 sec.
 Forward Flow Phase: 0.36 sec. 67.41 %

Measured Flow (L/m): RMS: 17.89 L/m
 Mean: 12.52 L/m
 Peak: 24.42 L/m

Measured Pressures (mm Hg): Mean: 6.56 mm Hg
 Peak Pressure: 16.55 mm Hg
 Pressure at max flow: 10.22 mm Hg

Valve Parameters Closing Volume: 9.11 ml, 11.83 %
 Leakage Volume: 1.94 ml, 2.51 %
 Regurgitant Fraction: 14.34 %

Effective Orifice Area (sq cm.): Peak: 3.08 Discharge Coefficient: 0.718
 Mean: 1.58 Performance Index: 0.543
 RMS: 2.26 Efficiency Index: 0.465



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 165 Valve Type: **SHELHIGH** Serial No. **S1069** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

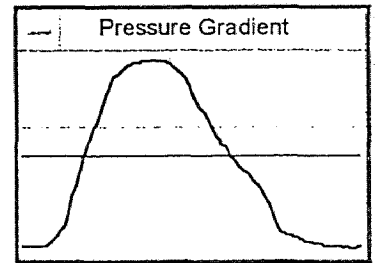
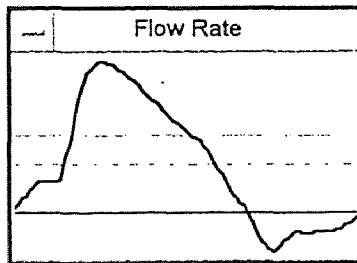
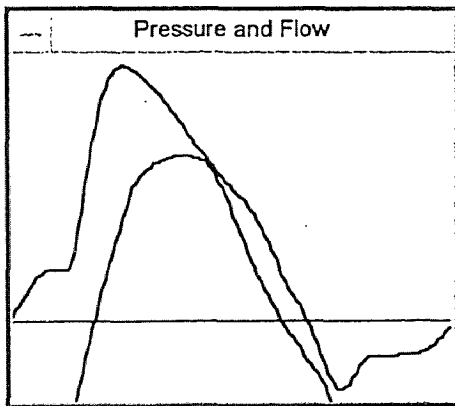
System Parameters: Heart Rate: 118.11 bpm
 Stroke Volume: 76.96 ml
 Cardiac Output: 9.09 L/m
 Duration of valve cycle: 0.51 sec.
 Forward Flow Phase: 0.34 sec. 67.72 %

Measured Flow (L/m): RMS: 18.94 L/m
 Mean: 13.22 L/m
 Peak: 25.93 L/m

Measured Pressures (mm Hg): Mean: 6.97 mm Hg
 Peak Pressure: 16.80 mm Hg
 Pressure at max flow: 10.65 mm Hg

Valve Parameters Closing Volume: 6.50 ml, 8.44 %
 Leakage Volume: 3.81 ml, 4.95 %
 Regurgitant Fraction: 13.38 %

Effective Orifice Area (sq cm.): Peak: 3.17 Discharge Coefficient: 0.737
 Mean: 1.62 Performance Index: 0.557
 RMS: 2.32 Efficiency Index: 0.483



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 360 Valve Type: **SHELHIGH** Serial No. **S1106** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

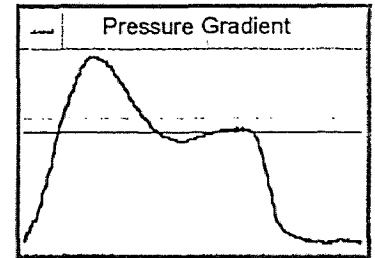
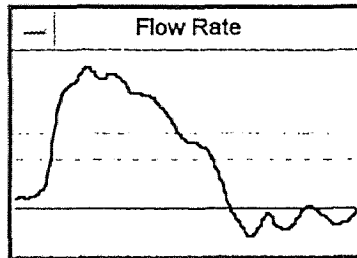
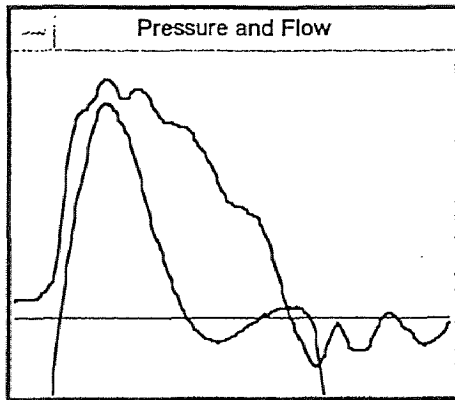
System Parameters: Heart Rate: 61.73 bpm
 Stroke Volume: 77.44 ml
 Cardiac Output: 4.78 L/m
 Duration of valve cycle: 0.97 sec.
 Forward Flow Phase: 0.65 sec. 66.82 %

Measured Flow (L/m): RMS: 10.11 L/m
 Mean: 7.09 L/m
 Peak: 12.65 L/m

Measured Pressures (mm Hg): Mean: 2.90 mm Hg
 Peak Pressure: 11.37 mm Hg
 Pressure at max flow: 11.37 mm Hg

Valve Parameters Closing Volume: 2.71 ml, 3.50 %
 Leakage Volume: 3.78 ml, 4.88 %
 Regurgitant Fraction: 8.38 %

Effective Orifice Area (sq cm.): Peak: 2.40 Discharge Coefficient: 0.611
 Mean: 1.35 Performance Index: 0.462
 RMS: 1.92 Efficiency Index: 0.423



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 361 Valve Type: **SHELHIGH** Serial No. **S1106** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

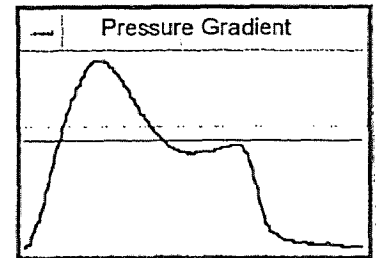
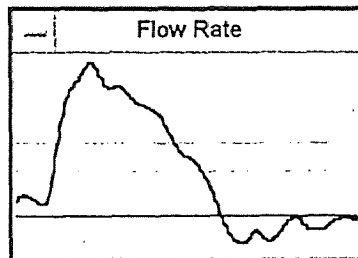
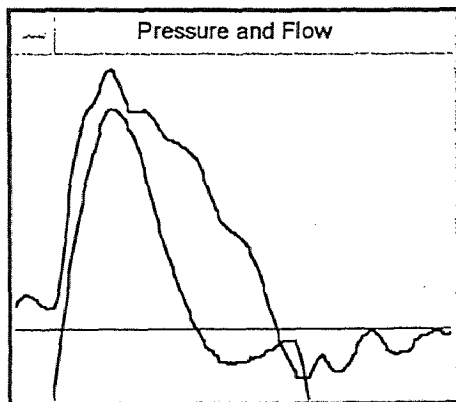
System Parameters: Heart Rate: 69.44 bpm
 Stroke Volume: 70.61 ml
 Cardiac Output: 4.90 L/m
 Duration of valve cycle: 0.86 sec.
 Forward Flow Phase: 0.52 sec. 59.91 %

Measured Flow (L/m): RMS: 12.12 L/m
 Mean: 8.11 L/m
 Peak: 15.27 L/m

Measured Pressures (mm Hg): Mean: 3.86 mm Hg
 Peak Pressure: 13.02 mm Hg
 Pressure at max flow: 13.02 mm Hg

Valve Parameters Closing Volume: 4.65 ml, 6.59 %
 Leakage Volume: 2.88 ml, 4.08 %
 Regurgitant Fraction: 10.67 %

Effective Orifice Area (sq cm.): Peak: 2.51 Discharge Coefficient: 0.633
 Mean: 1.33 Performance Index: 0.479
 RMS: **1.99** Efficiency Index: 0.428



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 362 Valve Type: **SHELHIGH** Serial No. **S1106** Valve size: **23 mm** Mitral Positio:
 Operator: E. Sean Parker

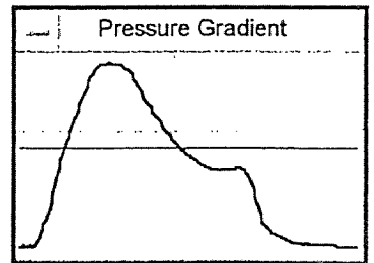
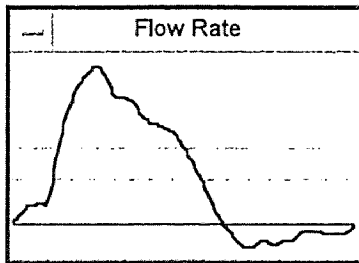
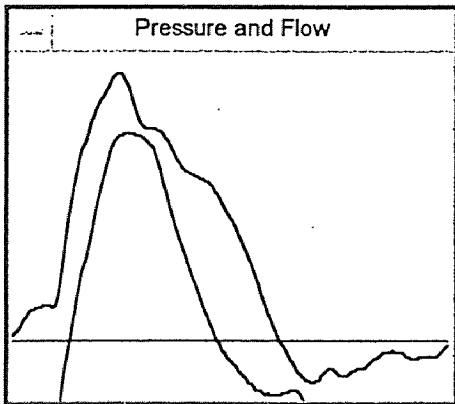
System Parameters: Heart Rate: 81.52 bpm
 Stroke Volume: 73.08 ml
 Cardiac Output: 5.96 L/m
 Duration of valve cycle: 0.74 sec.
 Forward Flow Phase: 0.45 sec. 61.11 %

Measured Flow (L/m): RMS: 14.40 L/m
 Mean: 9.64 L/m
 Peak: 18.72 L/m

Measured Pressures (mm Hg): Mean: 4.89 mm Hg
 Peak Pressure: 14.60 mm Hg
 Pressure at max flow: 14.30 mm Hg

Valve Parameters Closing Volume: 6.83 ml, 9.35 %
 Leakage Volume: 0.85 ml, 1.17 %
 Regurgitant Fraction: 10.52 %

Effective Orifice Area (sq cm.): Peak: 2.73 Discharge Coefficient: 0.669
 Mean: 1.41 Performance Index: 0.506
 RMS: 2.10 Efficiency Index: 0.453



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 363 Valve Type: **SHELHIGH** Serial No. **S1106** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

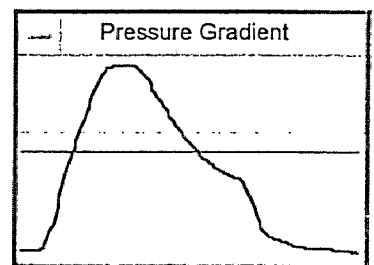
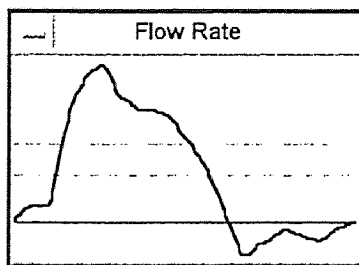
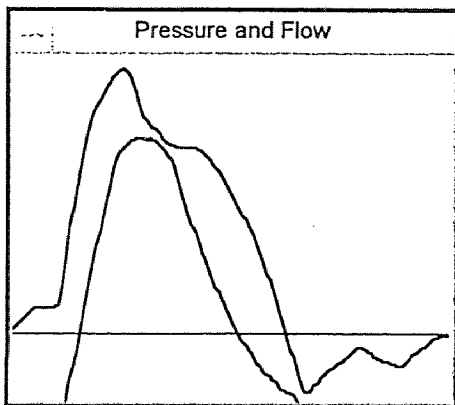
System Parameters: Heart Rate: 88.24 bpm
 Stroke Volume: 76.16 ml
 Cardiac Output: 6.72 L/m
 Duration of valve cycle: 0.68 sec.
 Forward Flow Phase: 0.43 sec. 63.03 %

Measured Flow (L/m): RMS: 15.44 L/m
 Mean: 10.53 L/m
 Peak: 20.07 L/m

Measured Pressures (mm Hg): Mean: 5.28 mm Hg
 Peak Pressure: 14.87 mm Hg
 Pressure at max flow: 14.17 mm Hg

Valve Parameters Closing Volume: 5.76 ml, 7.57 %
 Leakage Volume: 2.45 ml, 3.21 %
 Regurgitant Fraction: 10.78 %

Effective Orifice Area (sq cm.): Peak: 2.82 Discharge Coefficient: 0.690
 Mean: 1.48 Performance Index: 0.522
 RMS: 2.17 Efficiency Index: 0.466



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 364 Valve Type: **SHELHIGH** Serial No. **S1106** Valve size: **23 mm** Mitral Position:
 Operator: E. Sean Parker

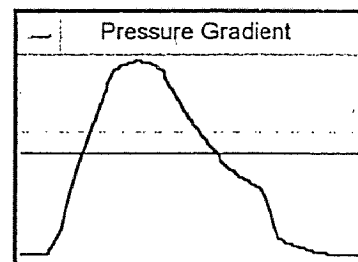
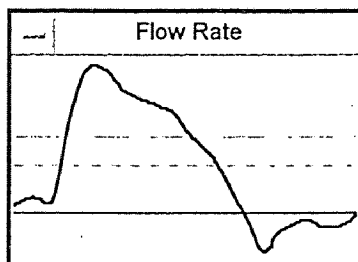
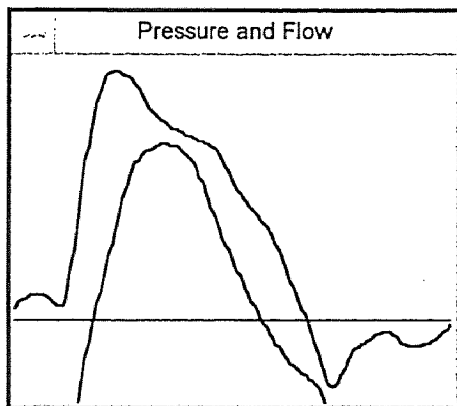
System Parameters: Heart Rate: 96.77 bpm
 Stroke Volume: 80.40 ml
 Cardiac Output: 7.78 L/m
 Duration of valve cycle: 0.62 sec.
 Forward Flow Phase: 0.42 sec. 67.11 %

Measured Flow (L/m): RMS: 16.40 L/m
 Mean: 11.44 L/m
 Peak: 21.86 L/m

Measured Pressures (mm Hg): Mean: 5.57 mm Hg
 Peak Pressure: 15.50 mm Hg
 Pressure at max flow: 7.82 mm Hg

Valve Parameters Closing Volume: 4.52 ml, 5.62 %
 Leakage Volume: 3.37 ml, 4.19 %
 Regurgitant Fraction: 9.81 %

Effective Orifice Area (sq cm.): Peak: 2.99 Discharge Coefficient: 0.714
 Mean: 1.57 Performance Index: 0.540
 RMS: **2.24** Efficiency Index: 0.487



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 365 Valve Type: **SHELHIGH** Serial No. **S1106** Valve size: **23 mm** Mitral Position.
 Operator: E. Sean Parker

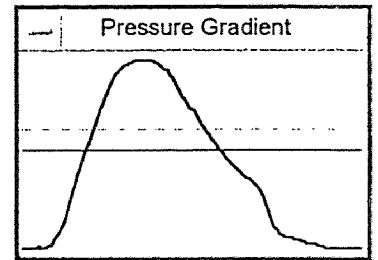
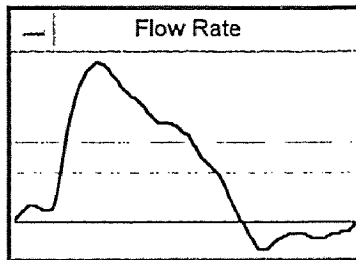
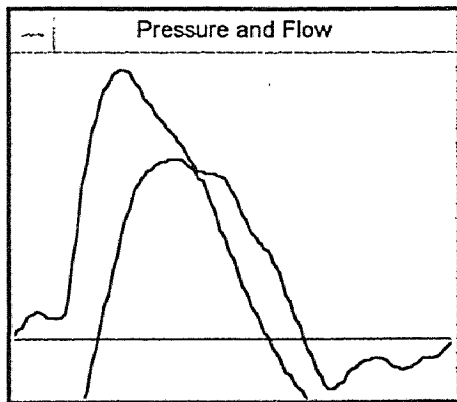
System Parameters: Heart Rate: 104.90 bpm
 Stroke Volume: 76.67 ml
 Cardiac Output: 8.04 L/m
 Duration of valve cycle: 0.57 sec.
 Forward Flow Phase: 0.38 sec. 66.20 %

Measured Flow (L/m): RMS: 17.46 L/m
 Mean: 11.98 L/m
 Peak: 23.84 L/m

Measured Pressures (mm Hg): Mean: 5.93 mm Hg
 Peak Pressure: 15.90 mm Hg
 Pressure at max flow: 9.62 mm Hg

Valve Parameters Closing Volume: 4.88 ml, 6.36 %
 Leakage Volume: 2.43 ml, 3.17 %
 Regurgitant Fraction: 9.53 %

Effective Orifice Area (sq cm.): Peak: 3.16 Discharge Coefficient: 0.736
 Mean: 1.59 Performance Index: 0.557
 RMS: **2.31** Efficiency Index: 0.504



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 366 Valve Type: **SHELHIGH** Serial No. **S1106** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

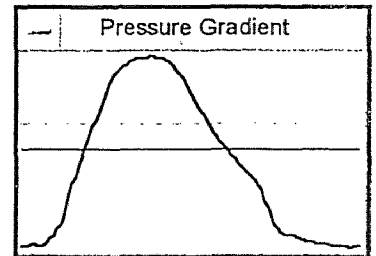
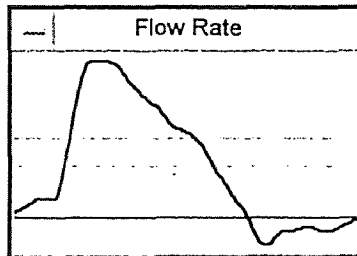
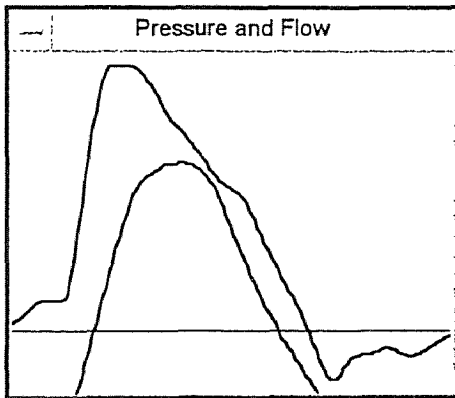
System Parameters: Heart Rate: 115.38 bpm
 Stroke Volume: 77.86 ml
 Cardiac Output: 8.98 L/m
 Duration of valve cycle: 0.52 sec.
 Forward Flow Phase: 0.35 sec. 67.72 %

Measured Flow (L/m): RMS: 19.05 L/m
 Mean: 13.06 L/m
 Peak: 25.95 L/m

Measured Pressures (mm Hg): Mean: 6.59 mm Hg
 Peak Pressure: 16.45 mm Hg
 Pressure at max flow: 5.52 mm Hg

Valve Parameters Closing Volume: 3.56 ml, 4.57 %
 Leakage Volume: 3.15 ml, 4.05 %
 Regurgitant Fraction: 8.62 %

Effective Orifice Area (sq cm.): Peak: 3.27 Discharge Coefficient: 0.763
 Mean: 1.64 Performance Index: 0.577
 RMS: 2.40 Efficiency Index: 0.527



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 351 Valve Type: **SHELHIGH** Serial No. **S1108** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

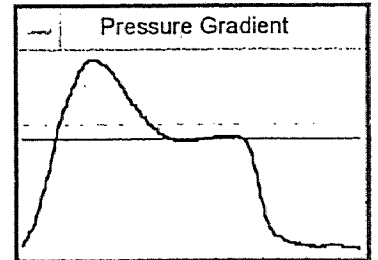
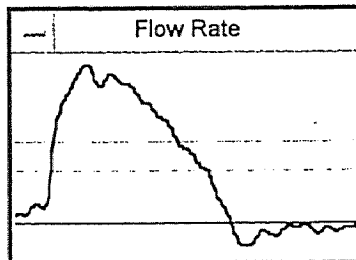
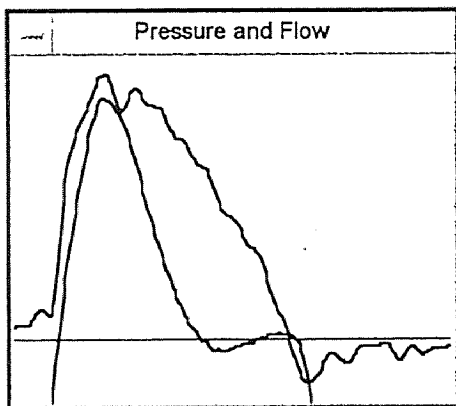
System Parameters: Heart Rate: 63.56 bpm
 Stroke Volume: 74.14 ml
 Cardiac Output: 4.71 L/m
 Duration of valve cycle: 0.94 sec.
 Forward Flow Phase: 0.60 sec. 63.06 %

Measured Flow (L/m): RMS: 10.74 L/m
 Mean: 7.41 L/m
 Peak: 13.17 L/m

Measured Pressures (mm Hg): Mean: 3.44 mm Hg
 Peak Pressure: 12.02 mm Hg
 Pressure at max flow: 11.95 mm Hg

Valve Parameters Closing Volume: 2.35 ml, 3.17 %
 Leakage Volume: 2.02 ml, 2.73 %
 Regurgitant Fraction: 5.90 %

Effective Orifice Area (sq cm.): Peak: 2.29 Discharge Coefficient: 0.595
 Mean: 1.29 Performance Index: 0.450
 RMS: 1.87 Efficiency Index: 0.423



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 352 Valve Type: **SHELHIGH** Serial No. **S1108** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

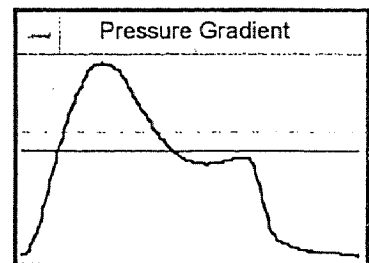
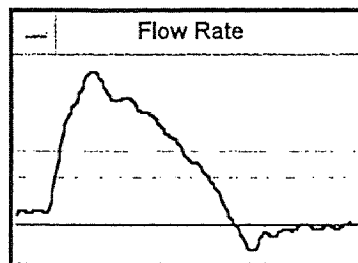
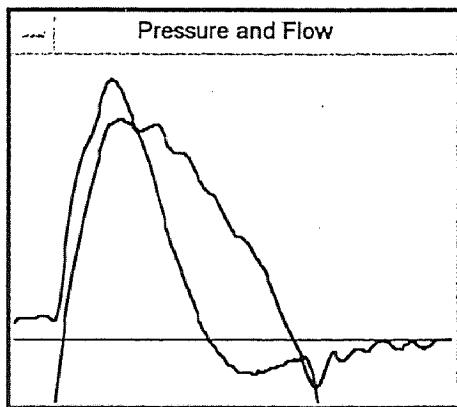
System Parameters: Heart Rate: 71.77 bpm
 Stroke Volume: 75.62 ml
 Cardiac Output: 5.43 L/m
 Duration of valve cycle: 0.84 sec.
 Forward Flow Phase: 0.54 sec. 64.29 %

Measured Flow (L/m): RMS: 12.25 L/m
 Mean: 8.36 L/m
 Peak: 16.56 L/m

Measured Pressures (mm Hg): Mean: 4.30 mm Hg
 Peak Pressure: 14.05 mm Hg
 Pressure at max flow: 13.80 mm Hg

Valve Parameters Closing Volume: 2.41 ml, 3.18 %
 Leakage Volume: 1.81 ml, 2.39 %
 Regurgitant Fraction: 5.58 %

Effective Orifice Area (sq cm.): Peak: 2.58 Discharge Coefficient: 0.607
 Mean: 1.30 Performance Index: 0.459
 RMS: 1.91 Efficiency Index: 0.434



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 353 Valve Type: **SHELHIGH** Serial No. **S1108** Valve size: **23 mm** Mitral Position:
 Operator: E. Sean Parker

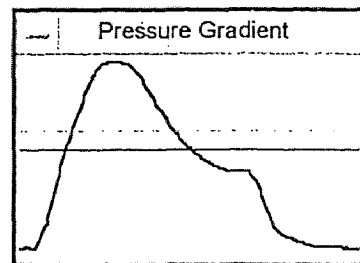
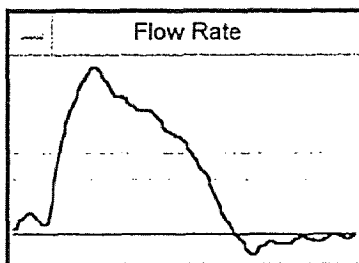
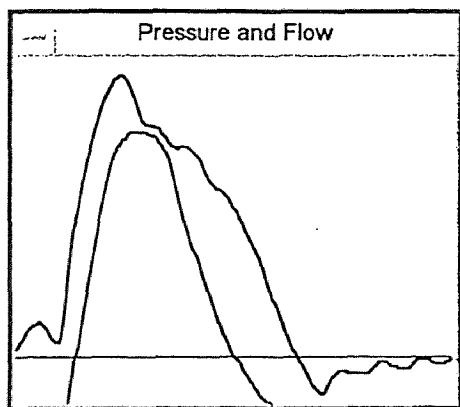
System Parameters: Heart Rate: 81.97 bpm
 Stroke Volume: 77.79 ml
 Cardiac Output: 6.38 L/m
 Duration of valve cycle: 0.73 sec.
 Forward Flow Phase: 0.48 sec. 65.12 %

Measured Flow (L/m): RMS: 14.13 L/m
 Mean: 9.68 L/m
 Peak: 18.87 L/m

Measured Pressures (mm Hg): Mean: 5.16 mm Hg
 Peak Pressure: 15.15 mm Hg
 Pressure at max flow: 14.32 mm Hg

Valve Parameters Closing Volume: 1.75 ml, 2.25 %
 Leakage Volume: 1.83 ml, 2.35 %
 Regurgitant Fraction: 4.60 %

Effective Orifice Area (sq cm.): Peak: 2.68 Discharge Coefficient: 0.639
 Mean: 1.38 Performance Index: 0.483
 RMS: 2.01 Efficiency Index: 0.461



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 354 Valve Type: **SHELHIGH** Serial No. **S1108** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

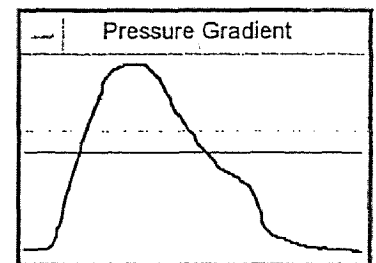
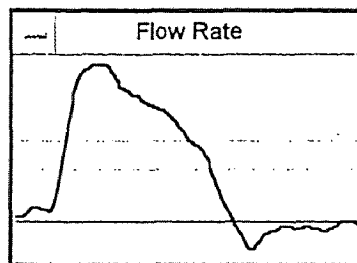
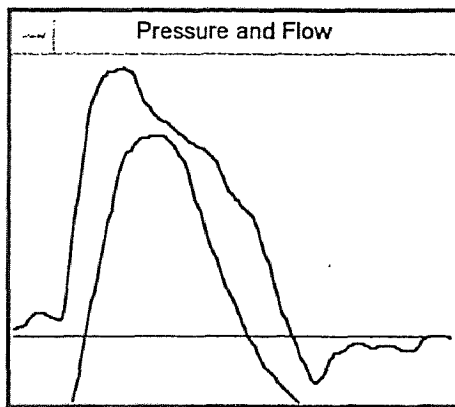
System Parameters: Heart Rate: 96.15 bpm
 Stroke Volume: 76.19 ml
 Cardiac Output: 7.33 L/m
 Duration of valve cycle: 0.62 sec.
 Forward Flow Phase: 0.41 sec. 66.46 %

Measured Flow (L/m): RMS: 16.05 L/m
 Mean: 10.89 L/m
 Peak: 21.18 L/m

Measured Pressures (mm Hg): Mean: 5.59 mm Hg
 Peak Pressure: 15.90 mm Hg
 Pressure at max flow: 14.15 mm Hg

Valve Parameters Closing Volume: 2.38 ml, 3.12 %
 Leakage Volume: 1.65 ml, 2.17 %
 Regurgitant Fraction: 5.29 %

Effective Orifice Area (sq cm.): Peak: 2.89 Discharge Coefficient: 0.698
 Mean: 1.49 Performance Index: 0.527
 RMS: 2.19 Efficiency Index: 0.500



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 355 Valve Type: **SHELHIGH** Serial No. **S1108** Valve size: **23 mm** Mitral Positic
 Operator: E. Sean Parker

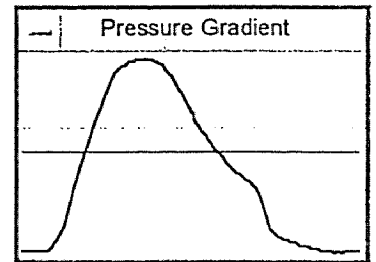
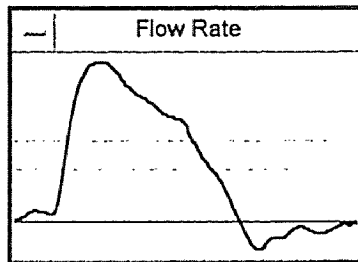
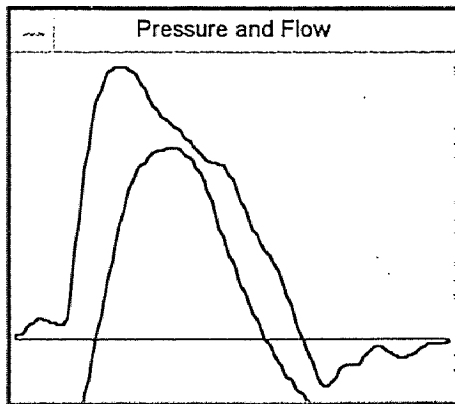
System Parameters: Heart Rate: 102.74 bpm
 Stroke Volume: 77.99 ml
 Cardiac Output: 8.01 L/m
 Duration of valve cycle: 0.58 sec.
 Forward Flow Phase: 0.39 sec. 66.67 %

Measured Flow (L/m): RMS: 17.37 L/m
 Mean: 11.85 L/m
 Peak: 23.05 L/m

Measured Pressures (mm Hg): Mean: 6.04 mm Hg
 Peak Pressure: 16.22 mm Hg
 Pressure at max flow: 9.90 mm Hg

Valve Parameters Closing Volume: 2.97 ml, 3.81 %
 Leakage Volume: 2.15 ml, 2.75 %
 Regurgitant Fraction: 6.57 %

Effective Orifice Area (sq cm.): Peak: 3.03 Discharge Coefficient: 0.726
 Mean: 1.56 Performance Index: 0.549
 RMS: 2.28 Efficiency Index: 0.513



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 356 Valve Type: **SHELHIGH** Serial No. **S1108** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

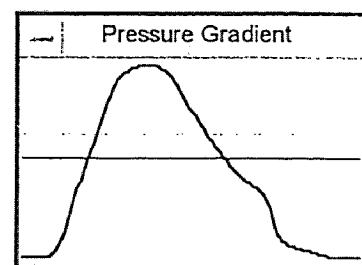
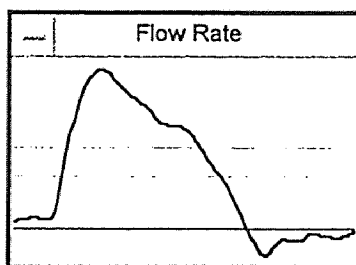
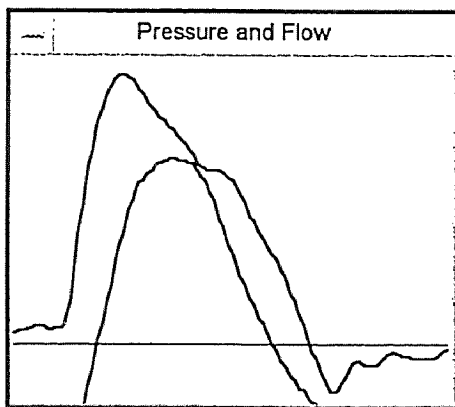
System Parameters: Heart Rate: 104.17 bpm
 Stroke Volume: 79.79 ml
 Cardiac Output: 8.31 L/m
 Duration of valve cycle: 0.58 sec.
 Forward Flow Phase: 0.39 sec. 68.57 %

Measured Flow (L/m): RMS: 17.18 L/m
 Mean: 11.95 L/m
 Peak: 23.59 L/m

Measured Pressures (mm Hg): Mean: 6.04 mm Hg
 Peak Pressure: 16.25 mm Hg
 Pressure at max flow: 9.82 mm Hg

Valve Parameters Closing Volume: 2.66 ml, 3.34 %
 Leakage Volume: 2.52 ml, 3.16 %
 Regurgitant Fraction: 6.49 %

Effective Orifice Area (sq cm.): Peak: 3.10 Discharge Coefficient: 0.718
 Mean: 1.57 Performance Index: 0.543
 RMS: 2.26 Efficiency Index: 0.508



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 358 Valve Type: **SHELHIGH** Serial No. **S1108** Valve size: **23 mm** Mitral Position:
 Operator: E. Sean Parker

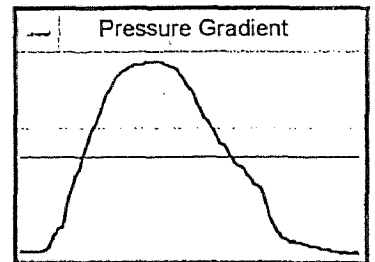
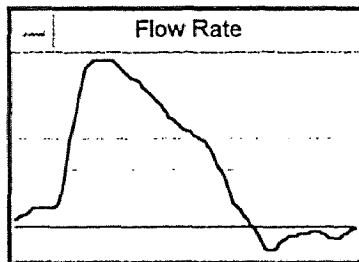
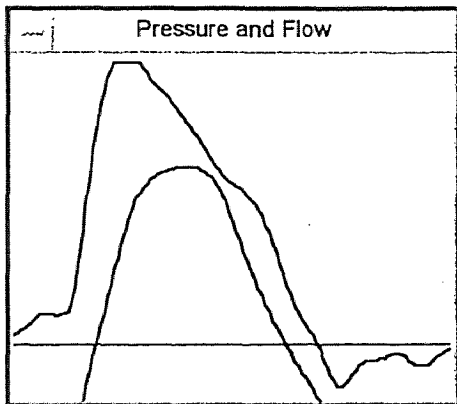
System Parameters: Heart Rate: 118.11 bpm
 Stroke Volume: 80.55 ml
 Cardiac Output: 9.51 L/m
 Duration of valve cycle: 0.51 sec.
 Forward Flow Phase: 0.35 sec. 69.67 %

Measured Flow (L/m): RMS: 19.33 L/m
 Mean: 13.44 L/m
 Peak: 26.30 L/m

Measured Pressures (mm Hg): Mean: 6.80 mm Hg
 Peak Pressure: 16.62 mm Hg
 Pressure at max flow: 7.05 mm Hg

Valve Parameters Closing Volume: 2.49 ml, 3.10 %
 Leakage Volume: 1.93 ml, 2.40 %
 Regurgitant Fraction: 5.50 %

Effective Orifice Area (sq cm.): Peak: 3.26 Discharge Coefficient: 0.762
 Mean: 1.66 Performance Index: 0.576
 RMS: **2.39** Efficiency Index: 0.544



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 367 Valve Type: **SHELHIGH** Serial No. **S1109** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

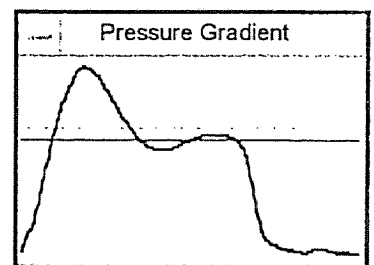
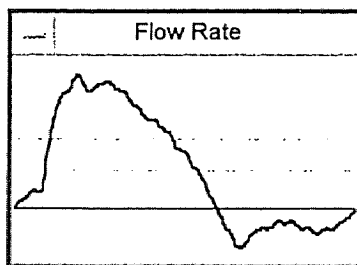
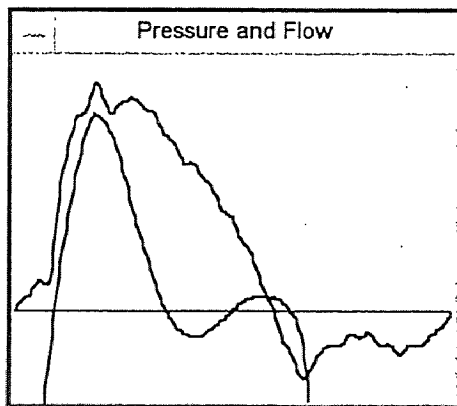
System Parameters: Heart Rate: 61.48 bpm
 Stroke Volume: 68.71 ml
 Cardiac Output: 4.22 L/m
 Duration of valve cycle: 0.98 sec.
 Forward Flow Phase: 0.58 sec. 58.94 %

Measured Flow (L/m): RMS: 10.60 L/m
 Mean: 7.11 L/m
 Peak: 12.51 L/m

Measured Pressures (mm Hg): Mean: 2.84 mm Hg
 Peak Pressure: 10.80 mm Hg
 Pressure at max flow: 10.77 mm Hg

Valve Parameters Closing Volume: 7.36 ml, 10.71 %
 Leakage Volume: 5.20 ml, 7.57 %
 Regurgitant Fraction: 18.28 %

Effective Orifice Area (sq cm.): Peak: 2.40 Discharge Coefficient: 0.534
 Mean: 1.36 Performance Index: 0.414
 RMS: 2.03 Efficiency Index: 0.338



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 368 Valve Type: **SHELHIGH** Serial No. **S1109** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

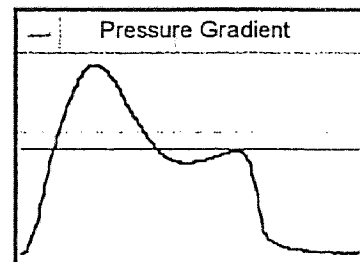
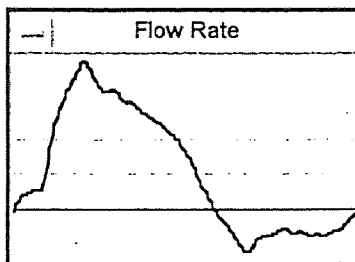
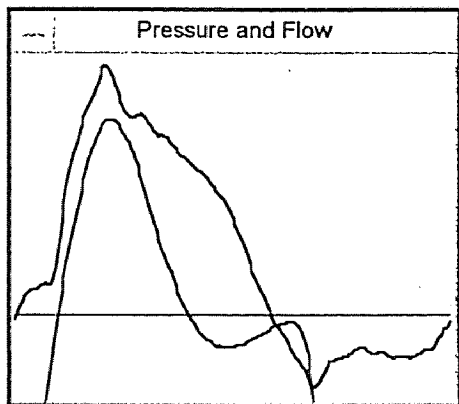
System Parameters: Heart Rate: 75.38 bpm
 Stroke Volume: 70.88 ml
 Cardiac Output: 5.34 L/m
 Duration of valve cycle: 0.80 sec.
 Forward Flow Phase: 0.46 sec. 58.25 %

Measured Flow (L/m): RMS: 13.65 L/m
 Mean: 9.08 L/m
 Peak: 17.35 L/m

Measured Pressures (mm Hg): Mean: 4.08 mm Hg
 Peak Pressure: 13.60 mm Hg
 Pressure at max flow: 13.55 mm Hg

Valve Parameters Closing Volume: 7.57 ml, 10.68 %
 Leakage Volume: 7.49 ml, 10.57 %
 Regurgitant Fraction: 21.25 %

Effective Orifice Area (sq cm.): Peak: 2.77 Discharge Coefficient: 0.574
 Mean: 1.45 Performance Index: 0.444
 RMS: 2.18 Efficiency Index: 0.350



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 370 Valve Type: **SHELHIGH** Serial No. **S1109** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

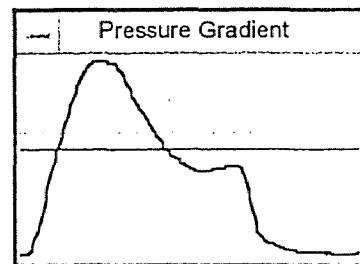
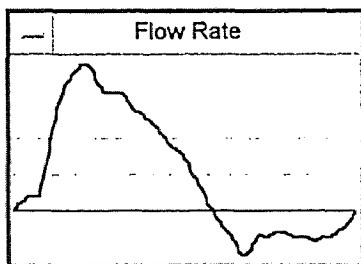
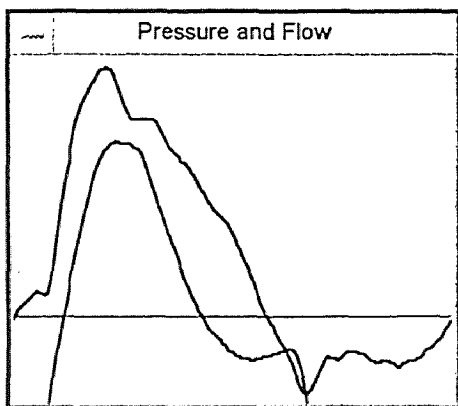
System Parameters: Heart Rate: 80.21 bpm
 Stroke Volume: 76.76 ml
 Cardiac Output: 6.16 L/m
 Duration of valve cycle: 0.75 sec.
 Forward Flow Phase: 0.43 sec. 57.22 %

Measured Flow (L/m): RMS: 16.32 L/m
 Mean: 10.65 L/m
 Peak: 20.15 L/m

Measured Pressures (mm Hg): Mean: 4.78 mm Hg
 Peak Pressure: 14.17 mm Hg
 Pressure at max flow: 13.72 mm Hg

Valve Parameters Closing Volume: 7.90 ml, 10.29 %
 Leakage Volume: 10.00 ml, 13.03 %
 Regurgitant Fraction: 23.32 %

Effective Orifice Area (sq cm.): Peak: 2.98 Discharge Coefficient: 0.634
 Mean: 1.57 Performance Index: 0.491
 RMS: 2.41 Efficiency Index: 0.377



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 371 Valve Type: **SHELHIGH** Serial No. **S1109** Valve size: **25 mm** Mitral Position:
 Operator: E. Sean Parker

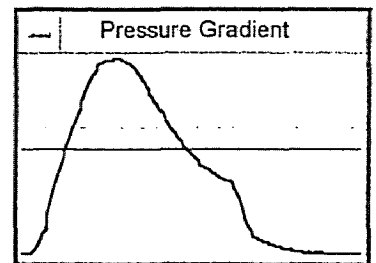
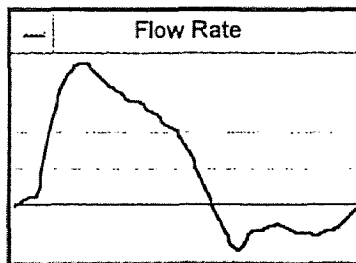
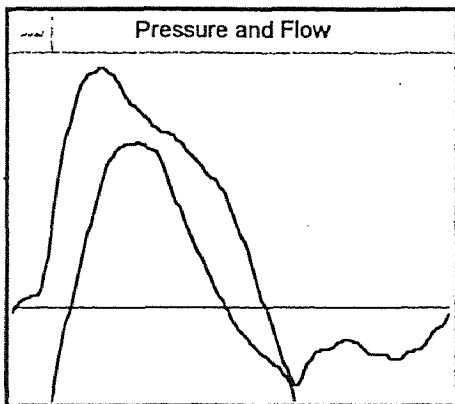
System Parameters: Heart Rate: 92.02 bpm
 Stroke Volume: 75.59 ml
 Cardiac Output: 6.96 L/m
 Duration of valve cycle: 0.65 sec.
 Forward Flow Phase: 0.38 sec. 57.67 %

Measured Flow (L/m): RMS: 17.97 L/m
 Mean: 11.91 L/m
 Peak: 20.97 L/m

Measured Pressures (mm Hg): Mean: 5.48 mm Hg
 Peak Pressure: 14.50 mm Hg
 Pressure at max flow: 11.07 mm Hg

Valve Parameters Closing Volume: 6.96 ml, 9.21 %
 Leakage Volume: 9.54 ml, 12.63 %
 Regurgitant Fraction: 21.84 %

Effective Orifice Area (sq cm.): Peak: 2.89 Discharge Coefficient: 0.652
 Mean: 1.64 Performance Index: 0.505
 RMS: 2.48 Efficiency Index: 0.395



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 373 Valve Type: **SHELHIGH** Serial No. **S1109** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

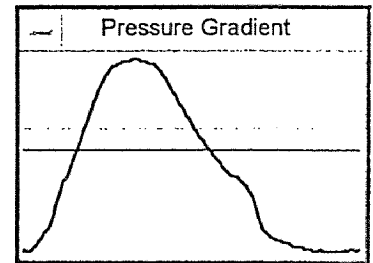
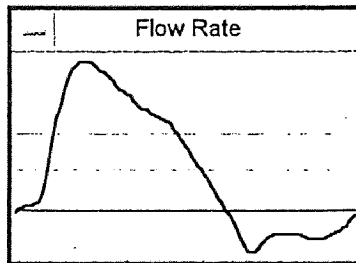
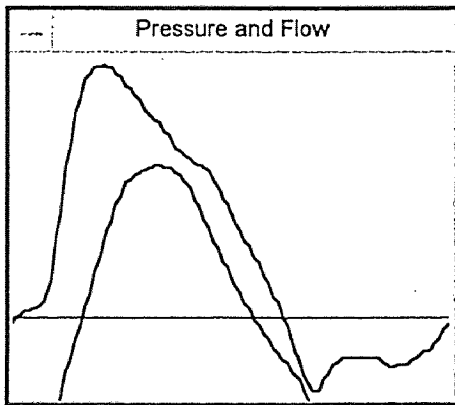
System Parameters: Heart Rate: 108.70 bpm
 Stroke Volume: 76.63 ml
 Cardiac Output: 8.33 L/m
 Duration of valve cycle: 0.55 sec.
 Forward Flow Phase: 0.34 sec. 61.87 %

Measured Flow (L/m): RMS: 19.86 L/m
 Mean: 13.27 L/m
 Peak: 24.94 L/m

Measured Pressures (mm Hg): Mean: 6.07 mm Hg
 Peak Pressure: 15.10 mm Hg
 Pressure at max flow: 7.85 mm Hg

Valve Parameters Closing Volume: 8.64 ml, 11.28 %
 Leakage Volume: 5.75 ml, 7.50 %
 Regurgitant Fraction: 18.78 %

Effective Orifice Area (sq cm.): Peak: 3.27 Discharge Coefficient: 0.685
 Mean: 1.74 Performance Index: 0.530
 RMS: 2.60 Efficiency Index: 0.431



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 372 Valve Type: **SHELHIGH** Serial No. **S1109** Valve size: **25 mm** Mitral Position:
 Operator: E. Sean Parker

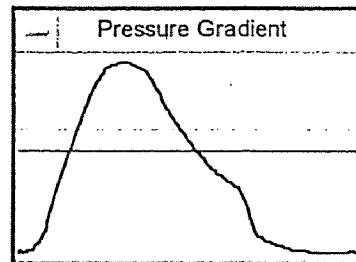
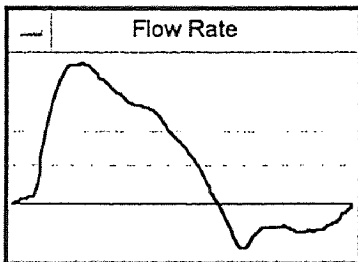
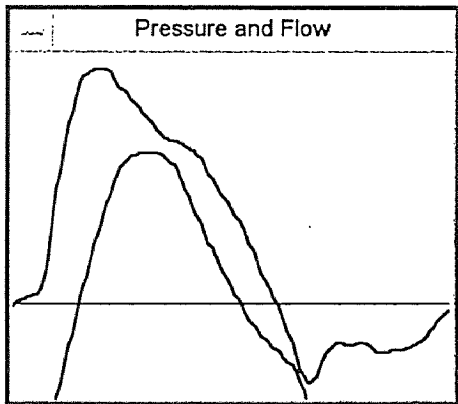
System Parameters: Heart Rate: 102.04 bpm
 Stroke Volume: 75.48 ml
 Cardiac Output: 7.70 L/m
 Duration of valve cycle: 0.59 sec.
 Forward Flow Phase: 0.36 sec. 60.40 %

Measured Flow (L/m): RMS: 18.75 L/m
 Mean: 12.58 L/m
 Peak: 22.74 L/m

Measured Pressures (mm Hg): Mean: 5.71 mm Hg
 Peak Pressure: 14.77 mm Hg
 Pressure at max flow: 9.05 mm Hg

Valve Parameters Closing Volume: 8.21 ml, 10.88 %
 Leakage Volume: 7.15 ml, 9.47 %
 Regurgitant Fraction: 20.35 %

Effective Orifice Area (sq cm.): Peak: 3.07 Discharge Coefficient: 0.666
 Mean: 1.70 Performance Index: 0.516
 RMS: **2.53** Efficiency Index: 0.411



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 374 Valve Type: **SHELHIGH** Serial No. **S1109** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

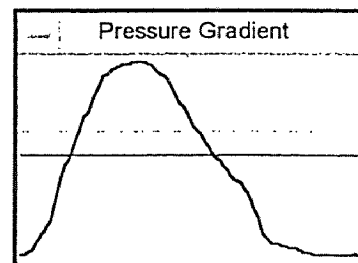
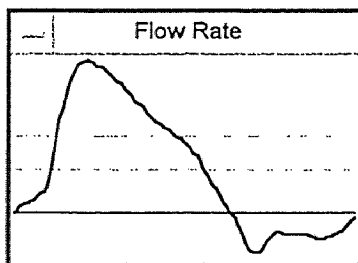
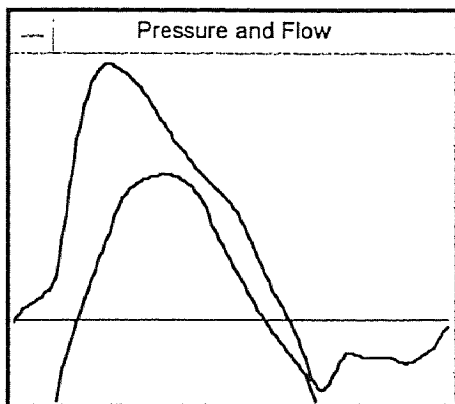
System Parameters: Heart Rate: 120.00 bpm
 Stroke Volume: 78.09 ml
 Cardiac Output: 9.37 L/m
 Duration of valve cycle: 0.50 sec.
 Forward Flow Phase: 0.31 sec. 62.40 %

Measured Flow (L/m): RMS: 22.04 L/m
 Mean: 14.78 L/m
 Peak: 28.33 L/m

Measured Pressures (mm Hg): Mean: 7.04 mm Hg
 Peak Pressure: 16.12 mm Hg
 Pressure at max flow: 9.92 mm Hg

Valve Parameters Closing Volume: 6.32 ml, 8.09 %
 Leakage Volume: 6.84 ml, 8.76 %
 Regurgitant Fraction: 16.84 %

Effective Orifice Area (sq cm.): Peak: 3.45 Discharge Coefficient: 0.706
 Mean: 1.80 Performance Index: 0.546
 RMS: 2.68 Efficiency Index: 0.454



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 234 Valve Type: **SHELHIGH** Serial No. **S4043** Valve size: **25 mm** Mitral Positio
 Operator: E. Sean Parker

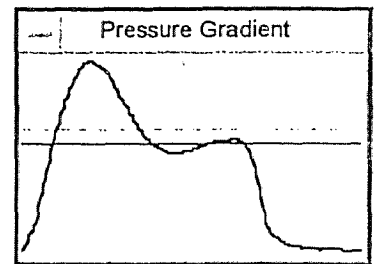
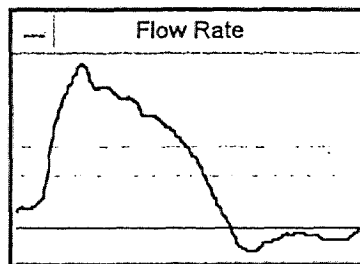
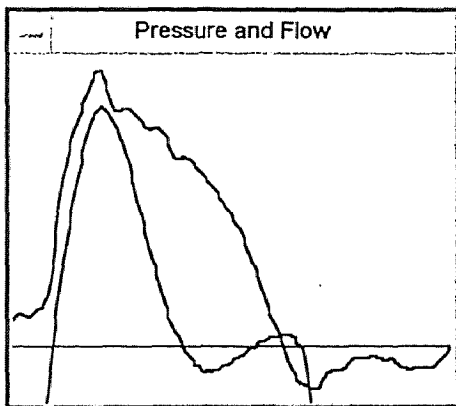
System Parameters: Heart Rate: 66.67 bpm
 Stroke Volume: 79.07 ml
 Cardiac Output: 5.27 L/m
 Duration of valve cycle: 0.90 sec.
 Forward Flow Phase: 0.56 sec. 61.93 %

Measured Flow (L/m): RMS: 12.14 L/m
 Mean: 8.44 L/m
 Peak: 15.27 L/m

Measured Pressures (mm Hg): Mean: 3.68 mm Hg
 Peak Pressure: 13.22 mm Hg
 Pressure at max flow: 13.15 mm Hg

Valve Parameters Closing Volume: 4.02 ml, 5.08 %
 Leakage Volume: 2.44 ml, 3.09 %
 Regurgitant Fraction: 8.17 %

Effective Orifice Area (sq cm.): Peak: 2.57 Discharge Coefficient: 0.537
 Mean: 1.42 Performance Index: 0.416
 RMS: 2.04 Efficiency Index: 0.382



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 238 Valve Type: **SHELHIGH** Serial No. **S4043** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

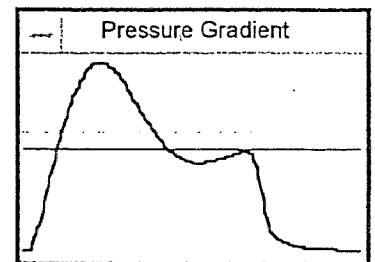
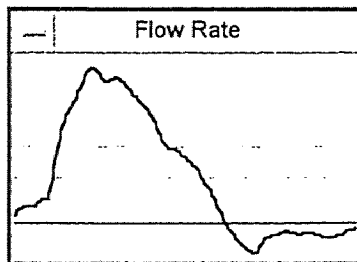
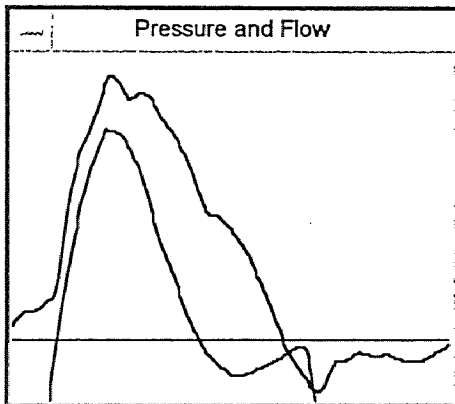
System Parameters: Heart Rate: 72.46 bpm
 Stroke Volume: 80.73 ml
 Cardiac Output: 5.85 L/m
 Duration of valve cycle: 0.83 sec.
 Forward Flow Phase: 0.51 sec. 62.00 %

Measured Flow (L/m): RMS: 13.83 L/m
 Mean: 9.35 L/m
 Peak: 17.62 L/m

Measured Pressures (mm Hg): Mean: 4.32 mm Hg
 Peak Pressure: 14.02 mm Hg
 Pressure at max flow: 13.95 mm Hg

Valve Parameters Closing Volume: 4.09 ml; 5.07 %
 Leakage Volume: 3.68 ml; 4.56 %
 Regurgitant Fraction: 9.62 %

Effective Orifice Area (sq cm.): Peak: 2.74 Discharge Coefficient: 0.565
 Mean: 1.45 Performance Index: 0.438
 RMS: 2.15 Efficiency Index: 0.396



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 242 Valve Type: **SHELHIGH** Serial No. **S4043** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

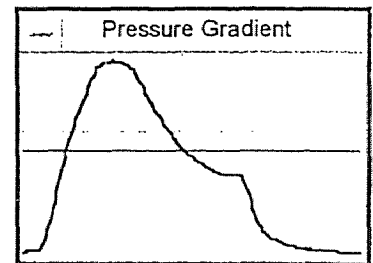
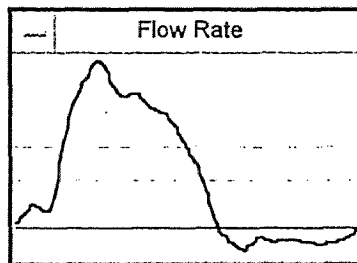
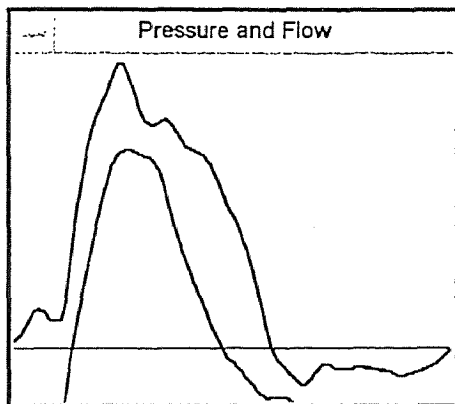
System Parameters: Heart Rate: 83.80 bpm
 Stroke Volume: 81.40 ml
 Cardiac Output: 6.82 L/m
 Duration of valve cycle: 0.72 sec.
 Forward Flow Phase: 0.42 sec. 58.99 %

Measured Flow (L/m): RMS: 17.25 L/m
 Mean: 11.44 L/m
 Peak: 21.49 L/m

Measured Pressures (mm Hg): Mean: 5.32 mm Hg
 Peak Pressure: 15.02 mm Hg
 Pressure at max flow: 14.80 mm Hg

Valve Parameters Closing Volume: 2.87 ml, 3.53 %
 Leakage Volume: 5.33 ml, 6.55 %
 Regurgitant Fraction: 10.08 %

Effective Orifice Area (sq cm.): Peak: 3.01 Discharge Coefficient: 0.635
 Mean: 1.60 Performance Index: 0.492
 RMS: 2.42 Efficiency Index: 0.442



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 246 Valve Type: **SHELHIGH** Serial No. **S4043** Valve size: **25 mm** Mitral Positic
 Operator: E. Sean Parker

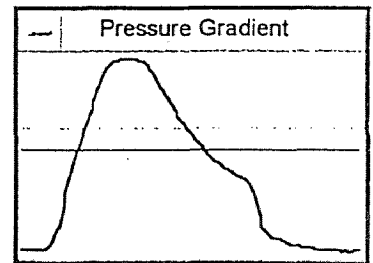
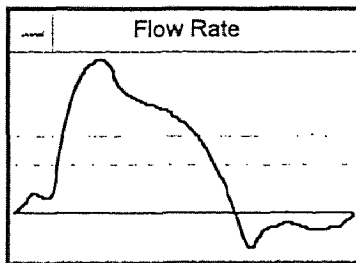
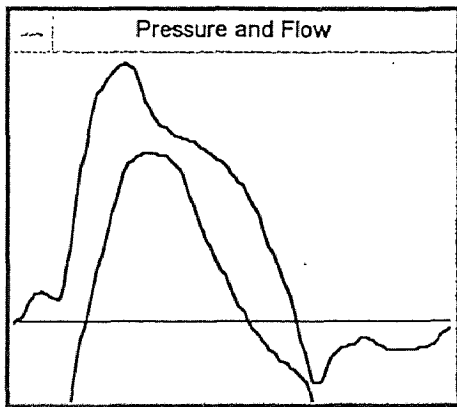
System Parameters: Heart Rate: 96.77 bpm
 Stroke Volume: 83.19 ml
 Cardiac Output: 8.05 L/m
 Duration of valve cycle: 0.62 sec.
 Forward Flow Phase: 0.40 sec. 64.52 %

Measured Flow (L/m): RMS: 17.82 L/m
 Mean: 12.32 L/m
 Peak: 23.31 L/m

Measured Pressures (mm Hg): Mean: 5.48 mm Hg
 Peak Pressure: 15.25 mm Hg
 Pressure at max flow: 14.02 mm Hg

Valve Parameters Closing Volume: 3.76 ml, 4.53 %
 Leakage Volume: 5.15 ml, 6.19 %
 Regurgitant Fraction: 10.72 %

Effective Orifice Area (sq cm.): Peak: 3.22 Discharge Coefficient: 0.647
 Mean: 1.70 Performance Index: 0.501
 RMS: 2.46 Efficiency Index: 0.447



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 250 Valve Type: **SHELHIGH** Serial No. **S4043** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

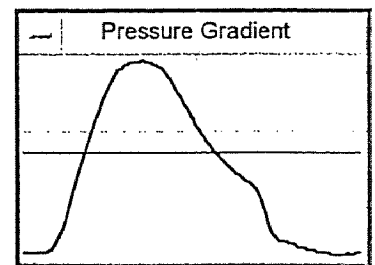
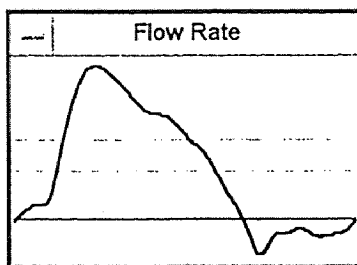
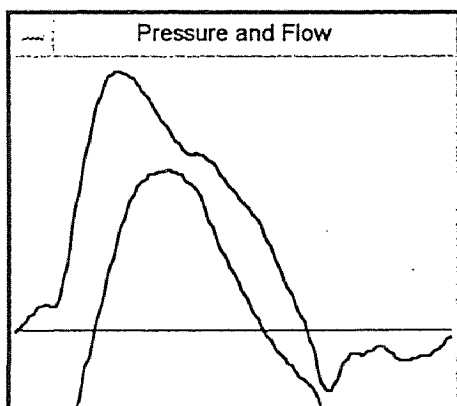
System Parameters: Heart Rate: 103.45 bpm
 Stroke Volume: 85.05 ml
 Cardiac Output: 8.80 L/m
 Duration of valve cycle: 0.58 sec.
 Forward Flow Phase: 0.39 sec. 66.67 %

Measured Flow (L/m): RMS: 18.68 L/m
 Mean: 13.02 L/m
 Peak: 24.83 L/m

Measured Pressures (mm Hg): Mean: 5.66 mm Hg
 Peak Pressure: 15.47 mm Hg
 Pressure at max flow: 9.07 mm Hg

Valve Parameters Closing Volume: 3.84 ml, 4.51 %
 Leakage Volume: 4.51 ml, 5.30 %
 Regurgitant Fraction: 9.81 %

Effective Orifice Area (sq cm.): Peak: 3.37 Discharge Coefficient: 0.667
 Mean: 1.77 Performance Index: 0.517
 RMS: 2.54 Efficiency Index: 0.466



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 254 Valve Type: **SHELHIGH** Serial No. **S4043** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

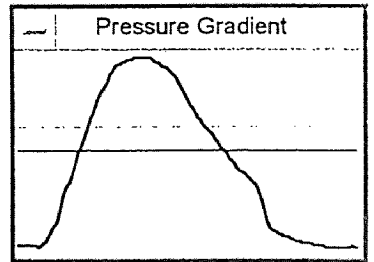
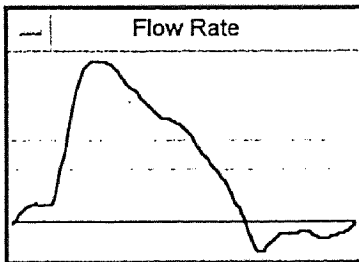
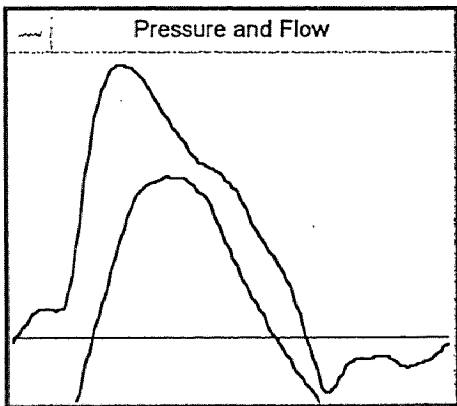
System Parameters: Heart Rate: 111.94 bpm
 Stroke Volume: 84.22 ml
 Cardiac Output: 9.43 L/m
 Duration of valve cycle: 0.54 sec.
 Forward Flow Phase: 0.36 sec. 66.92 %

Measured Flow (L/m): RMS: 20.05 L/m
 Mean: 13.88 L/m
 Peak: 26.99 L/m

Measured Pressures (mm Hg): Mean: 6.39 mm Hg
 Peak Pressure: 16.17 mm Hg
 Pressure at max flow: 10.05 mm Hg

Valve Parameters Closing Volume: 3.34 ml, 3.97 %
 Leakage Volume: 3.88 ml, 4.60 %
 Regurgitant Fraction: 8.57 %

Effective Orifice Area (sq cm.): Peak: 3.45 Discharge Coefficient: 0.674
 Mean: 1.77 Performance Index: 0.522
 RMS: 2.56 Efficiency Index: 0.477



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 258 Valve Type: **SHELHIGH** Serial No. **S4043** Valve size: **25 mm** Mitral Positio
 Operator: E. Sean Parker

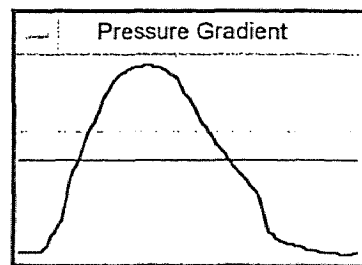
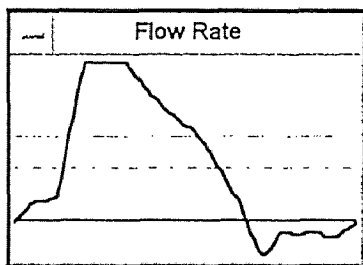
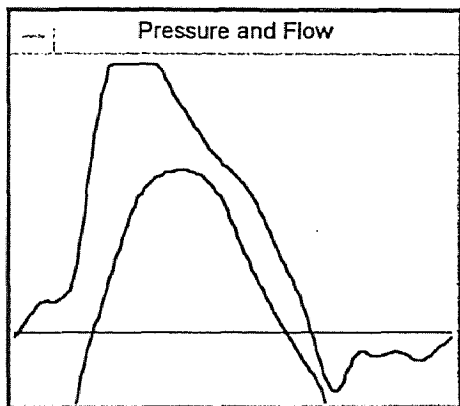
System Parameters: Heart Rate: 123.97 bpm
 Stroke Volume: 81.58 ml
 Cardiac Output: 10.11 L/m
 Duration of valve cycle: 0.48 sec.
 Forward Flow Phase: 0.33 sec. 67.21 %

Measured Flow (L/m): RMS: 21.32 L/m
 Mean: 14.80 L/m
 Peak: 27.23 L/m

Measured Pressures (mm Hg): Mean: 6.99 mm Hg
 Peak Pressure: 16.62 mm Hg
 Pressure at max flow: 6.50 mm Hg

Valve Parameters Closing Volume: 3.38 ml, 4.15 %
 Leakage Volume: 3.62 ml, 4.44 %
 Regurgitant Fraction: 8.59 %

Effective Orifice Area (sq cm.): Peak: 3.33 Discharge Coefficient: 0.685
 Mean: 1.81 Performance Index: 0.531
 RMS: 2.61 Efficiency Index: 0.485



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 375 Valve Type: **SHELHIGH** Serial No. **S1107** Valve size: **25 mm** Mitral Position
Operator: E. Sean Parker

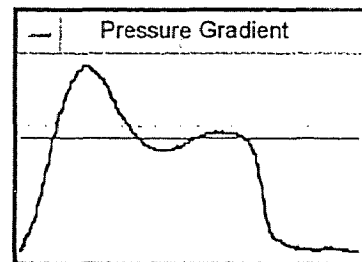
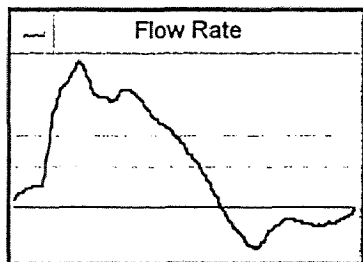
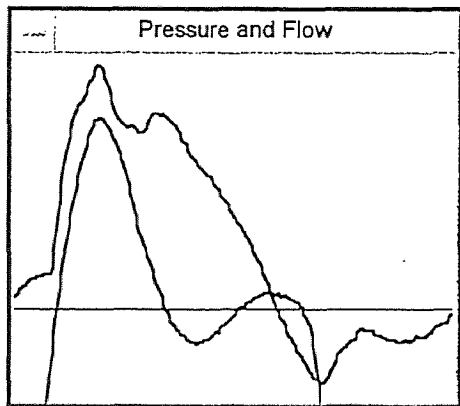
System Parameters: Heart Rate: 62.24 bpm
Stroke Volume: 70.74 ml
Cardiac Output: 4.40 L/m
Duration of valve cycle: 0.96 sec.
Forward Flow Phase: 0.58 sec. 60.43 %

Measured Flow (L/m): RMS: 10.58 L/m
Mean: 7.23 L/m
Peak: 13.44 L/m

Measured Pressures (mm Hg): Mean: 2.67 mm Hg
Peak Pressure: 10.62 mm Hg
Pressure at max flow: 10.60 mm Hg

Valve Parameters Closing Volume: 7.05 ml, 9.96 %
Leakage Volume: 4.83 ml, 6.82 %
Regurgitant Fraction: 16.78 %

Effective Orifice Area (sq cm.): Peak: 2.66 Discharge Coefficient: 0.550
Mean: 1.43 Performance Index: 0.426
RMS: 2.09 Efficiency Index: 0.354



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 376 Valve Type: **SHELHIGH** Serial No. **S1107** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

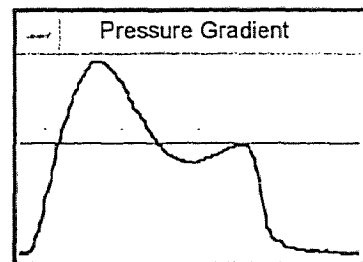
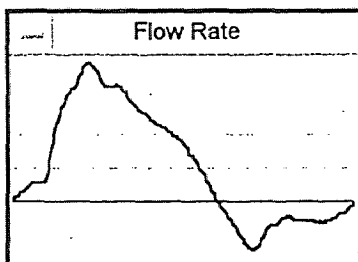
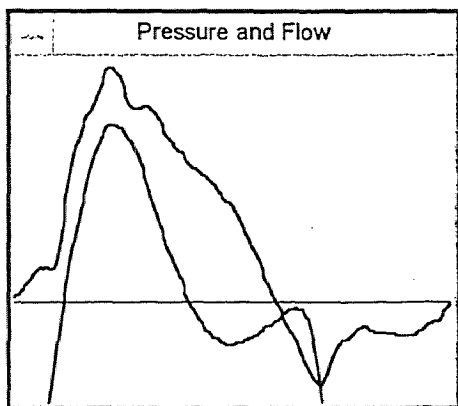
System Parameters: Heart Rate: 72.46 bpm
 Stroke Volume: 70.40 ml
 Cardiac Output: 5.10 L/m
 Duration of valve cycle: 0.83 sec.
 Forward Flow Phase: 0.50 sec. 60.00 %

Measured Flow (L/m): RMS: 12.62 L/m
 Mean: 8.42 L/m
 Peak: 16.42 L/m

Measured Pressures (mm Hg): Mean: 3.54 mm Hg
 Peak Pressure: 12.42 mm Hg
 Pressure at max flow: 12.37 mm Hg

Valve Parameters Closing Volume: 10.03 ml, 14.24 %
 Leakage Volume: 3.92 ml, 5.56 %
 Regurgitant Fraction: 19.81 %

Effective Orifice Area (sq cm.): Peak: 2.82 Discharge Coefficient: 0.569
 Mean: 1.45 Performance Index: 0.441
 RMS: 2.17 Efficiency Index: 0.354



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 376 Valve Type: **SHELHIGH** Serial No. **S1107** Valve size: **25 mm** Mitral Position
Operator: E. Sean Parker

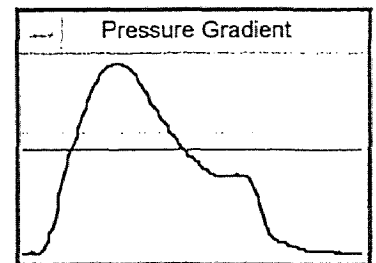
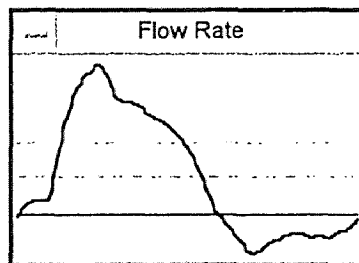
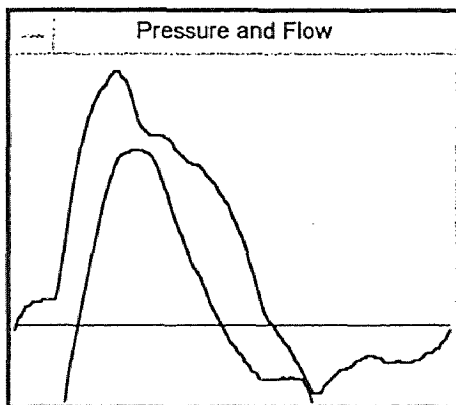
System Parameters: Heart Rate: 85.23 bpm
Stroke Volume: 72.38 ml
Cardiac Output: 6.17 L/m
Duration of valve cycle: 0.70 sec.
Forward Flow Phase: 0.41 sec. 58.19 %

Measured Flow (L/m): RMS: 15.92 L/m
Mean: 10.48 L/m
Peak: 19.94 L/m

Measured Pressures (mm Hg): Mean: 4.64 mm Hg
Peak Pressure: 13.75 mm Hg
Pressure at max flow: 12.82 mm Hg

Valve Parameters Closing Volume: 10.78 ml, 14.90 %
Leakage Volume: 3.18 ml, 4.39 %
Regurgitant Fraction: 19.29 %

Effective Orifice Area (sq cm.): Peak: 2.99 Discharge Coefficient: 0.628
Mean: 1.57 Performance Index: 0.486
RMS: **2.39** Efficiency Index: 0.392



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 377 Valve Type: **SHELHIGH** Serial No. **S1107** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

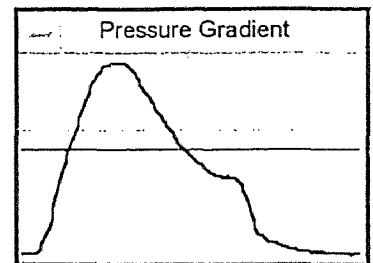
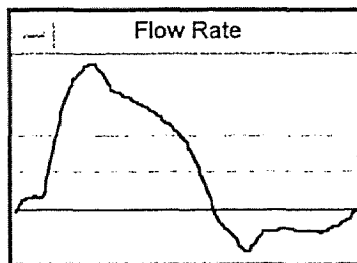
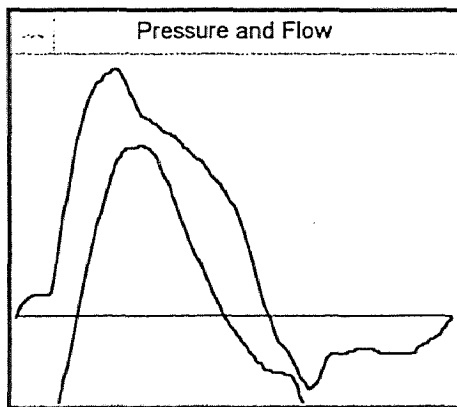
System Parameters: Heart Rate: 88.76 bpm
 Stroke Volume: 73.00 ml
 Cardiac Output: 6.48 L/m
 Duration of valve cycle: 0.68 sec.
 Forward Flow Phase: 0.39 sec. 57.65 %

Measured Flow (L/m): RMS: 16.78 L/m
 Mean: 11.11 L/m
 Peak: 20.06 L/m

Measured Pressures (mm Hg): Mean: 4.89 mm Hg
 Peak Pressure: 13.82 mm Hg
 Pressure at max flow: 12.25 mm Hg

Valve Parameters Closing Volume: 7.75 ml, 10.62 %
 Leakage Volume: 6.41 ml, 8.78 %
 Regurgitant Fraction: 19.40 %

Effective Orifice Area (sq cm.): Peak: 2.93 Discharge Coefficient: 0.645
 Mean: 1.62 Performance Index: 0.499
 RMS: 2.45 Efficiency Index: 0.402



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 378 Valve Type: **SHELHIGH** Serial No. **S1107** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

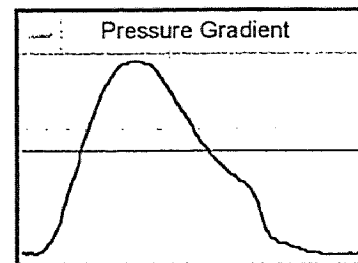
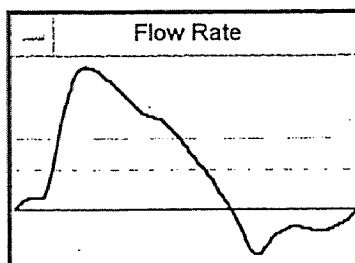
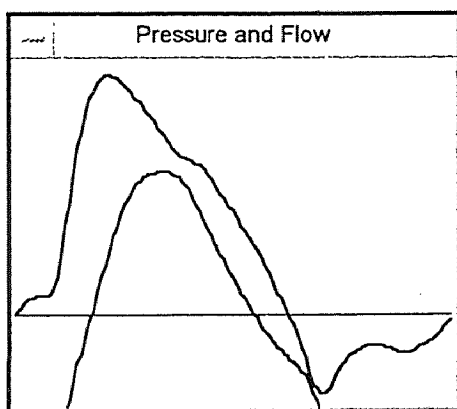
System Parameters: Heart Rate: 102.04 bpm
 Stroke Volume: 76.70 ml
 Cardiac Output: 7.83 L/m
 Duration of valve cycle: 0.59 sec.
 Forward Flow Phase: 0.37 sec. 62.33 %

Measured Flow (L/m): RMS: 18.43 L/m
 Mean: 12.39 L/m
 Peak: 23.61 L/m

Measured Pressures (mm Hg): Mean: 5.29 mm Hg
 Peak Pressure: 14.17 mm Hg
 Pressure at max flow: 5.80 mm Hg

Valve Parameters Closing Volume: 8.21 ml, 10.70 %
 Leakage Volume: 5.62 ml, 7.32 %
 Regurgitant Fraction: 18.02 %

Effective Orifice Area (sq cm.): Peak: 3.31 Discharge Coefficient: 0.680
 Mean: 1.74 Performance Index: 0.527
 RMS: 2.59 Efficiency Index: 0.432



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 379 Valve Type: **SHELHIGH** Serial No. **S1107** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

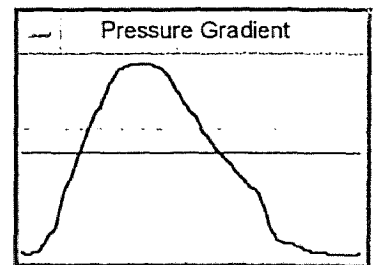
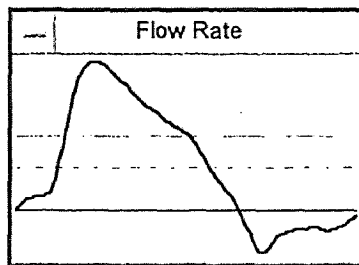
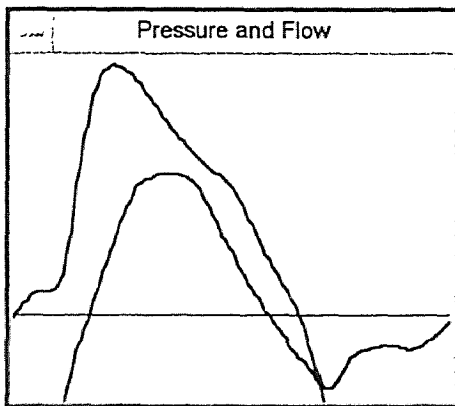
System Parameters: Heart Rate: 112.78 bpm
 Stroke Volume: 77.92 ml
 Cardiac Output: 8.79 L/m
 Duration of valve cycle: 0.53 sec.
 Forward Flow Phase: 0.34 sec. 64.39 %

Measured Flow (L/m): RMS: 19.83 L/m
 Mean: 13.44 L/m
 Peak: 26.19 L/m

Measured Pressures (mm Hg): Mean: 5.99 mm Hg
 Peak Pressure: 14.92 mm Hg
 Pressure at max flow: 7.72 mm Hg

Valve Parameters Closing Volume: 8.74 ml, 11.21 %
 Leakage Volume: 3.29 ml, 4.23 %
 Regurgitant Fraction: 15.44 %

Effective Orifice Area (sq cm.): Peak: 3.46 Discharge Coefficient: 0.688
 Mean: 1.77 Performance Index: 0.533
 RMS: 2.62 Efficiency Index: 0.451



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 380 Valve Type: **SHELHIGH** Serial No. **S1107** Valve size: **25 mm** Mitral Positio
 Operator: E. Sean Parker

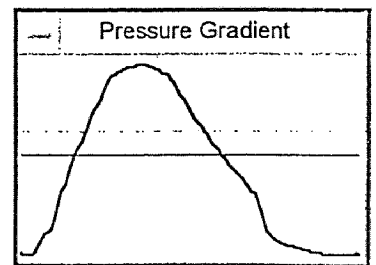
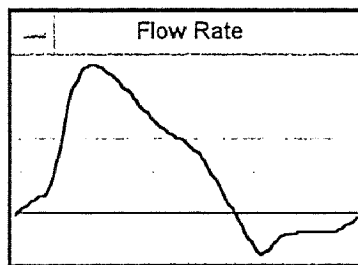
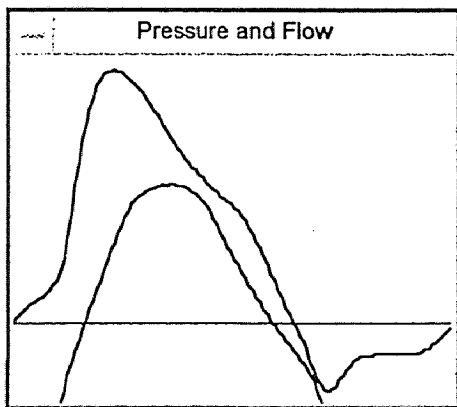
System Parameters: Heart Rate: 120.97 bpm
 Stroke Volume: 78.48 ml
 Cardiac Output: 9.49 L/m
 Duration of valve cycle: 0.50 sec.
 Forward Flow Phase: 0.31 sec. 63.41 %

Measured Flow (L/m): RMS: 21.81 L/m
 Mean: 14.73 L/m
 Peak: 28.52 L/m

Measured Pressures (mm Hg): Mean: 6.74 mm Hg
 Peak Pressure: 15.72 mm Hg
 Pressure at max flow: 9.12 mm Hg

Valve Parameters Closing Volume: 8.60 ml, 10.96 %
 Leakage Volume: 3.12 ml, 3.98 %
 Regurgitant Fraction: 14.94 %

Effective Orifice Area (sq cm.): Peak: 3.55 Discharge Coefficient: 0.714
 Mean: 1.83 Performance Index: 0.553
 RMS: 2.71 Efficiency Index: 0.470



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 16 Valve Type: **SHELHIGH** Serial No. **3946** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

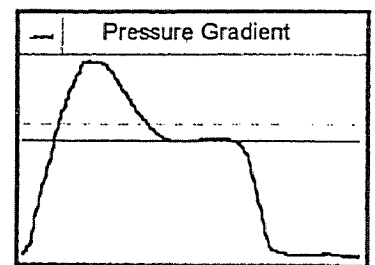
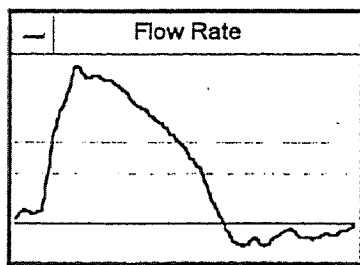
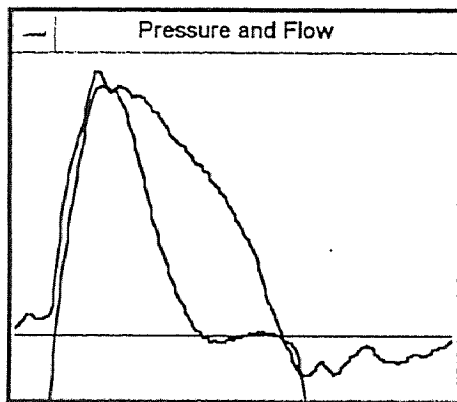
System Parameters: Heart Rate: 61.22 bpm
 Stroke Volume: 74.18 ml
 Cardiac Output: 4.54 L/m
 Duration of valve cycle: 0.98 sec.
 Forward Flow Phase: 0.60 sec. 61.44 %

Measured Flow (L/m): RMS: 10.78 L/m
 Mean: 7.33 L/m
 Peak: 13.22 L/m

Measured Pressures (mm Hg): Mean: 3.76 mm Hg
 Peak Pressure: 12.45 mm Hg
 Pressure at max flow: 12.32 mm Hg

Valve Parameters Closing Volume: 3.20 ml, 4.31 %
 Leakage Volume: 3.70 ml, 4.99 %
 Regurgitant Fraction: 9.30 %

Effective Orifice Area (sq cm.): Peak: 2.20 Discharge Coefficient: 0.705
 Mean: 1.22 Performance Index: 0.432
 RMS: 1.80 Efficiency Index: 0.392



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 17 Valve Type: **SHELHIGH** Serial No. **3946** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

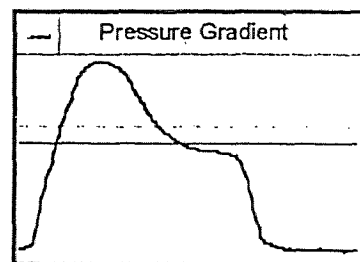
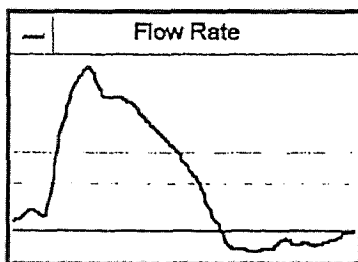
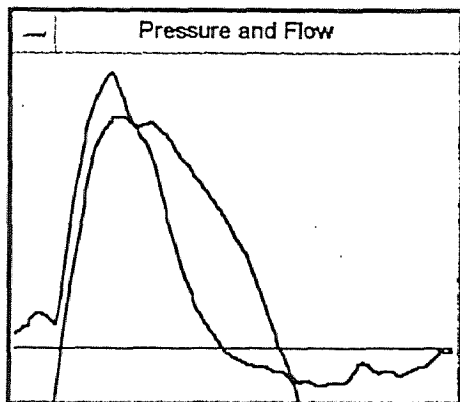
System Parameters: Heart Rate: 74.26 bpm
 Stroke Volume: 72.52 ml
 Cardiac Output: 5.39 L/m
 Duration of valve cycle: 0.81 sec.
 Forward Flow Phase: 0.49 sec. 60.80 %

Measured Flow (L/m): RMS: 13.09 L/m
 Mean: 8.77 L/m
 Peak: 16.97 L/m

Measured Pressures (mm Hg): Mean: 4.97 mm Hg
 Peak Pressure: 14.30 mm Hg
 Pressure at max flow: 14.00 mm Hg

Valve Parameters Closing Volume: 4.90 ml, 6.76 %
 Leakage Volume: 2.52 ml, 3.48 %
 Regurgitant Fraction: 10.24 %

Effective Orifice Area (sq cm.): Peak: 2.46 Discharge Coefficient: 0.745
 Mean: 1.27 Performance Index: 0.456
 RMS: 1.90 Efficiency Index: 0.410



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 18 Valve Type: **SHELHIGH** Serial No. **3946** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

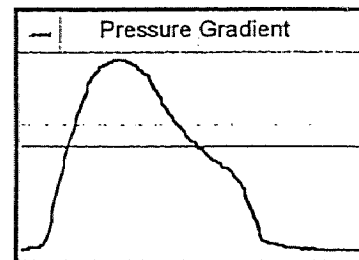
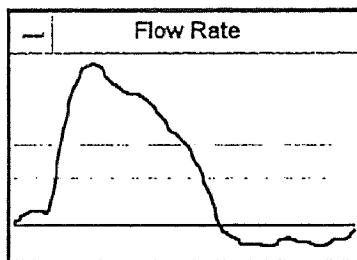
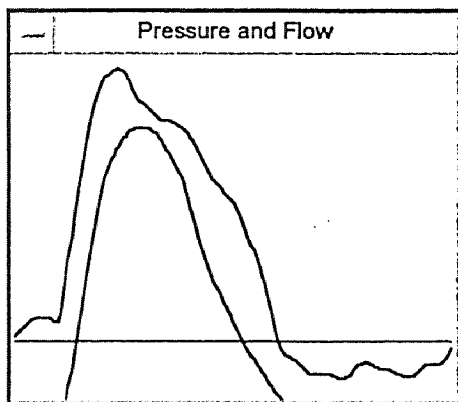
System Parameters: Heart Rate: 86.21 bpm
 Stroke Volume: 73.57 ml
 Cardiac Output: 6.34 L/m
 Duration of valve cycle: 0.70 sec.
 Forward Flow Phase: 0.42 sec. 60.23 %

Measured Flow (L/m): RMS: 15.65 L/m
 Mean: 10.41 L/m
 Peak: 19.13 L/m

Measured Pressures (mm Hg): Mean: 5.85 mm Hg
 Peak Pressure: 15.10 mm Hg
 Pressure at max flow: 13.77 mm Hg

Valve Parameters Closing Volume: 6.45 ml, 8.77 %
 Leakage Volume: 2.38 ml, 3.23 %
 Regurgitant Fraction: 12.00 %

Effective Orifice Area (sq cm.): Peak: 2.55 Discharge Coefficient: 0.821
 Mean: 1.39 Performance Index: 0.503
 RMS: 2.09 Efficiency Index: 0.443



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 19 Valve Type: **SHELHIGH** Serial No. **3946** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

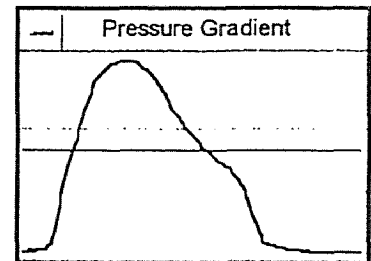
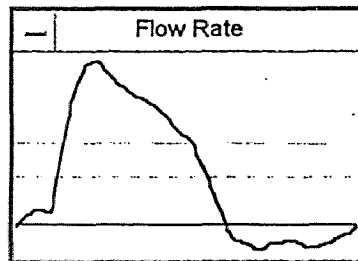
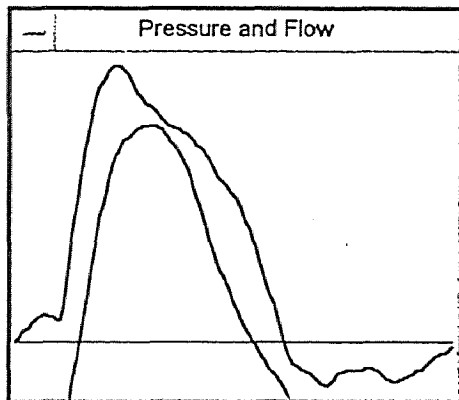
System Parameters: Heart Rate: 90.36 bpm
 Stroke Volume: 74.83 ml
 Cardiac Output: 6.76 L/m
 Duration of valve cycle: 0.66 sec.
 Forward Flow Phase: 0.41 sec. 61.21 %

Measured Flow (L/m): RMS: 16.29 L/m
 Mean: 10.91 L/m
 Peak: 20.14 L/m

Measured Pressures (mm Hg): Mean: 6.39 mm Hg
 Peak Pressure: 15.85 mm Hg
 Pressure at max flow: 13.90 mm Hg

Valve Parameters Closing Volume: 4.68 ml, 6.25 %
 Leakage Volume: 4.10 ml, 5.48 %
 Regurgitant Fraction: 11.74 %

Effective Orifice Area (sq cm.): Peak: 2.57 Discharge Coefficient: 0.818
 Mean: 1.40 Performance Index: 0.501
 RMS: 2.08 Efficiency Index: 0.442



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 20 Valve Type: **SHELHIGH** Serial No. **3946** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

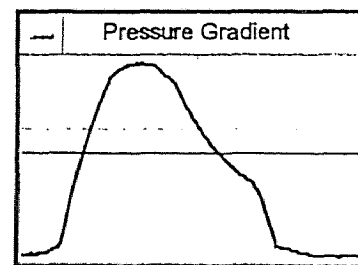
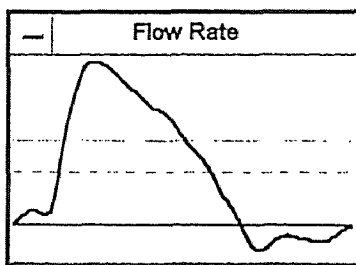
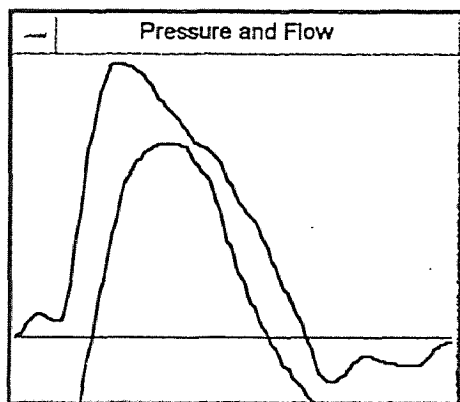
System Parameters: Heart Rate: 101.35 bpm
 Stroke Volume: 77.43 ml
 Cardiac Output: 7.85 L/m
 Duration of valve cycle: 0.59 sec.
 Forward Flow Phase: 0.39 sec. 66.21 %

Measured Flow (L/m): RMS: 17.09 L/m
 Mean: 11.69 L/m
 Peak: 22.48 L/m

Measured Pressures (mm Hg): Mean: 6.30 mm Hg
 Peak Pressure: 15.95 mm Hg
 Pressure at max flow: 9.92 mm Hg

Valve Parameters Closing Volume: 3.55 ml, 4.59 %
 Leakage Volume: 3.07 ml, 3.96 %
 Regurgitant Fraction: 8.55 %

Effective Orifice Area (sq cm.): Peak: 2.89 Discharge Coefficient: 0.864
 Mean: 1.50 Performance Index: 0.529
 RMS: 2.20 Efficiency Index: 0.484



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 21 Valve Type: **SHELHIGH** Serial No. **3946** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

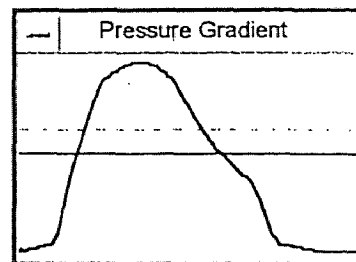
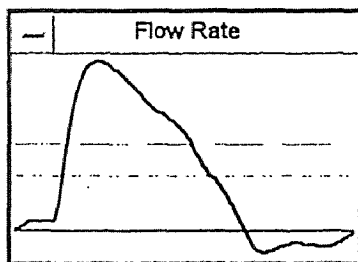
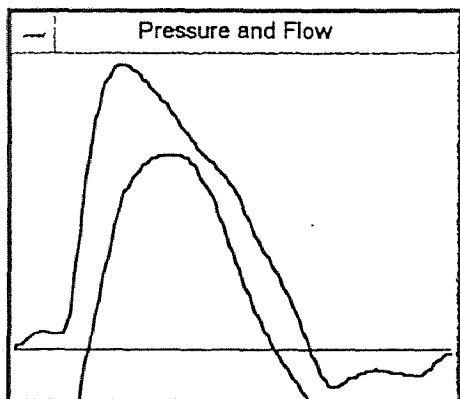
System Parameters: Heart Rate: 110.29 bpm
 Stroke Volume: 76.89 ml
 Cardiac Output: 8.48 L/m
 Duration of valve cycle: 0.54 sec.
 Forward Flow Phase: 0.37 sec. 67.88 %

Measured Flow (L/m): RMS: 18.02 L/m
 Mean: 12.31 L/m
 Peak: 24.20 L/m

Measured Pressures (mm Hg): Mean: 6.78 mm Hg
 Peak Pressure: 16.65 mm Hg
 Pressure at max flow: 13.57 mm Hg

Valve Parameters Closing Volume: 4.15 ml, 5.40 %
 Leakage Volume: 1.44 ml, 1.87 %
 Regurgitant Fraction: 7.27 %

Effective Orifice Area (sq cm.): Peak: 3.00 Discharge Coefficient: 0.878
 Mean: 1.53 Performance Index: 0.538
 RMS: 2.23 Efficiency Index: 0.499



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 22 Valve Type: **SHELHIGH** Serial No. **3946** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

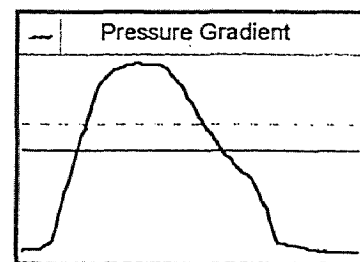
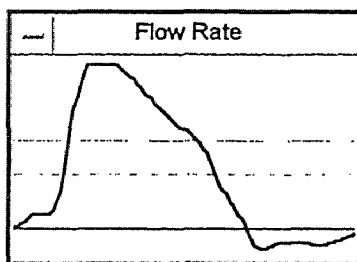
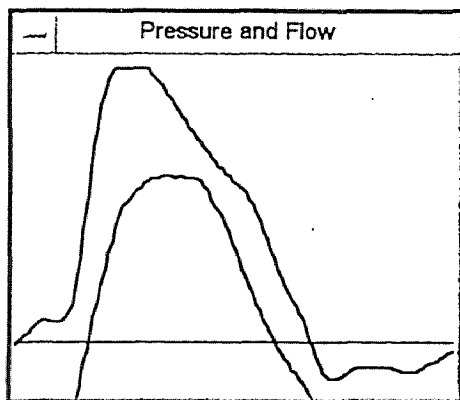
System Parameters: Heart Rate: 121.95 bpm
 Stroke Volume: 76.59 ml
 Cardiac Output: 9.34 L/m
 Duration of valve cycle: 0.49 sec.
 Forward Flow Phase: 0.33 sec. 66.94 %

Measured Flow (L/m): RMS: 20.07 L/m
 Mean: 13.73 L/m
 Peak: 25.96 L/m

Measured Pressures (mm Hg): Mean: 6.95 mm Hg
 Peak Pressure: 15.92 mm Hg
 Pressure at max flow: 11.30 mm Hg

Valve Parameters Closing Volume: 4.05 ml, 5.29 %
 Leakage Volume: 2.13 ml, 2.78 %
 Regurgitant Fraction: 8.07 %

Effective Orifice Area (sq cm.): Peak: 3.18 Discharge Coefficient: 0.966
 Mean: 1.68 Performance Index: 0.592
 RMS: 2.46 Efficiency Index: 0.544



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 37 Valve Type: **SHELHIGH** Serial No. **4635** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

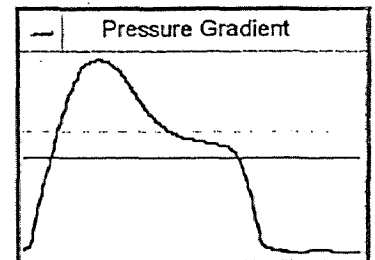
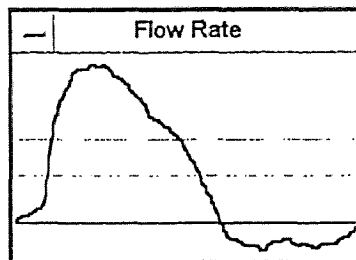
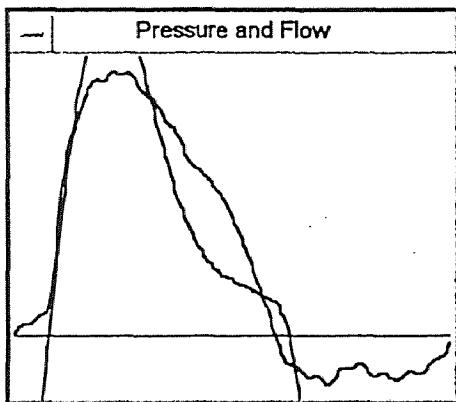
System Parameters: Heart Rate: 63.29 bpm
 Stroke Volume: 73.45 ml
 Cardiac Output: 4.65 L/m
 Duration of valve cycle: 0.95 sec.
 Forward Flow Phase: 0.57 sec. 60.09 %

Measured Flow (L/m): RMS: 11.41 L/m
 Mean: 7.67 L/m
 Peak: 13.18 L/m

Measured Pressures (mm Hg): Mean: 7.07 mm Hg
 Peak Pressure: 16.05 mm Hg
 Pressure at max flow: 16.05 mm Hg

Valve Parameters Closing Volume: 6.36 ml, 8.65 %
 Leakage Volume: 3.90 ml, 5.31 %
 Regurgitant Fraction: 13.96 %

Effective Orifice Area (sq cm.): Peak: 1.60 Discharge Coefficient: 0.544
 Mean: 0.93 Performance Index: 0.333
 RMS: 1.39 Efficiency Index: 0.287



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 38 Valve Type: **SHELHIGH** Serial No. **4635** Valve size: 23 mm Mitral Position
 Operator: E. Sean Parker

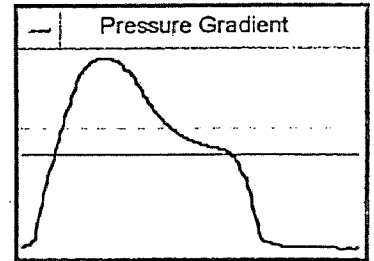
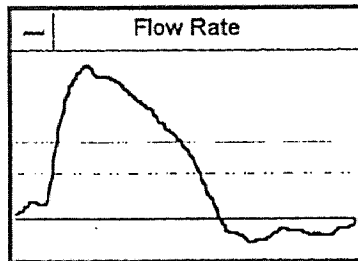
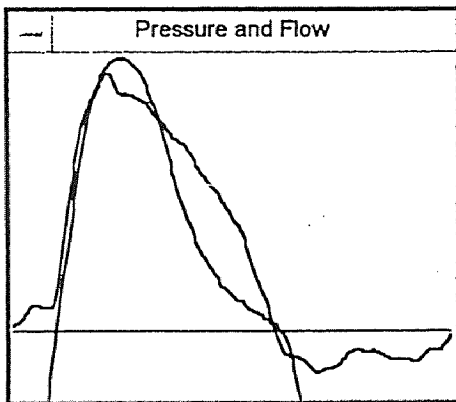
System Parameters: Heart Rate: 73.53 bpm
 Stroke Volume: 71.81 ml
 Cardiac Output: 5.28 L/m
 Duration of valve cycle: 0.82 sec.
 Forward Flow Phase: 0.49 sec. 60.20 %

Measured Flow (L/m): RMS: 13.00 L/m
 Mean: 8.69 L/m
 Peak: 15.85 L/m

Measured Pressures (mm Hg): Mean: 7.08 mm Hg
 Peak Pressure: 16.85 mm Hg
 Pressure at max flow: 16.35 mm Hg

Valve Parameters Closing Volume: 4.59 ml, 6.39 %
 Leakage Volume: 3.60 ml, 5.02 %
 Regurgitant Fraction: 11.41 %

Effective Orifice Area (sq cm.): Peak: 1.92 Discharge Coefficient: 0.620
 Mean: 1.05 Performance Index: 0.380
 RMS: 1.58 Efficiency Index: 0.336



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 40 Valve Type: **SHELHIGH** Serial No. **4635** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

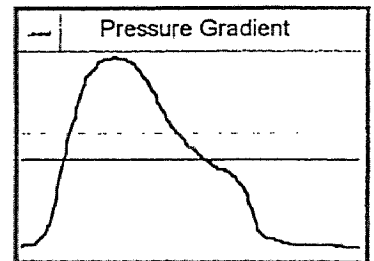
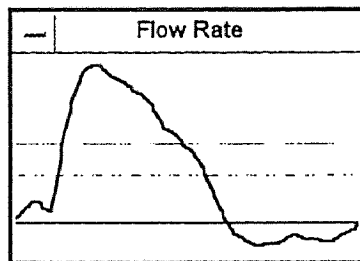
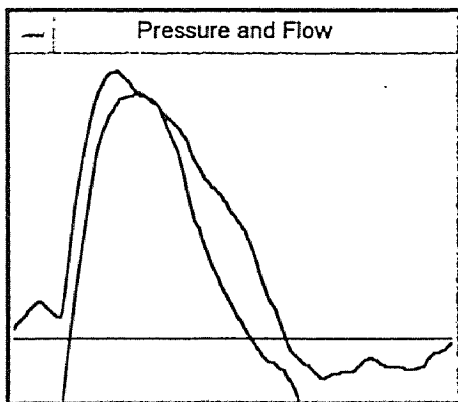
System Parameters: Heart Rate: 83.80 bpm
 Stroke Volume: 71.71 ml
 Cardiac Output: 6.01 L/m
 Duration of valve cycle: 0.72 sec.
 Forward Flow Phase: 0.44 sec. 61.58 %

Measured Flow (L/m): RMS: 14.40 L/m
 Mean: 9.65 L/m
 Peak: 17.99 L/m

Measured Pressures (mm Hg): Mean: 6.61 mm Hg
 Peak Pressure: 16.45 mm Hg
 Pressure at max flow: 15.90 mm Hg

Valve Parameters Closing Volume: 7.91 ml, 11.03 %
 Leakage Volume: -0.01 ml, -0.02 %
 Regurgitant Fraction: 11.01 %

Effective Orifice Area (sq cm.): Peak: 2.26 Discharge Coefficient: 0.711
 Mean: 1.21 Performance Index: 0.435
 RMS: 1.81 Efficiency Index: 0.388



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 39 Valve Type: **SHELHIGH** Serial No. **4635** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

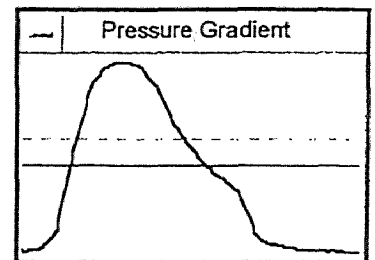
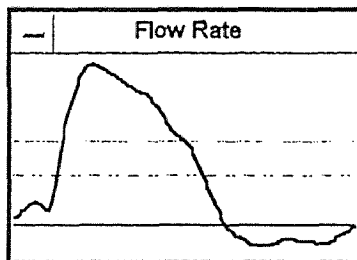
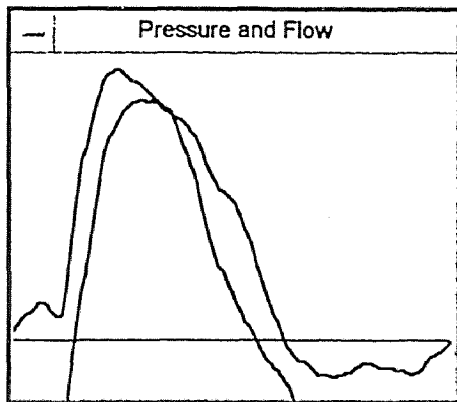
System Parameters: Heart Rate: 89.29 bpm
 Stroke Volume: 72.35 ml
 Cardiac Output: 6.46 L/m
 Duration of valve cycle: 0.67 sec.
 Forward Flow Phase: 0.41 sec. 61.68 %

Measured Flow (L/m): RMS: 15.46 L/m
 Mean: 10.35 L/m
 Peak: 19.03 L/m

Measured Pressures (mm Hg): Mean: 6.93 mm Hg
 Peak Pressure: 16.77 mm Hg
 Pressure at max flow: 15.37 mm Hg

Valve Parameters Closing Volume: 7.80 ml, 10.78 %
 Leakage Volume: -0.01 ml, -0.01 %
 Regurgitant Fraction: 10.77 %

Effective Orifice Area (sq cm.): Peak: 2.33 Discharge Coefficient: 0.745
 Mean: 1.27 Performance Index: 0.456
 RMS: 1.90 Efficiency Index: 0.407



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 41 Valve Type: **SHELHIGH** Serial No. **4635** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

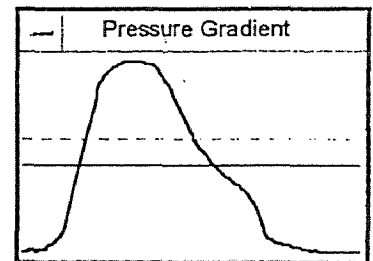
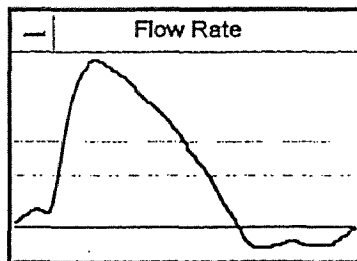
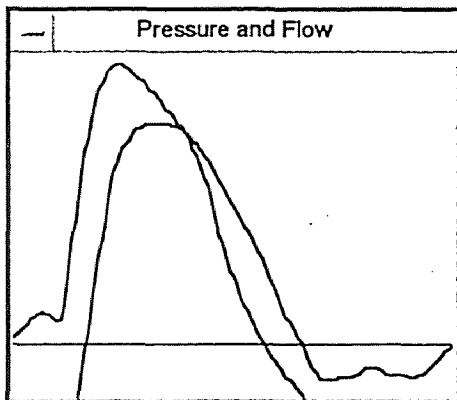
System Parameters: Heart Rate: 99.34 bpm
 Stroke Volume: 74.12 ml
 Cardiac Output: 7.36 L/m
 Duration of valve cycle: 0.60 sec.
 Forward Flow Phase: 0.40 sec. 66.00 %

Measured Flow (L/m): RMS: 16.19 L/m
 Mean: 11.01 L/m
 Peak: 21.32 L/m

Measured Pressures (mm Hg): Mean: 6.73 mm Hg
 Peak Pressure: 16.82 mm Hg
 Pressure at max flow: 14.47 mm Hg

Valve Parameters Closing Volume: 7.08 ml, 9.56 %
 Leakage Volume: -0.00 ml, -0.01 %
 Regurgitant Fraction: 9.55 %

Effective Orifice Area (sq cm.): Peak: 2.65 Discharge Coefficient: 0.792
 Mean: 1.37 Performance Index: 0.485
 RMS: 2.02 Efficiency Index: 0.439



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 42 Valve Type: **SHELHIGH** Serial No. **4635** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

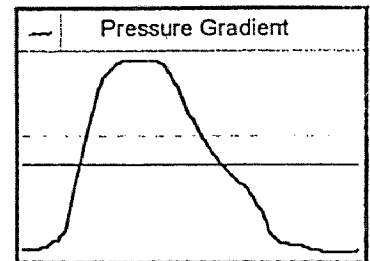
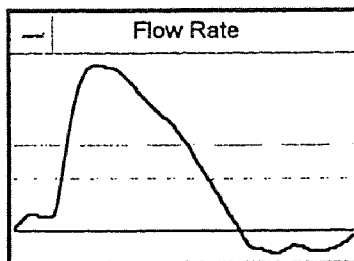
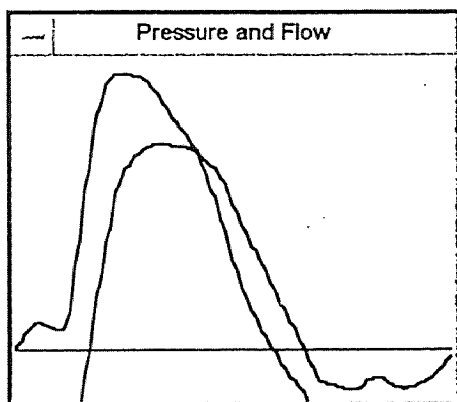
System Parameters: Heart Rate: 107.91 bpm
 Stroke Volume: 73.80 ml
 Cardiac Output: 7.96 L/m
 Duration of valve cycle: 0.56 sec.
 Forward Flow Phase: 0.37 sec. 66.67 %

Measured Flow (L/m): RMS: 17.36 L/m
 Mean: 11.78 L/m
 Peak: 22.72 L/m

Measured Pressures (mm Hg): Mean: 7.14 mm Hg
 Peak Pressure: 17.00 mm Hg
 Pressure at max flow: 14.55 mm Hg

Valve Parameters Closing Volume: 7.61 ml, 10.32 %
 Leakage Volume: -0.02 ml, -0.03 %
 Regurgitant Fraction: 10.29 %

Effective Orifice Area (sq cm.): Peak: 2.75 Discharge Coefficient: 0.824
 Mean: 1.42 Performance Index: 0.505
 RMS: 2.10 Efficiency Index: 0.453



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 43 Valve Type: SHELHIGH Serial No. 4635 Valve size: 23 mm Mitral Position
Operator: E. Sean Parker

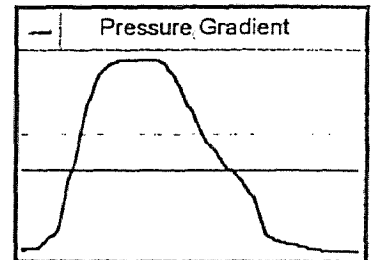
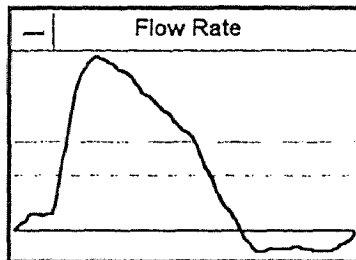
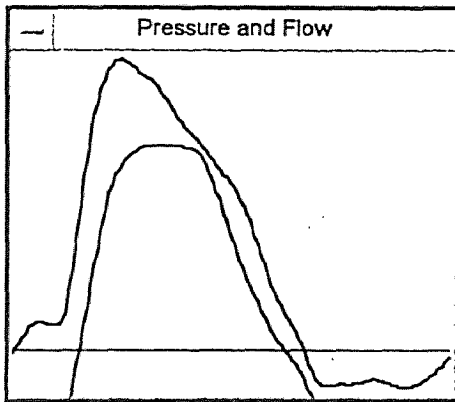
System Parameters: Heart Rate: 118.11 bpm
Stroke Volume: 74.96 ml
Cardiac Output: 8.85 L/m
Duration of valve cycle: 0.51 sec.
Forward Flow Phase: 0.33 sec. 65.87 %

Measured Flow (L/m): RMS: 19.50 L/m
Mean: 13.23 L/m
Peak: 25.49 L/m

Measured Pressures (mm Hg): Mean: 8.49 mm Hg
Peak Pressure: 18.00 mm Hg
Pressure at max flow: 16.35 mm Hg

Valve Parameters Closing Volume: 7.55 ml, 10.08 %
Leakage Volume: -0.00 ml, -0.00 %
Regurgitant Fraction: 10.07 %

Effective Orifice Area (sq cm.): Peak: 2.83 Discharge Coefficient: 0.849
Mean: 1.47 Performance Index: 0.520
RMS: 2.16 Efficiency Index: 0.468



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 72 Valve Type: **SHELHIGH** Serial No. **4026** Valve size: **23 mm** Mitral Positio
 Operator: E. Sean Parker

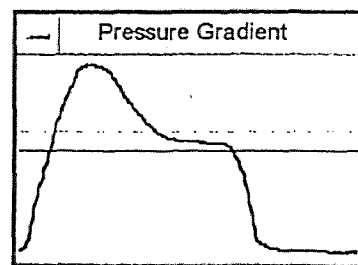
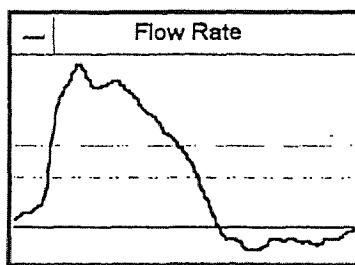
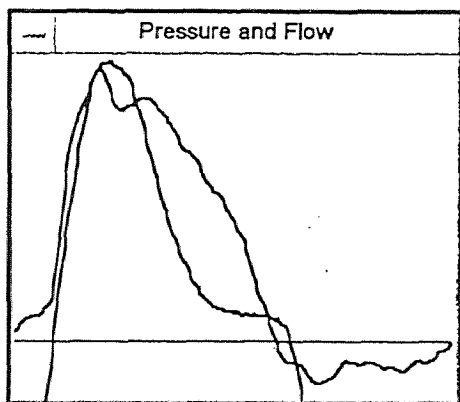
System Parameters: Heart Rate: 66.96 bpm
 Stroke Volume: 72.74 ml
 Cardiac Output: 4.87 L/m
 Duration of valve cycle: 0.90 sec.
 Forward Flow Phase: 0.54 sec. 59.91 %

Measured Flow (L/m): RMS: 11.94 L/m
 Mean: 8.06 L/m
 Peak: 14.37 L/m

Measured Pressures (mm Hg): Mean: 5.68 mm Hg
 Peak Pressure: 14.70 mm Hg
 Pressure at max flow: 14.30 mm Hg

Valve Parameters Closing Volume: 4.48 ml, 6.16 %
 Leakage Volume: 3.13 ml, 4.31 %
 Regurgitant Fraction: 10.47 %

Effective Orifice Area (sq cm.): Peak: 1.95 Discharge Coefficient: 0.636
 Mean: 1.09 Performance Index: 0.389
 RMS: 1.62 Efficiency Index: 0.349



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 73 Valve Type: SHELHIGH Serial No. 4026 Valve size: 23 mm Mitral Position
Operator: E. Sean Parker

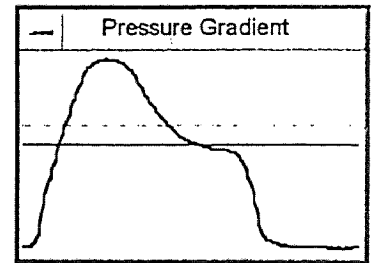
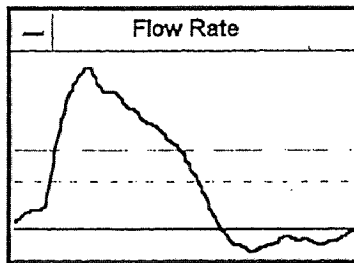
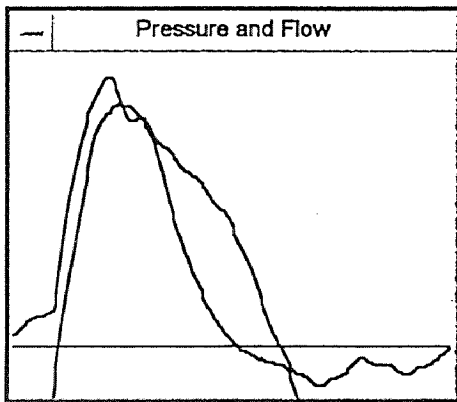
System Parameters: Heart Rate: 74.63 bpm
Stroke Volume: 72.46 ml
Cardiac Output: 5.41 L/m
Duration of valve cycle: 0.80 sec.
Forward Flow Phase: 0.49 sec. 61.11 %

Measured Flow (L/m): RMS: 12.97 L/m
Mean: 8.76 L/m
Peak: 16.62 L/m

Measured Pressures (mm Hg): Mean: 5.60 mm Hg
Peak Pressure: 14.97 mm Hg
Pressure at max flow: 14.45 mm Hg

Valve Parameters Closing Volume: 4.21 ml, 5.81 %
Leakage Volume: 2.80 ml, 3.87 %
Regurgitant Fraction: 9.68 %

Effective Orifice Area (sq cm.): Peak: 2.27 Discharge Coefficient: 0.696
Mean: 1.20 Performance Index: 0.426
RMS: 1.77 Efficiency Index: 0.385



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 74 Valve Type: **SHELHIGH** Serial No. **4026** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

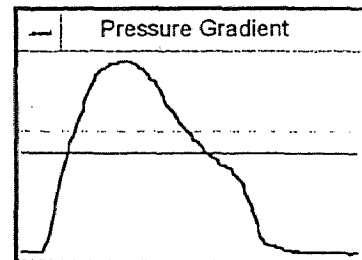
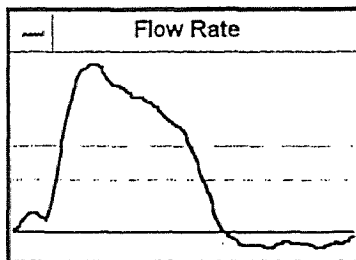
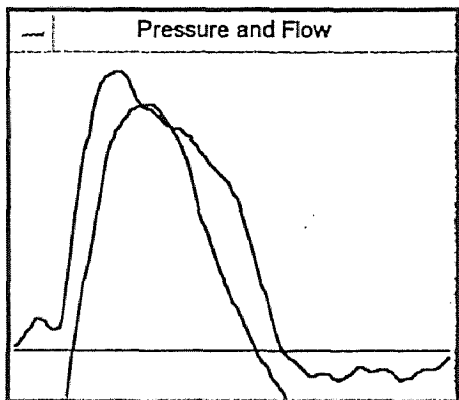
System Parameters: Heart Rate: 86.71 bpm
 Stroke Volume: 74.90 ml
 Cardiac Output: 6.49 L/m
 Duration of valve cycle: 0.69 sec.
 Forward Flow Phase: 0.43 sec. 61.90 %

Measured Flow (L/m): RMS: 15.42 L/m
 Mean: 10.37 L/m
 Peak: 18.89 L/m

Measured Pressures (mm Hg): Mean: 6.85 mm Hg
 Peak Pressure: 16.62 mm Hg
 Pressure at max flow: 15.27 mm Hg

Valve Parameters Closing Volume: 3.22 ml, 4.30 %
 Leakage Volume: 2.79 ml, 3.72 %
 Regurgitant Fraction: 8.02 %

Effective Orifice Area (sq cm.): Peak: 2.33 Discharge Coefficient: 0.748
 Mean: 1.28 Performance Index: 0.458
 RMS: 1.90 Efficiency Index: 0.421



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 75 Valve Type: SHELHIGH Serial No. 4026 Valve size: 23 mm Mitral Positi
 Operator: E. Sean Parker

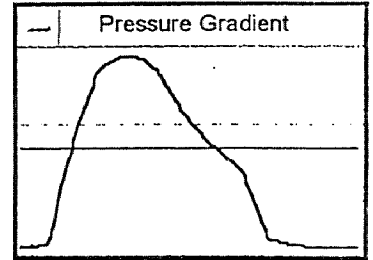
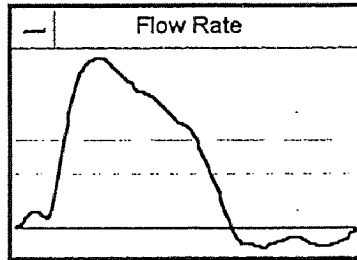
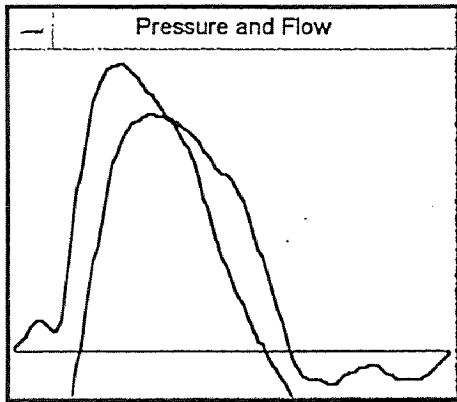
System Parameters: Heart Rate: 92.59 bpm
 Stroke Volume: 77.27 ml
 Cardiac Output: 7.15 L/m
 Duration of valve cycle: 0.65 sec.
 Forward Flow Phase: 0.41 sec. 63.52 %

Measured Flow (L/m): RMS: 16.32 L/m
 Mean: 11.12 L/m
 Peak: 20.22 L/m

Measured Pressures (mm Hg): Mean: 6.88 mm Hg
 Peak Pressure: 16.67 mm Hg
 Pressure at max flow: 14.82 mm Hg

Valve Parameters Closing Volume: 3.74 ml, 4.84 %
 Leakage Volume: 2.49 ml, 3.22 %
 Regurgitant Fraction: 8.06 %

Effective Orifice Area (sq cm.): Peak: 2.49 Discharge Coefficient: 0.789
 Mean: 1.37 Performance Index: 0.483
 RMS: 2.01 Efficiency Index: 0.444



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 76 Valve Type: **SHELHIGH** Serial No. **4026** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

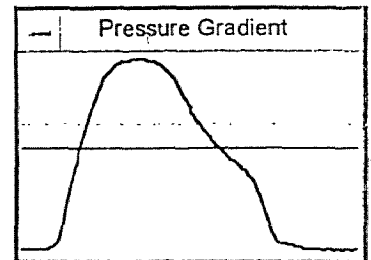
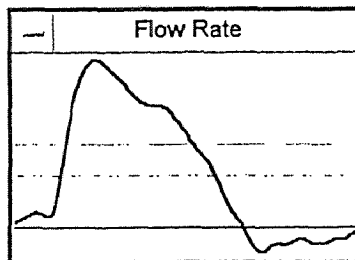
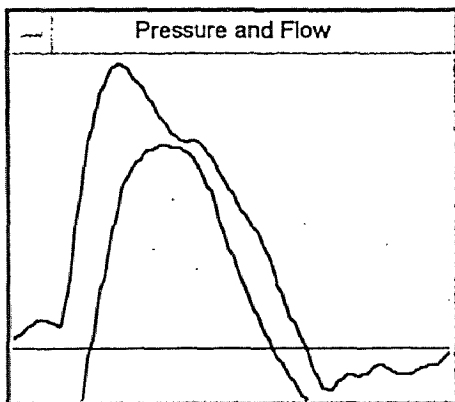
System Parameters: Heart Rate: 101.35 bpm
 Stroke Volume: 77.16 ml
 Cardiac Output: 7.82 L/m
 Duration of valve cycle: 0.59 sec.
 Forward Flow Phase: 0.40 sec. 67.12 %

Measured Flow (L/m): RMS: 16.66 L/m
 Mean: 11.50 L/m
 Peak: 22.40 L/m

Measured Pressures (mm Hg): Mean: 6.42 mm Hg
 Peak Pressure: 16.02 mm Hg
 Pressure at max flow: 12.62 mm Hg

Valve Parameters Closing Volume: 3.14 ml, 4.07 %
 Leakage Volume: 3.09 ml, 4.00 %
 Regurgitant Fraction: 8.07 %

Effective Orifice Area (sq cm.): Peak: 2.86 Discharge Coefficient: 0.834
 Mean: 1.47 Performance Index: 0.511
 RMS: 2.12 Efficiency Index: 0.470



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 77 Valve Type: **SHELHIGH** Serial No. **4026** Valve size: **23 mm** Mitral Position
Operator: E. Sean Parker

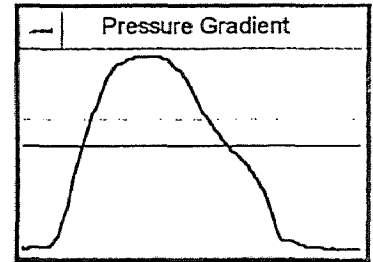
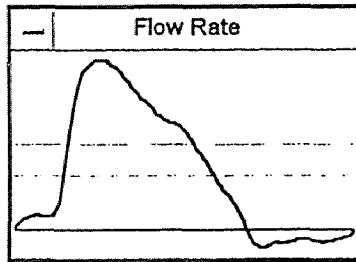
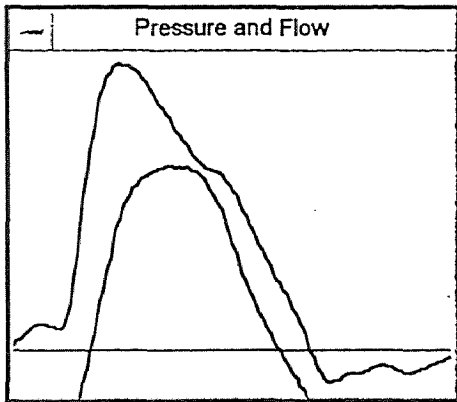
System Parameters: Heart Rate: 113.64 bpm
Stroke Volume: 76.87 ml
Cardiac Output: 8.74 L/m
Duration of valve cycle: 0.53 sec.
Forward Flow Phase: 0.36 sec. 68.70 %

Measured Flow (L/m): RMS: 18.19 L/m
Mean: 12.53 L/m
Peak: 25.08 L/m

Measured Pressures (mm Hg): Mean: 6.76 mm Hg
Peak Pressure: 16.20 mm Hg
Pressure at max flow: 11.77 mm Hg

Valve Parameters Closing Volume: 3.90 ml, 5.08 %
Leakage Volume: 1.08 ml, 1.41 %
Regurgitant Fraction: 6.48 %

Effective Orifice Area (sq cm.): Peak: 3.12 Discharge Coefficient: 0.888
Mean: 1.56 Performance Index: 0.544
RMS: 2.26 Efficiency Index: 0.509



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 78 Valve Type: **SHELHIGH** Serial No. **4026** Valve size: **23 mm** Mitral Position:
 Operator: E. Sean Parker

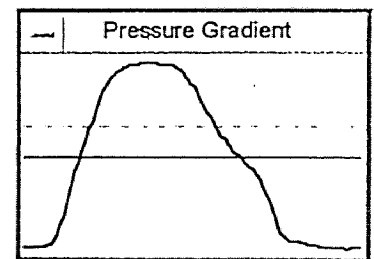
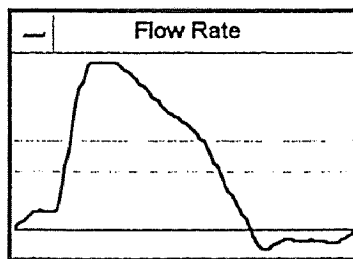
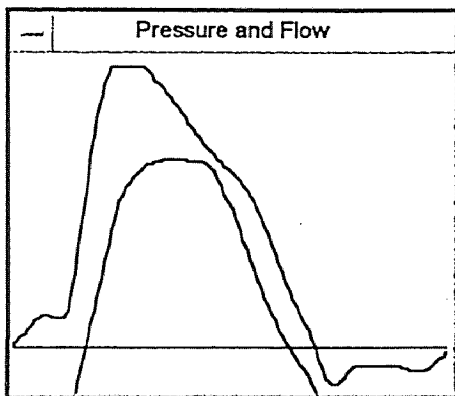
System Parameters: Heart Rate: 122.95 bpm
 Stroke Volume: 79.82 ml
 Cardiac Output: 9.81 L/m
 Duration of valve cycle: 0.49 sec.
 Forward Flow Phase: 0.34 sec. 69.17 %

Measured Flow (L/m): RMS: 19.88 L/m
 Mean: 13.95 L/m
 Peak: 25.92 L/m

Measured Pressures (mm Hg): Mean: 8.05 mm Hg
 Peak Pressure: 17.55 mm Hg
 Pressure at max flow: 11.10 mm Hg

Valve Parameters Closing Volume: 2.34 ml, 2.93 %
 Leakage Volume: 2.25 ml, 2.82 %
 Regurgitant Fraction: 5.76 %

Effective Orifice Area (sq cm.): Peak: 2.95 Discharge Coefficient: 0.889
 Mean: 1.59 Performance Index: 0.545
 RMS: 2.26 Efficiency Index: 0.513



Test No. 86 Valve Type: **SHELHIGH** Serial No. **4022** Valve size: **23 mm** Mitral Position:
 Operator: E. Sean Parker

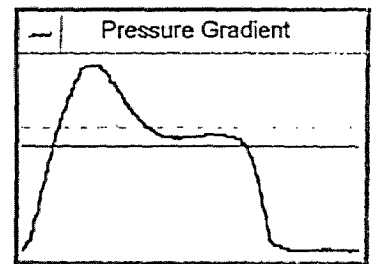
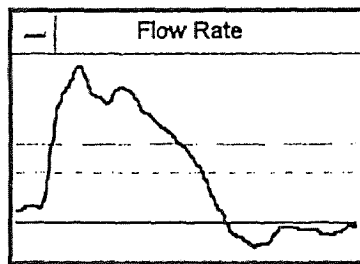
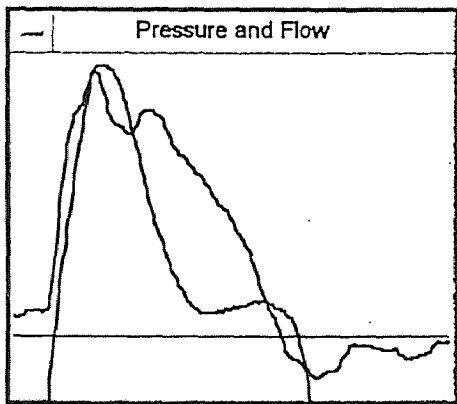
System Parameters: Heart Rate: 60.48 bpm
 Stroke Volume: 73.98 ml
 Cardiac Output: 4.47 L/m
 Duration of valve cycle: 0.99 sec.
 Forward Flow Phase: 0.61 sec. 61.60 %

Measured Flow (L/m): RMS: 10.49 L/m
 Mean: 7.21 L/m
 Peak: 13.22 L/m

Measured Pressures (mm Hg): Mean: 4.63 mm Hg
 Peak Pressure: 13.57 mm Hg
 Pressure at max flow: 13.40 mm Hg

Valve Parameters Closing Volume: 3.66 ml, 4.95 %
 Leakage Volume: 2.17 ml, 2.93 %
 Regurgitant Fraction: 7.88 %

Effective Orifice Area (sq cm.): Peak: 1.98 Discharge Coefficient: 0.618
 Mean: 1.08 Performance Index: 0.379
 RMS: 1.57 Efficiency Index: 0.349



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 87 Valve Type: **SHELHIGH** Serial No. **4022** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

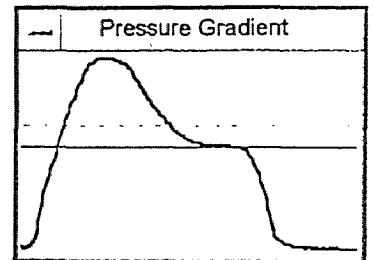
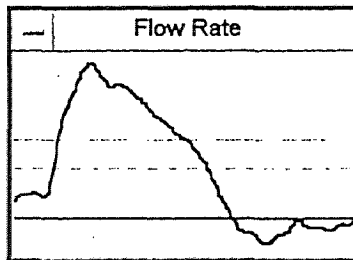
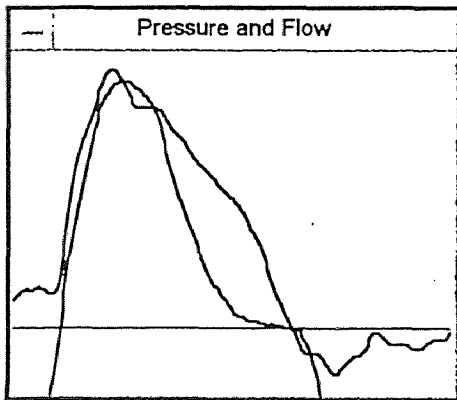
System Parameters: Heart Rate: 71.43 bpm
 Stroke Volume: 77.75 ml
 Cardiac Output: 5.55 L/m
 Duration of valve cycle: 0.84 sec.
 Forward Flow Phase: 0.54 sec. 63.78 %

Measured Flow (L/m): RMS: 12.36 L/m
 Mean: 8.63 L/m
 Peak: 16.01 L/m

Measured Pressures (mm Hg): Mean: 5.79 mm Hg
 Peak Pressure: 15.30 mm Hg
 Pressure at max flow: 15.02 mm Hg

Valve Parameters Closing Volume: 4.32 ml, 5.56 %
 Leakage Volume: 2.01 ml, 2.58 %
 Regurgitant Fraction: 8.14 %

Effective Orifice Area (sq cm.): Peak: 2.15 Discharge Coefficient: 0.652
 Mean: 1.16 Performance Index: 0.399
 RMS: 1.66 Efficiency Index: 0.367



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 88 Valve Type: **SHELHIGH** Serial No. **4022** Valve size: **23 mm** Mitral Position:
 Operator: E. Sean Parker

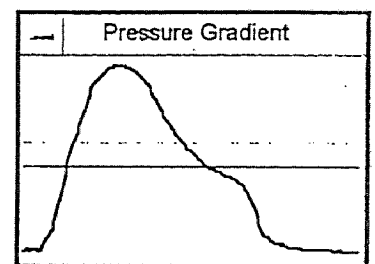
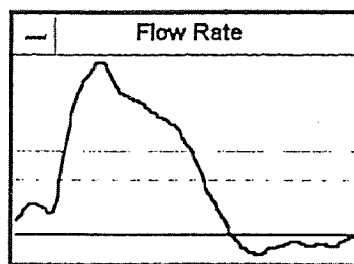
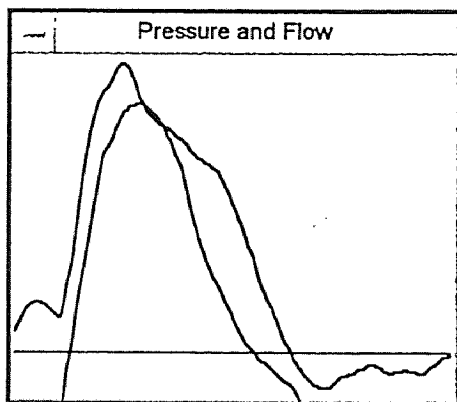
System Parameters: Heart Rate: 84.75 bpm
 Stroke Volume: 77.41 ml
 Cardiac Output: 6.56 L/m
 Duration of valve cycle: 0.71 sec.
 Forward Flow Phase: 0.45 sec. 63.16 %

Measured Flow (L/m): RMS: 14.96 L/m
 Mean: 10.27 L/m
 Peak: 19.49 L/m

Measured Pressures (mm Hg): Mean: 6.51 mm Hg
 Peak Pressure: 16.82 mm Hg
 Pressure at max flow: 16.00 mm Hg

Valve Parameters Closing Volume: 4.20 ml, 5.42 %
 Leakage Volume: 1.35 ml, 1.74 %
 Regurgitant Fraction: 7.17 %

Effective Orifice Area (sq cm.): Peak: 2.47 Discharge Coefficient: 0.744
 Mean: 1.30 Performance Index: 0.455
 RMS: 1.89 Efficiency Index: 0.423



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 89 Valve Type: **SHELHIGH** Serial No. **4022** Valve size: **23 mm** Mitral Positio
 Operator: E. Sean Parker

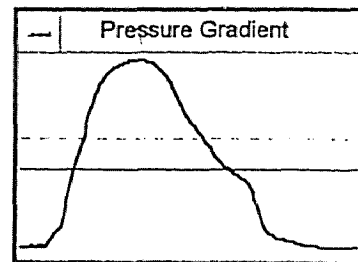
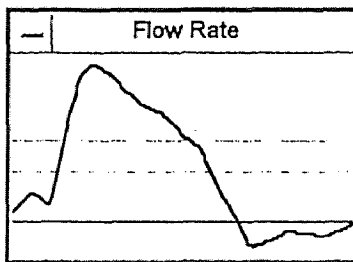
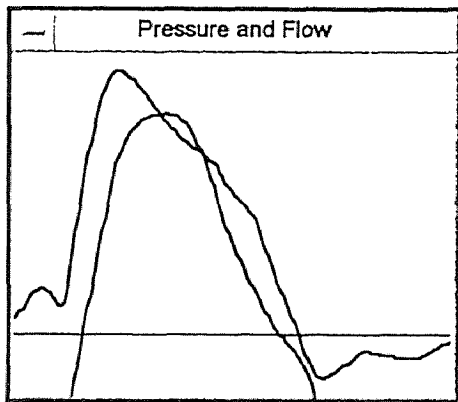
System Parameters: Heart Rate: 96.77 bpm
 Stroke Volume: 78.98 ml
 Cardiac Output: 7.64 L/m
 Duration of valve cycle: 0.62 sec.
 Forward Flow Phase: 0.41 sec. 65.56 %

Measured Flow (L/m): RMS: 16.48 L/m
 Mean: 11.51 L/m
 Peak: 21.62 L/m

Measured Pressures (mm Hg): Mean: 7.75 mm Hg
 Peak Pressure: 18.12 mm Hg
 Pressure at max flow: 14.80 mm Hg

Valve Parameters Closing Volume: 4.94 ml, 6.25 %
 Leakage Volume: 1.89 ml, 2.39 %
 Regurgitant Fraction: 8.65 %

Effective Orifice Area (sq cm.): Peak: 2.51 Discharge Coefficient: 0.751
 Mean: 1.34 Performance Index: 0.460
 RMS: 1.91 Efficiency Index: 0.420



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 90 Valve Type: **SHELHIGH** Serial No. **4022** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

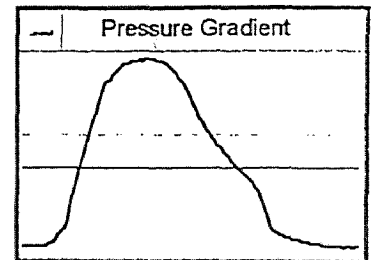
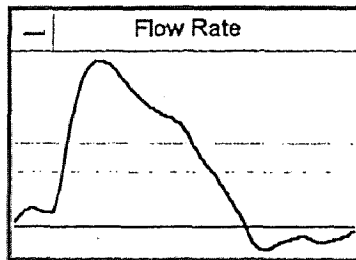
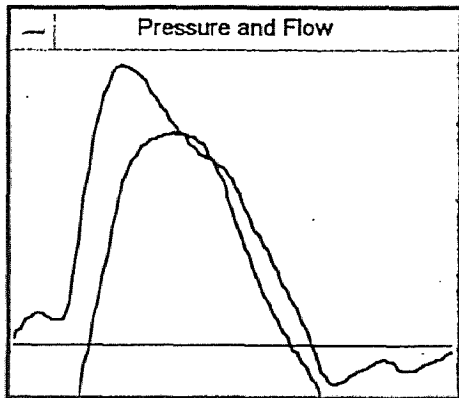
System Parameters: Heart Rate: 107.14 bpm
 Stroke Volume: 78.40 ml
 Cardiac Output: 8.40 L/m
 Duration of valve cycle: 0.56 sec.
 Forward Flow Phase: 0.38 sec. 67.88 %

Measured Flow (L/m): RMS: 17.56 L/m
 Mean: 12.20 L/m
 Peak: 23.95 L/m

Measured Pressures (mm Hg): Mean: 7.90 mm Hg
 Peak Pressure: 18.15 mm Hg
 Pressure at max flow: 14.05 mm Hg

Valve Parameters Closing Volume: 3.96 ml, 5.05 %
 Leakage Volume: 1.65 ml, 2.10 %
 Regurgitant Fraction: 7.15 %

Effective Orifice Area (sq cm.): Peak: 2.75 Discharge Coefficient: 0.793
 Mean: 1.40 Performance Index: 0.486
 RMS: 2.02 Efficiency Index: 0.451



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 91 Valve Type: **SHELHIGH** Serial No. **4022** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

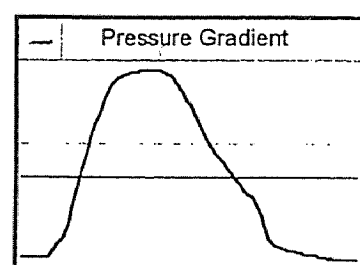
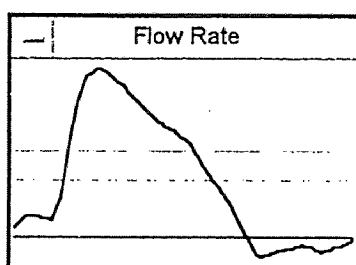
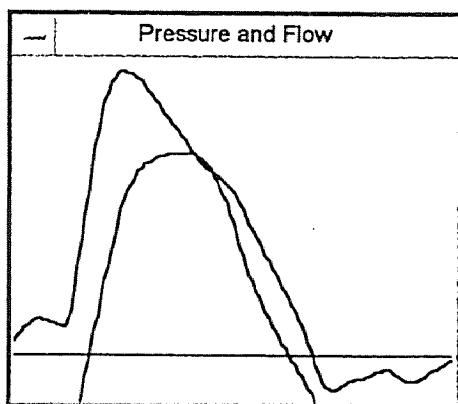
System Parameters: Heart Rate: 111.11 bpm
 Stroke Volume: 79.47 ml
 Cardiac Output: 8.83 L/m
 Duration of valve cycle: 0.54 sec.
 Forward Flow Phase: 0.37 sec. 68.94 %

Measured Flow (L/m): RMS: 18.03 L/m
 Mean: 12.62 L/m
 Peak: 24.90 L/m

Measured Pressures (mm Hg): Mean: 7.72 mm Hg
 Peak Pressure: 17.80 mm Hg
 Pressure at max flow: 13.95 mm Hg

Valve Parameters Closing Volume: 4.38 ml, 5.51 %
 Leakage Volume: 0.96 ml, 1.21 %
 Regurgitant Fraction: 6.73 %

Effective Orifice Area (sq cm.): Peak: 2.90 Discharge Coefficient: 0.823
 Mean: 1.47 Performance Index: 0.504
 RMS: 2.10 Efficiency Index: 0.470



SHELHIGH Inc. Millburn, NJ 07041**** SHELHIGH Pulse Duplicator System ****

Test No. 92 Valve Type: **SHELHIGH** Serial No. **4022** Valve size: **23 mm** Mitral Position
 Operator: E. Sean Parker

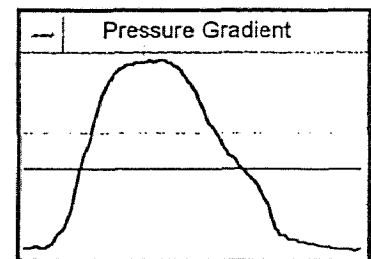
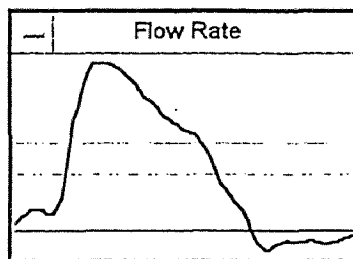
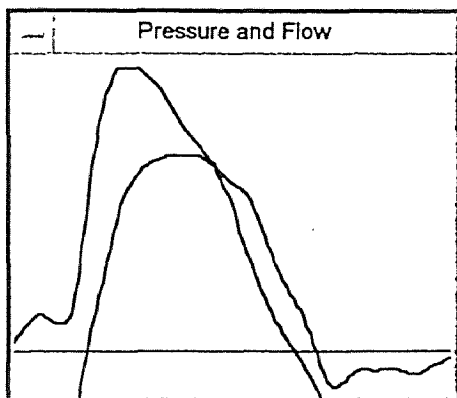
System Parameters: Heart Rate: 119.05 bpm
 Stroke Volume: 79.52 ml
 Cardiac Output: 9.47 L/m
 Duration of valve cycle: 0.50 sec.
 Forward Flow Phase: 0.35 sec. 69.35 %

Measured Flow (L/m): RMS: 19.15 L/m
 Mean: 13.44 L/m
 Peak: 25.94 L/m

Measured Pressures (mm Hg): Mean: 8.14 mm Hg
 Peak Pressure: 18.12 mm Hg
 Pressure at max flow: 13.62 mm Hg

Valve Parameters Closing Volume: 2.49 ml, 3.13 %
 Leakage Volume: 2.21 ml, 2.78 %
 Regurgitant Fraction: 5.92 %

Effective Orifice Area (sq cm.): Peak: 2.94 Discharge Coefficient: 0.851
 Mean: 1.52 Performance Index: 0.521
 RMS: 2.17 Efficiency Index: 0.490



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 12 Valve Type: **SHELHIGH** Serial No. **3494** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

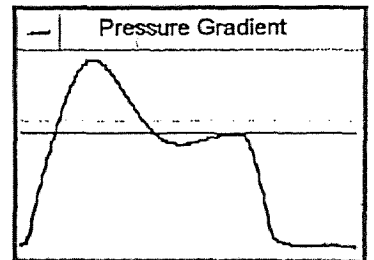
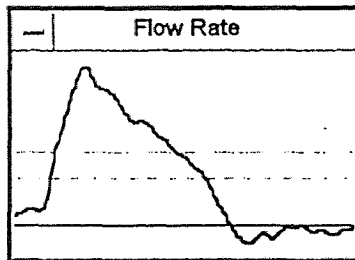
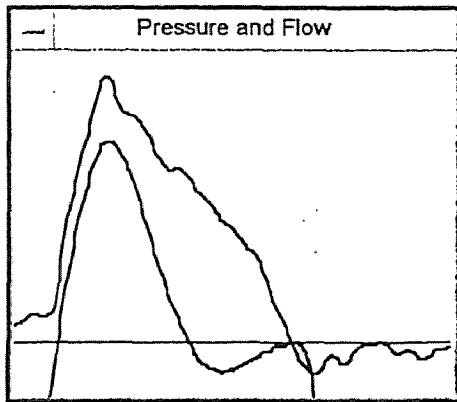
System Parameters: Heart Rate: 65.50 bpm
 Stroke Volume: 76.83 ml
 Cardiac Output: 5.03 L/m
 Duration of valve cycle: 0.92 sec.
 Forward Flow Phase: 0.60 sec. 65.28 %

Measured Flow (L/m): RMS: 11.09 L/m
 Mean: 7.64 L/m
 Peak: 15.66 L/m

Measured Pressures (mm Hg): Mean: 3.18 mm Hg
 Peak Pressure: 11.92 mm Hg
 Pressure at max flow: 11.92 mm Hg

Valve Parameters Closing Volume: 1.93 ml, 2.51 %
 Leakage Volume: 1.87 ml, 2.43 %
 Regurgitant Fraction: 4.94 %

Effective Orifice Area (sq cm.): Peak: 2.84 Discharge Coefficient: 0.639
 Mean: 1.38 Performance Index: 0.409
 RMS: 2.01 Efficiency Index: 0.389



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 11 Valve Type: **SHELHIGH** Serial No. **3494** Valve size: **25 mm** Mitral Positiv
 Operator: E. Sean Parker

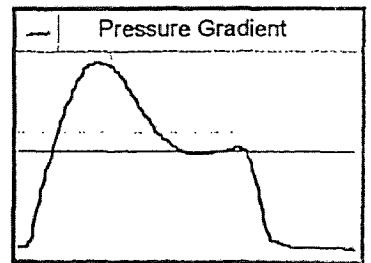
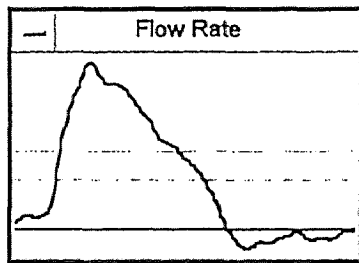
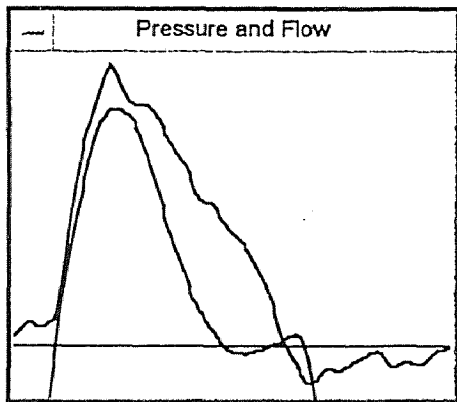
System Parameters: Heart Rate: 72.12 bpm
 Stroke Volume: 76.25 ml
 Cardiac Output: 5.50 L/m
 Duration of valve cycle: 0.83 sec.
 Forward Flow Phase: 0.52 sec. 62.31 %

Measured Flow (L/m): RMS: 13.01 L/m
 Mean: 8.74 L/m
 Peak: 17.36 L/m

Measured Pressures (mm Hg): Mean: 5.18 mm Hg
 Peak Pressure: 14.70 mm Hg
 Pressure at max flow: 14.70 mm Hg

Valve Parameters Closing Volume: 3.79 ml, 4.97 %
 Leakage Volume: 1.58 ml, 2.08 %
 Regurgitant Fraction: 7.05 %

Effective Orifice Area (sq cm.): Peak: 2.46 Discharge Coefficient: 0.587
 Mean: 1.24 Performance Index: 0.376
 RMS: 1.85 Efficiency Index: 0.349



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 9 Valve Type: **SHELHIGH** Serial No. **3494** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

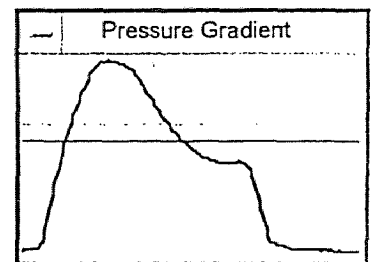
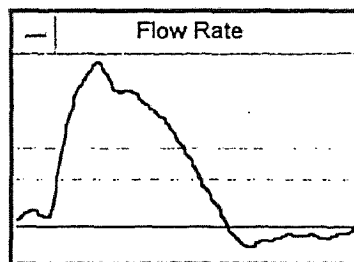
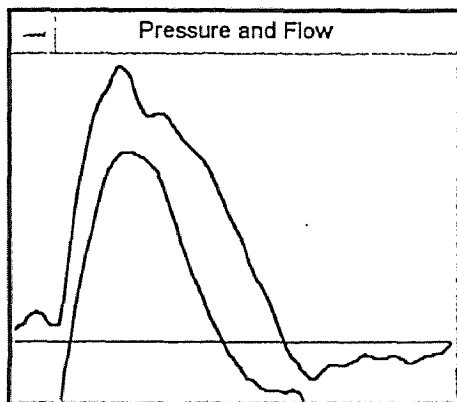
System Parameters: Heart Rate: 81.08 bpm
 Stroke Volume: 76.08 ml
 Cardiac Output: 6.17 L/m
 Duration of valve cycle: 0.74 sec.
 Forward Flow Phase: 0.46 sec. 61.88 %

Measured Flow (L/m): RMS: 14.86 L/m
 Mean: 9.86 L/m
 Peak: 19.36 L/m

Measured Pressures (mm Hg): Mean: 4.58 mm Hg
 Peak Pressure: 13.42 mm Hg
 Pressure at max flow: 13.35 mm Hg

Valve Parameters Closing Volume: 3.09 ml, 4.06 %
 Leakage Volume: 3.18 ml, 4.18 %
 Regurgitant Fraction: 8.24 %

Effective Orifice Area (sq cm.): Peak: 2.92 Discharge Coefficient: 0.713
 Mean: 1.49 Performance Index: 0.457
 RMS: 2.24 Efficiency Index: 0.419



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 10 Valve Type: **SHELHIGH** Serial No. **3494** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

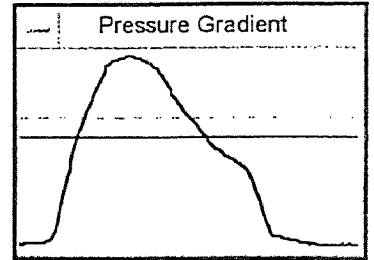
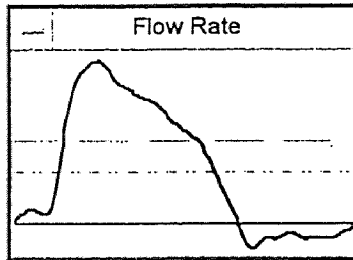
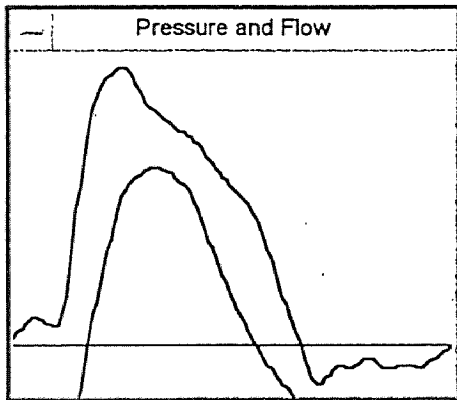
System Parameters: Heart Rate: 96.15 bpm
 Stroke Volume: 81.03 ml
 Cardiac Output: 7.79 L/m
 Duration of valve cycle: 0.62 sec.
 Forward Flow Phase: 0.41 sec. 66.01 %

Measured Flow (L/m): RMS: 16.83 L/m
 Mean: 11.65 L/m
 Peak: 21.93 L/m

Measured Pressures (mm Hg): Mean: 5.13 mm Hg
 Peak Pressure: 14.05 mm Hg
 Pressure at max flow: 11.82 mm Hg

Valve Parameters Closing Volume: 2.74 ml, 3.39 %
 Leakage Volume: 3.40 ml, 4.20 %
 Regurgitant Fraction: 7.59 %

Effective Orifice Area (sq cm.): Peak: 3.13 Discharge Coefficient: 0.764
 Mean: 1.66 Performance Index: 0.489
 RMS: 2.40 Efficiency Index: 0.452



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 13 Valve Type: **SHELHIGH** Serial No. **3494** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

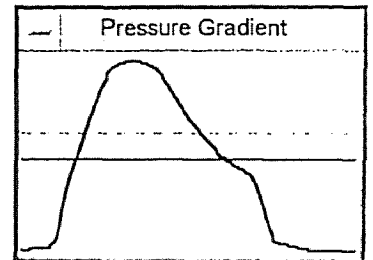
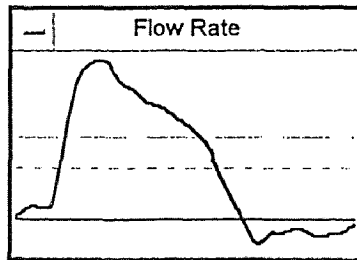
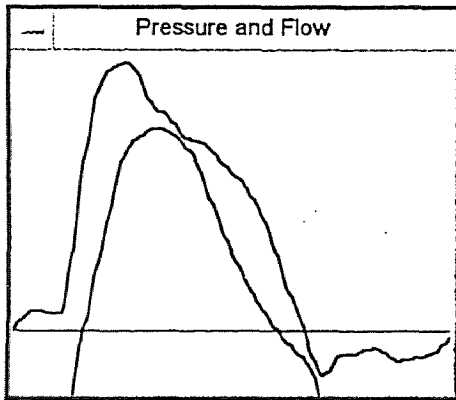
System Parameters: Heart Rate: 101.35 bpm
 Stroke Volume: 78.73 ml
 Cardiac Output: 7.98 L/m
 Duration of valve cycle: 0.59 sec.
 Forward Flow Phase: 0.40 sec. 67.11 %

Measured Flow (L/m): RMS: 16.84 L/m
 Mean: 11.73 L/m
 Peak: 22.17 L/m

Measured Pressures (mm Hg): Mean: 6.74 mm Hg
 Peak Pressure: 16.80 mm Hg
 Pressure at max flow: 15.27 mm Hg

Valve Parameters Closing Volume: 2.54 ml, 3.23 %
 Leakage Volume: 3.89 ml, 4.95 %
 Regurgitant Fraction: 8.17 %

Effective Orifice Area (sq cm.): Peak: 2.76 Discharge Coefficient: 0.667
 Mean: 1.46 Performance Index: 0.427
 RMS: 2.10 Efficiency Index: 0.392



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 14 Valve Type: **SHELHIGH** Serial No. **3494** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

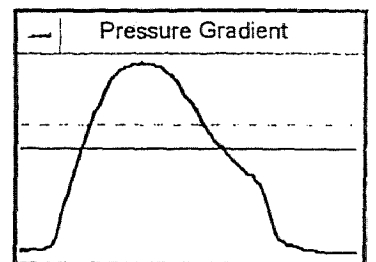
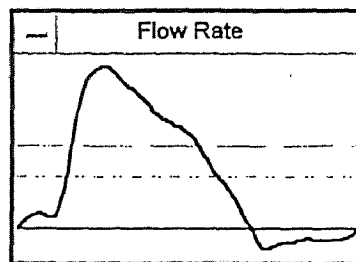
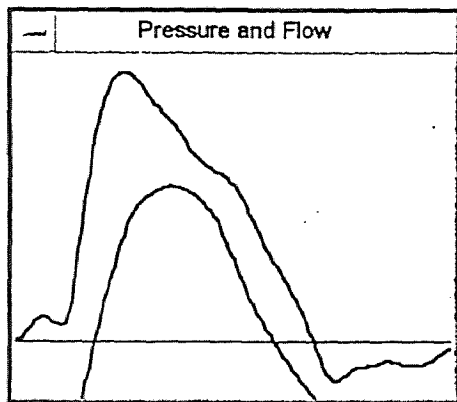
System Parameters: Heart Rate: 112.78 bpm
 Stroke Volume: 79.66 ml
 Cardiac Output: 8.98 L/m
 Duration of valve cycle: 0.53 sec.
 Forward Flow Phase: 0.36 sec. 68.18 %

Measured Flow (L/m): RMS: 18.74 L/m
 Mean: 12.98 L/m
 Peak: 25.56 L/m

Measured Pressures (mm Hg): Mean: 5.85 mm Hg
 Peak Pressure: 14.97 mm Hg
 Pressure at max flow: 10.52 mm Hg

Valve Parameters Closing Volume: 3.56 ml, 4.47 %
 Leakage Volume: 2.29 ml, 2.88 %
 Regurgitant Fraction: 7.35 %

Effective Orifice Area (sq cm.): Peak: 3.41 Discharge Coefficient: 0.796
 Mean: 1.73 Performance Index: 0.509
 RMS: 2.50 Efficiency Index: 0.472



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 15 Valve Type: **SHELHIGH** Serial No. **3494** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

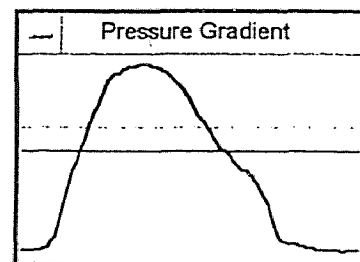
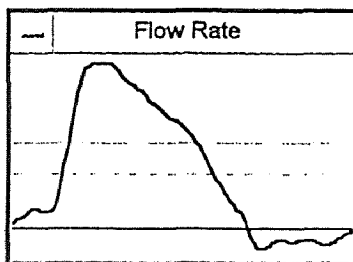
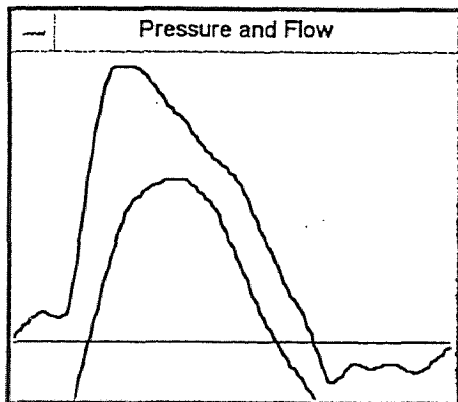
System Parameters: Heart Rate: 118.11 bpm
 Stroke Volume: 79.43 ml
 Cardiac Output: 9.38 L/m
 Duration of valve cycle: 0.51 sec.
 Forward Flow Phase: 0.35 sec. 68.50 %

Measured Flow (L/m): RMS: 19.44 L/m
 Mean: 13.48 L/m
 Peak: 25.99 L/m

Measured Pressures (mm Hg): Mean: 6.38 mm Hg
 Peak Pressure: 15.62 mm Hg
 Pressure at max flow: 9.40 mm Hg

Valve Parameters Closing Volume: 2.73 ml, 3.44 %
 Leakage Volume: 2.85 ml, 3.59 %
 Regurgitant Fraction: 7.02 %

Effective Orifice Area (sq cm.): Peak: 3.32 Discharge Coefficient: 0.791
 Mean: 1.72 Performance Index: 0.506
 RMS: 2.49 Efficiency Index: 0.471



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 44 Valve Type: **SHELHIGH** Serial No. **2264** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

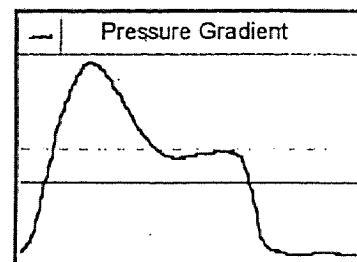
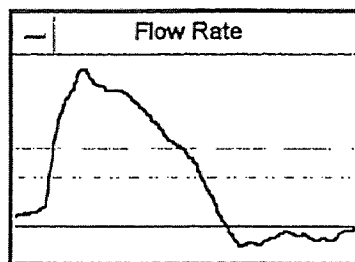
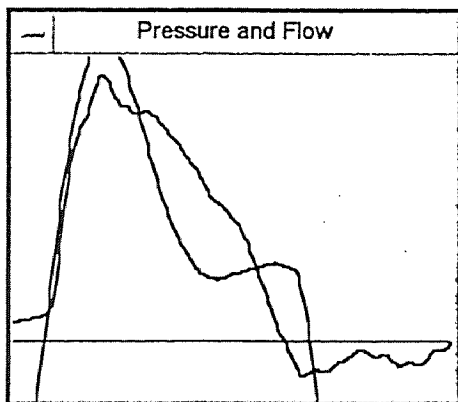
System Parameters: Heart Rate: 64.10 bpm
 Stroke Volume: 74.30 ml
 Cardiac Output: 4.76 L/m
 Duration of valve cycle: 0.94 sec.
 Forward Flow Phase: 0.58 sec. 62.11 %

Measured Flow (L/m): RMS: 11.16 L/m
 Mean: 7.60 L/m
 Peak: 14.03 L/m

Measured Pressures (mm Hg): Mean: 7.16 mm Hg
 Peak Pressure: 16.27 mm Hg
 Pressure at max flow: 16.27 mm Hg

Valve Parameters Closing Volume: 4.30 ml, 5.79 %
 Leakage Volume: 1.84 ml, 2.48 %
 Regurgitant Fraction: 8.27 %

Effective Orifice Area (sq cm.): Peak: 1.69 Discharge Coefficient: 0.429
 Mean: 0.92 Performance Index: 0.274
 RMS: 1.35 Efficiency Index: 0.252



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 47 Valve Type: **SHELHIGH** Serial No. **2264** Valve size: **25 mm** Mitral Positio.
 Operator: E. Sean Parker

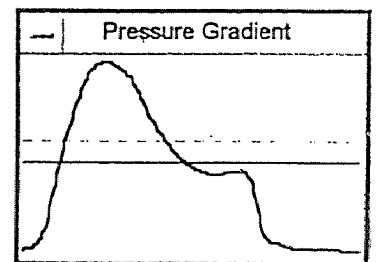
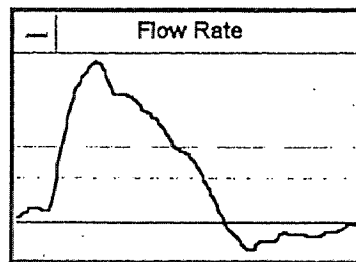
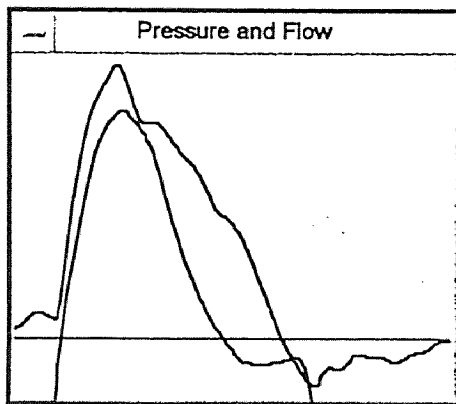
System Parameters: Heart Rate: 78.13 bpm
 Stroke Volume: 73.25 ml
 Cardiac Output: 5.72 L/m
 Duration of valve cycle: 0.77 sec.
 Forward Flow Phase: 0.47 sec. 61.17 %

Measured Flow (L/m): RMS: 13.94 L/m
 Mean: 9.26 L/m
 Peak: 18.37 L/m

Measured Pressures (mm Hg): Mean: 5.37 mm Hg
 Peak Pressure: 15.30 mm Hg
 Pressure at max flow: 15.15 mm Hg

Valve Parameters Closing Volume: 5.61 ml, 7.66 %
 Leakage Volume: 1.69 ml, 2.31 %
 Regurgitant Fraction: 9.97 %

Effective Orifice Area (sq cm.): Peak: 2.56 Discharge Coefficient: 0.618
 Mean: 1.29 Performance Index: 0.396
 RMS: 1.94 Efficiency Index: 0.356



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 46 Valve Type: **SHELHIGH** Serial No. **2264** Valve size: **25 mm** Mitral Positio
 Operator: E. Sean Parker

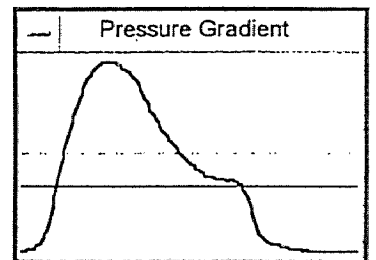
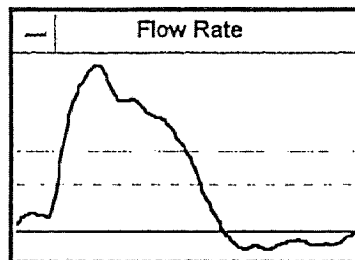
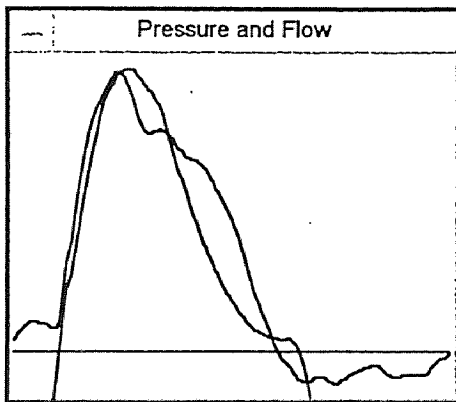
System Parameters: Heart Rate: 82.42 bpm
 Stroke Volume: 73.59 ml
 Cardiac Output: 6.07 L/m
 Duration of valve cycle: 0.73 sec.
 Forward Flow Phase: 0.44 sec. 60.89 %

Measured Flow (L/m): RMS: 14.82 L/m
 Mean: 9.85 L/m
 Peak: 18.96 L/m

Measured Pressures (mm Hg): Mean: 8.25 mm Hg
 Peak Pressure: 19.02 mm Hg
 Pressure at max flow: 18.80 mm Hg

Valve Parameters Closing Volume: 4.76 ml, 6.47 %
 Leakage Volume: 1.91 ml, 2.59 %
 Regurgitant Fraction: 9.07 %

Effective Orifice Area (sq cm.): Peak: 2.13 Discharge Coefficient: 0.530
 Mean: 1.11 Performance Index: 0.339
 RMS: 1.67 Efficiency Index: 0.309



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 45 Valve Type: **SHELHIGH** Serial No. **2264** Valve size: **25 mm** Mitral Positio
 Operator: E. Sean Parker

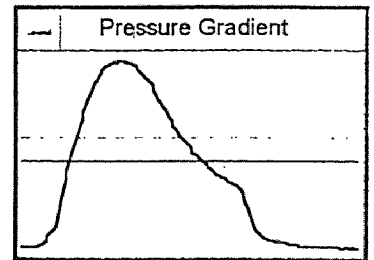
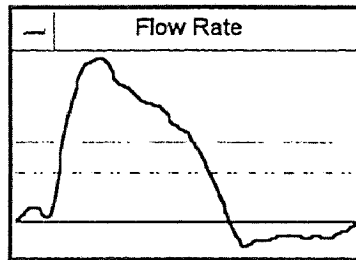
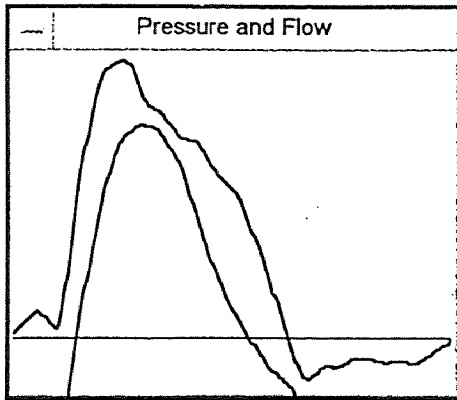
System Parameters: Heart Rate: 91.46 bpm
 Stroke Volume: 74.98 ml
 Cardiac Output: 6.86 L/m
 Duration of valve cycle: 0.66 sec.
 Forward Flow Phase: 0.41 sec. 62.96 %

Measured Flow (L/m): RMS: 15.99 L/m
 Mean: 10.76 L/m
 Peak: 20.46 L/m

Measured Pressures (mm Hg): Mean: 5.97 mm Hg
 Peak Pressure: 15.75 mm Hg
 Pressure at max flow: 14.70 mm Hg

Valve Parameters Closing Volume: 3.05 ml, 4.06 %
 Leakage Volume: 4.04 ml, 5.39 %
 Regurgitant Fraction: 9.45 %

Effective Orifice Area (sq cm.): Peak: 2.70 Discharge Coefficient: 0.672
 Mean: 1.42 Performance Index: 0.430
 RMS: 2.11 Efficiency Index: 0.390



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 48 Valve Type: **SHELHIGH** Serial No. **2264** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

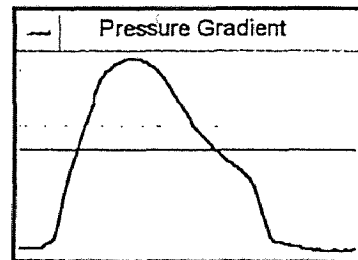
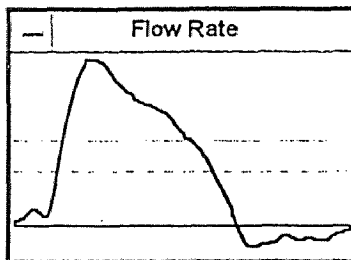
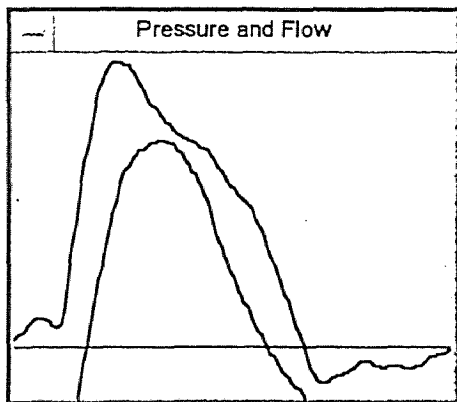
System Parameters: Heart Rate: 96.15 bpm
 Stroke Volume: 82.70 ml
 Cardiac Output: 7.95 L/m
 Duration of valve cycle: 0.62 sec.
 Forward Flow Phase: 0.42 sec. 66.67 %

Measured Flow (L/m): RMS: 16.95 L/m
 Mean: 11.77 L/m
 Peak: 22.46 L/m

Measured Pressures (mm Hg): Mean: 6.24 mm Hg
 Peak Pressure: 16.27 mm Hg
 Pressure at max flow: 11.72 mm Hg

Valve Parameters Closing Volume: 3.36 ml, 4.07 %
 Leakage Volume: 2.21 ml, 2.67 %
 Regurgitant Fraction: 6.74 %

Effective Orifice Area (sq cm.): Peak: 2.91 Discharge Coefficient: 0.698
 Mean: 1.52 Performance Index: 0.446
 RMS: 2.19 Efficiency Index: 0.416



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 49 Valve Type: **SHELHIGH** Serial No. **2264** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

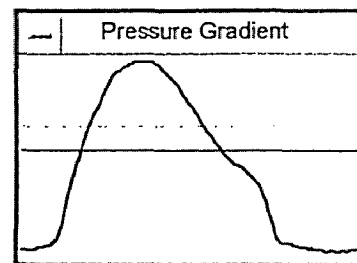
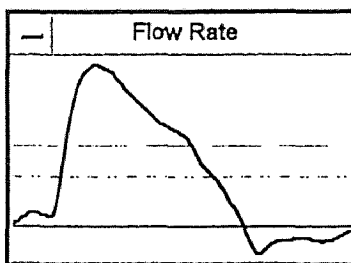
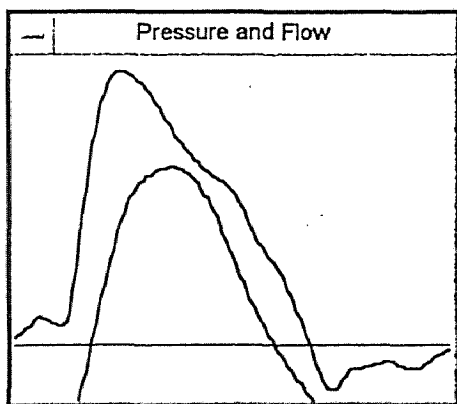
System Parameters: Heart Rate: 109.49 bpm
 Stroke Volume: 78.02 ml
 Cardiac Output: 8.54 L/m
 Duration of valve cycle: 0.55 sec.
 Forward Flow Phase: 0.37 sec. 67.65 %

Measured Flow (L/m): RMS: 18.08 L/m
 Mean: 12.45 L/m
 Peak: 24.79 L/m

Measured Pressures (mm Hg): Mean: 6.34 mm Hg
 Peak Pressure: 16.15 mm Hg
 Pressure at max flow: 10.95 mm Hg

Valve Parameters Closing Volume: 3.16 ml, 4.05 %
 Leakage Volume: 3.00 ml, 3.85 %
 Regurgitant Fraction: 7.90 %

Effective Orifice Area (sq cm.): Peak: 3.18 Discharge Coefficient: 0.738
 Mean: 1.60 Performance Index: 0.472
 RMS: **2.32** Efficiency Index: 0.435



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 50 Valve Type: **SHELHIGH** Serial No. **2264** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

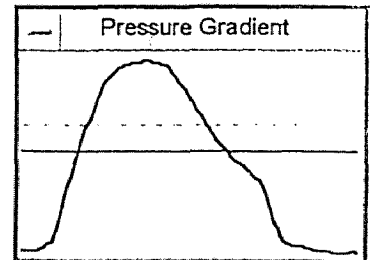
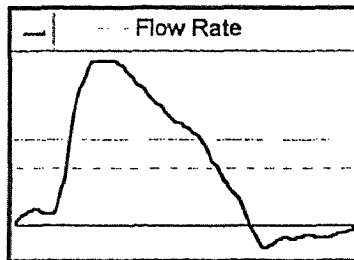
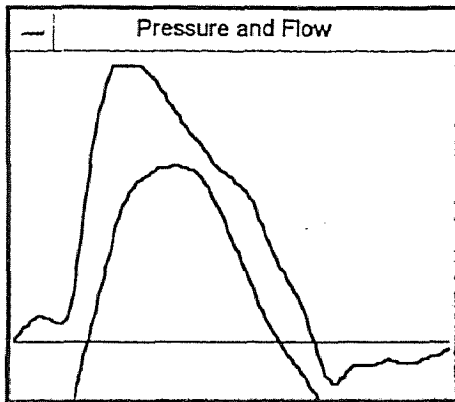
System Parameters: Heart Rate: 119.05 bpm
 Stroke Volume: 79.00 ml
 Cardiac Output: 9.40 L/m
 Duration of valve cycle: 0.50 sec.
 Forward Flow Phase: 0.35 sec. 68.80 %

Measured Flow (L/m): RMS: 19.39 L/m
 Mean: 13.45 L/m
 Peak: 25.94 L/m

Measured Pressures (mm Hg): Mean: 6.91 mm Hg
 Peak Pressure: 16.55 mm Hg
 Pressure at max flow: 9.65 mm Hg

Valve Parameters Closing Volume: 2.76 ml, 3.50 %
 Leakage Volume: 2.39 ml, 3.02 %
 Regurgitant Fraction: 6.52 %

Effective Orifice Area (sq cm.): Peak: 3.19 Discharge Coefficient: 0.758
 Mean: 1.65 Performance Index: 0.485
 RMS: 2.38 Efficiency Index: 0.454



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 65 Valve Type: **SHELHIGH** Serial No. **3953** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

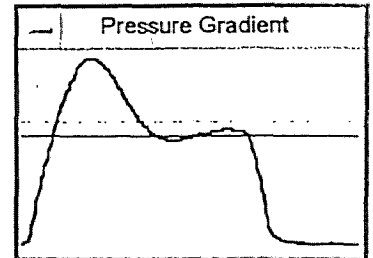
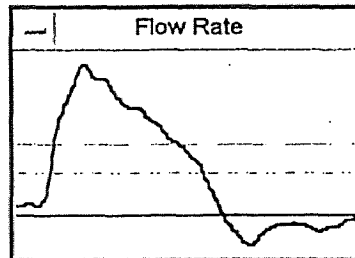
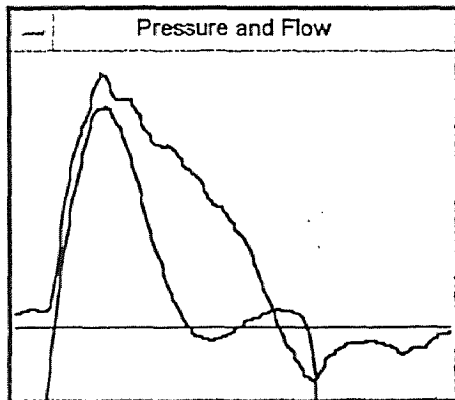
System Parameters: Heart Rate: 64.66 bpm
 Stroke Volume: 73.45 ml
 Cardiac Output: 4.75 L/m
 Duration of valve cycle: 0.93 sec.
 Forward Flow Phase: 0.56 sec. 60.62 %

Measured Flow (L/m): RMS: 11.55 L/m
 Mean: 7.77 L/m
 Peak: 14.83 L/m

Measured Pressures (mm Hg): Mean: 3.90 mm Hg
 Peak Pressure: 12.90 mm Hg
 Pressure at max flow: 12.87 mm Hg

Valve Parameters Closing Volume: 5.19 ml, 7.07 %
 Leakage Volume: 2.97 ml, 4.04 %
 Regurgitant Fraction: 11.11 %

Effective Orifice Area (sq cm.): Peak: 2.43 Discharge Coefficient: 0.601
 Mean: 1.27 Performance Index: 0.385
 RMS: 1.89 Efficiency Index: 0.342



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 66 Valve Type: **SHELHIGH** Serial No. **3953** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

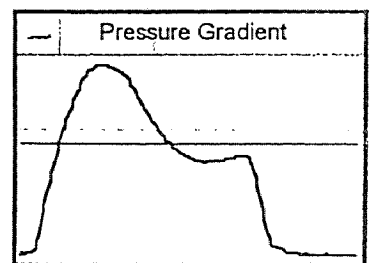
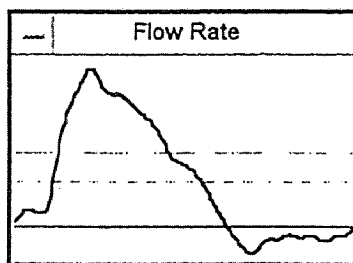
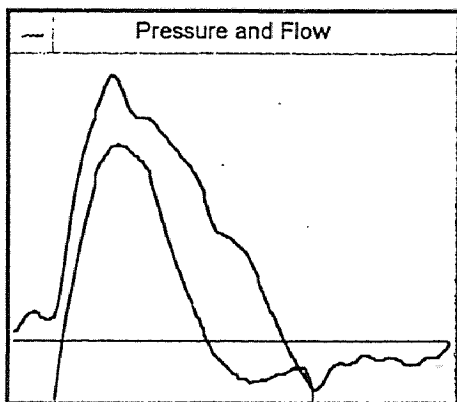
System Parameters: Heart Rate: 76.53 bpm
 Stroke Volume: 76.78 ml
 Cardiac Output: 5.88 L/m
 Duration of valve cycle: 0.78 sec.
 Forward Flow Phase: 0.49 sec. 62.83 %

Measured Flow (L/m): RMS: 13.83 L/m
 Mean: 9.26 L/m
 Peak: 18.69 L/m

Measured Pressures (mm Hg): Mean: 4.48 mm Hg
 Peak Pressure: 13.85 mm Hg
 Pressure at max flow: 13.72 mm Hg

Valve Parameters Closing Volume: 4.01 ml, 5.23 %
 Leakage Volume: 3.69 ml, 4.80 %
 Regurgitant Fraction: 10.03 %

Effective Orifice Area (sq cm.): Peak: 2.85 Discharge Coefficient: 0.672
 Mean: 1.41 Performance Index: 0.430
 RMS: 2.11 Efficiency Index: 0.387



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 67 Valve Type: **SHELHIGH** Serial No. **3953** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

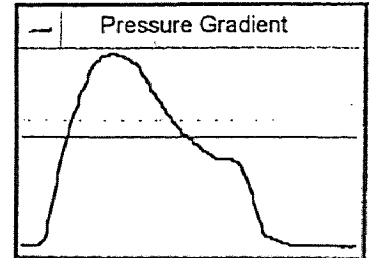
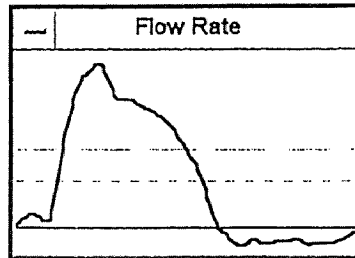
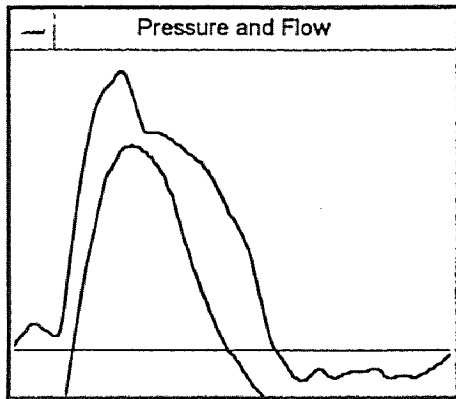
System Parameters: Heart Rate: 84.27 bpm
 Stroke Volume: 74.38 ml
 Cardiac Output: 6.27 L/m
 Duration of valve cycle: 0.71 sec.
 Forward Flow Phase: 0.43 sec. 60.23 %

Measured Flow (L/m): RMS: 15.57 L/m
 Mean: 10.29 L/m
 Peak: 19.71 L/m

Measured Pressures (mm Hg): Mean: 5.25 mm Hg
 Peak Pressure: 14.47 mm Hg
 Pressure at max flow: 13.97 mm Hg

Valve Parameters Closing Volume: 3.10 ml, 4.17 %
 Leakage Volume: 4.13 ml, 5.55 %
 Regurgitant Fraction: 9.72 %

Effective Orifice Area (sq cm.): Peak: 2.78 Discharge Coefficient: 0.698
 Mean: 1.45 Performance Index: 0.447
 RMS: 2.19 Efficiency Index: 0.403



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 68 Valve Type: **SHELHIGH** Serial No. **3953** Valve size: **25 mm** Mitral Positio
 Operator: E. Sean Parker

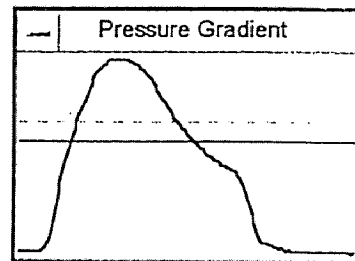
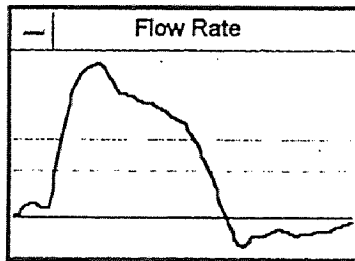
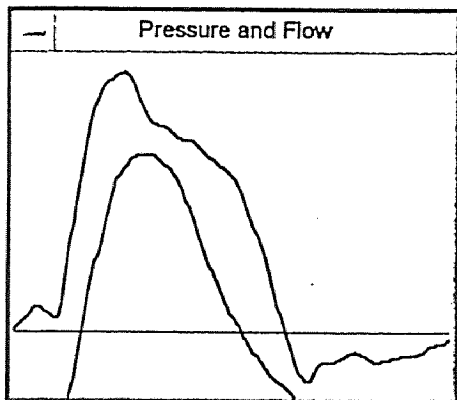
System Parameters: Heart Rate: 90.91 bpm
 Stroke Volume: 78.16 ml
 Cardiac Output: 7.11 L/m
 Duration of valve cycle: 0.66 sec.
 Forward Flow Phase: 0.41 sec. 62.20 %

Measured Flow (L/m): RMS: 16.61 L/m
 Mean: 11.29 L/m
 Peak: 20.62 L/m

Measured Pressures (mm Hg): Mean: 5.23 mm Hg
 Peak Pressure: 14.25 mm Hg
 Pressure at max flow: 13.32 mm Hg

Valve Parameters Closing Volume: 3.53 ml, 4.51 %
 Leakage Volume: 4.72 ml, 6.03 %
 Regurgitant Fraction: 10.55 %

Effective Orifice Area (sq cm.): Peak: 2.91 Discharge Coefficient: 0.746
 Mean: 1.59 Performance Index: 0.478
 RMS: 2.35 Efficiency Index: 0.427



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 69 Valve Type: **SHELHIGH** Serial No. **3953** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

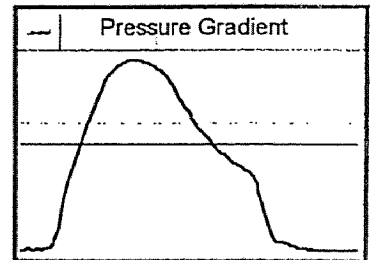
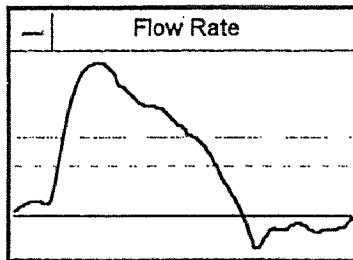
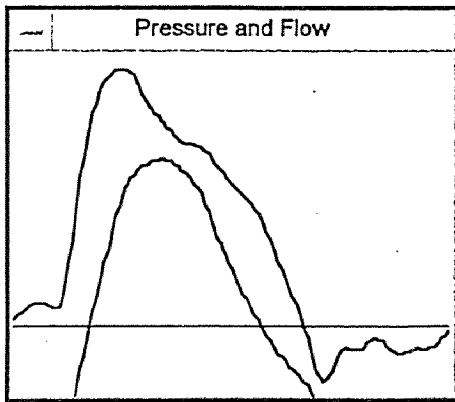
System Parameters: Heart Rate: 100.00 bpm
 Stroke Volume: 80.23 ml
 Cardiac Output: 8.02 L/m
 Duration of valve cycle: 0.60 sec.
 Forward Flow Phase: 0.40 sec. 66.89 %

Measured Flow (L/m): RMS: 16.98 L/m
 Mean: 11.83 L/m
 Peak: 22.65 L/m

Measured Pressures (mm Hg): Mean: 5.50 mm Hg
 Peak Pressure: 14.82 mm Hg
 Pressure at max flow: 11.62 mm Hg

Valve Parameters Closing Volume: 3.28 ml, 4.09 %
 Leakage Volume: 3.86 ml, 4.81 %
 Regurgitant Fraction: 8.90 %

Effective Orifice Area (sq cm.): Peak: 3.12 Discharge Coefficient: 0.745
 Mean: 1.63 Performance Index: 0.477
 RMS: 2.34 Efficiency Index: 0.434



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 70 Valve Type: **SHELHIGH** Serial No. **3953** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

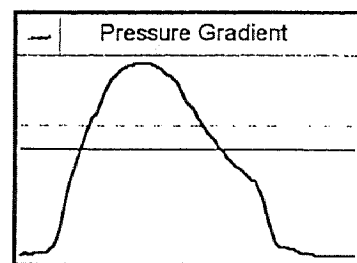
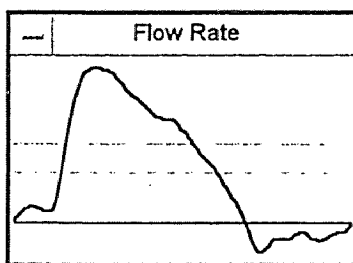
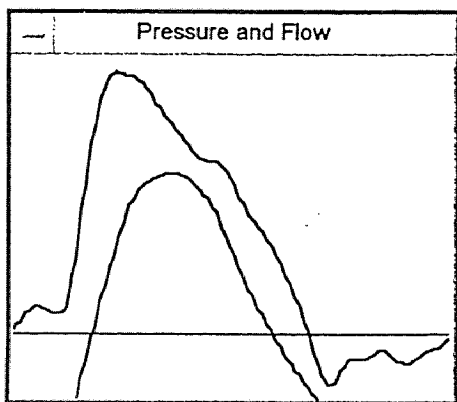
System Parameters: Heart Rate: 109.49 bpm
 Stroke Volume: 79.92 ml
 Cardiac Output: 8.75 L/m
 Duration of valve cycle: 0.55 sec.
 Forward Flow Phase: 0.37 sec. 68.38 %

Measured Flow (L/m): RMS: 18.11 L/m
 Mean: 12.61 L/m
 Peak: 24.58 L/m

Measured Pressures (mm Hg): Mean: 5.88 mm Hg
 Peak Pressure: 15.27 mm Hg
 Pressure at max flow: 8.52 mm Hg

Valve Parameters Closing Volume: 3.38 ml, 4.23 %
 Leakage Volume: 3.65 ml, 4.57 %
 Regurgitant Fraction: 8.80 %

Effective Orifice Area (sq cm.): Peak: 3.27 Discharge Coefficient: 0.768
 Mean: 1.68 Performance Index: 0.491
 RMS: 2.41 Efficiency Index: 0.448



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 71 Valve Type: SHELHIGH Serial No. 3953 Valve size: 25 mm Mitral Positic
 Operator: E. Sean Parker

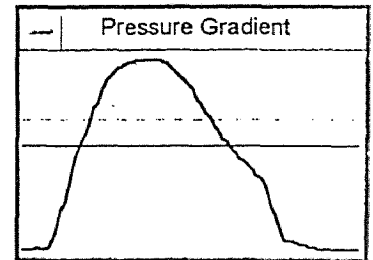
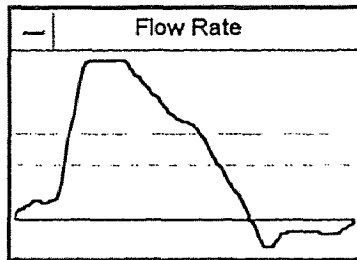
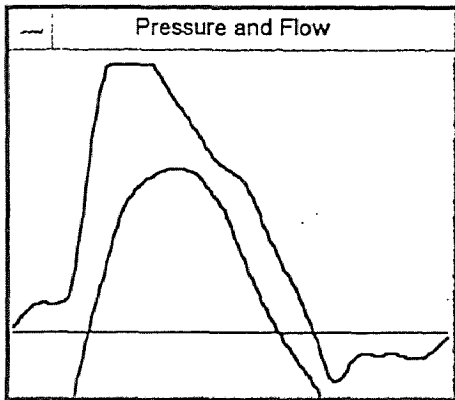
System Parameters: Heart Rate: 121.95 bpm
 Stroke Volume: 79.26 ml
 Cardiac Output: 9.67 L/m
 Duration of valve cycle: 0.49 sec.
 Forward Flow Phase: 0.34 sec. 68.85 %

Measured Flow (L/m): RMS: 19.80 L/m
 Mean: 13.81 L/m
 Peak: 25.88 L/m

Measured Pressures (mm Hg): Mean: 6.66 mm Hg
 Peak Pressure: 15.87 mm Hg
 Pressure at max flow: 8.05 mm Hg

Valve Parameters Closing Volume: 3.13 ml, 3.95 %
 Leakage Volume: 3.15 ml, 3.98 %
 Regurgitant Fraction: 7.93 %

Effective Orifice Area (sq cm.): Peak: 3.24 Discharge Coefficient: 0.789
 Mean: 1.73 Performance Index: 0.505
 RMS: 2.48 Efficiency Index: 0.465



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 79 Valve Type: **SHELHIGH** Serial No. **3955** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

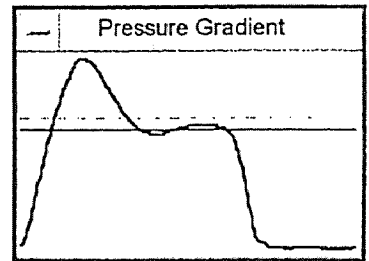
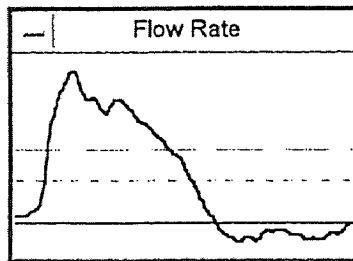
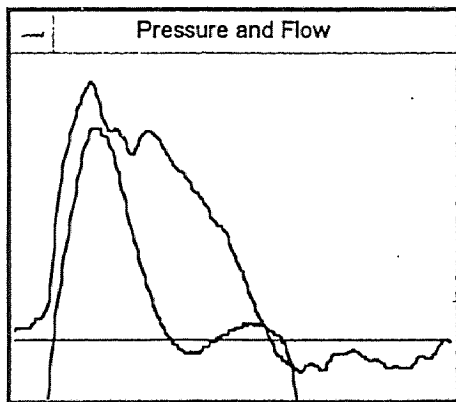
System Parameters: Heart Rate: 60.24 bpm
 Stroke Volume: 70.70 ml
 Cardiac Output: 4.26 L/m
 Duration of valve cycle: 1.00 sec.
 Forward Flow Phase: 0.59 sec. 58.96 %

Measured Flow (L/m): RMS: 10.79 L/m
 Mean: 7.17 L/m
 Peak: 13.58 L/m

Measured Pressures (mm Hg): Mean: 2.94 mm Hg
 Peak Pressure: 11.17 mm Hg
 Pressure at max flow: 11.10 mm Hg

Valve Parameters Closing Volume: 3.56 ml, 5.04 %
 Leakage Volume: 3.61 ml, 5.10 %
 Regurgitant Fraction: 10.14 %

Effective Orifice Area (sq cm.): Peak: 2.56 Discharge Coefficient: 0.647
 Mean: 1.35 Performance Index: 0.414
 RMS: **2.03** Efficiency Index: 0.372



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 80 Valve Type: **SHELHIGH** Serial No. **3955** Valve size: **25 mm** Mitral Positic
 Operator: E. Sean Parker

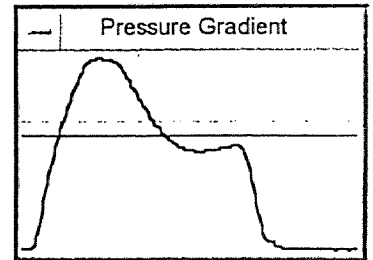
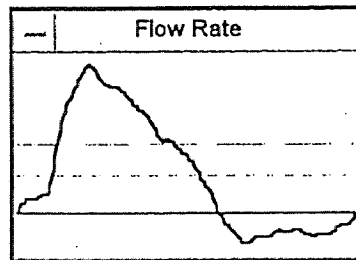
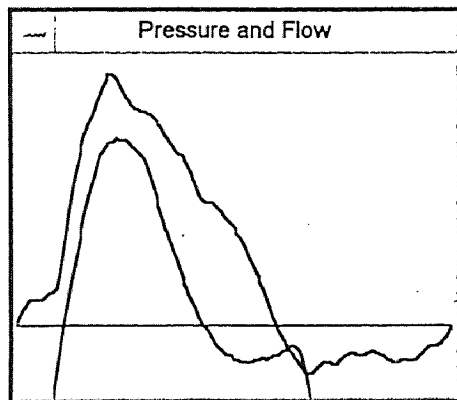
System Parameters: Heart Rate: 74.26 bpm
 Stroke Volume: 74.12 ml
 Cardiac Output: 5.50 L/m
 Duration of valve cycle: 0.81 sec.
 Forward Flow Phase: 0.48 sec. 60.00 %

Measured Flow (L/m): RMS: 13.69 L/m
 Mean: 9.08 L/m
 Peak: 17.73 L/m

Measured Pressures (mm Hg): Mean: 4.24 mm Hg
 Peak Pressure: 13.15 mm Hg
 Pressure at max flow: 12.87 mm Hg

Valve Parameters Closing Volume: 6.73 ml, 9.08 %
 Leakage Volume: 5.14 ml, 6.93 %
 Regurgitant Fraction: 16.02 %

Effective Orifice Area (sq cm.): Peak: 2.78 Discharge Coefficient: 0.683
 Mean: 1.42 Performance Index: 0.437
 RMS: 2.15 Efficiency Index: 0.367



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 81 Valve Type: **SHELHIGH** Serial No. **3955** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

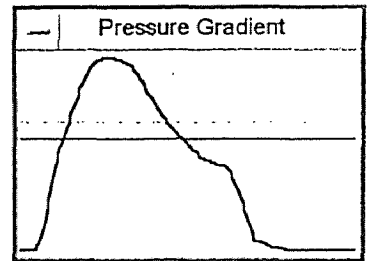
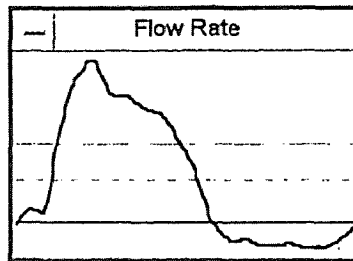
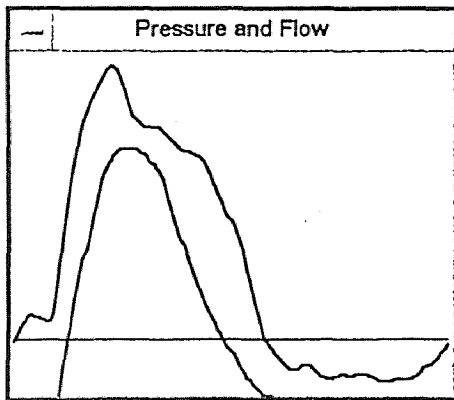
System Parameters: Heart Rate: 86.21 bpm
 Stroke Volume: 74.32 ml
 Cardiac Output: 6.41 L/m
 Duration of valve cycle: 0.70 sec.
 Forward Flow Phase: 0.40 sec. 58.05 %

Measured Flow (L/m): RMS: 16.56 L/m
 Mean: 10.91 L/m
 Peak: 20.17 L/m

Measured Pressures (mm Hg): Mean: 5.35 mm Hg
 Peak Pressure: 14.17 mm Hg
 Pressure at max flow: 13.57 mm Hg

Valve Parameters Closing Volume: 9.82 ml, 13.22 %
 Leakage Volume: 1.35 ml, 1.82 %
 Regurgitant Fraction: 15.03 %

Effective Orifice Area (sq cm.): Peak: 2.82 Discharge Coefficient: 0.736
 Mean: 1.52 Performance Index: 0.471
 RMS: 2.31 Efficiency Index: 0.400



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 82 Valve Type: **SHELHIGH** Serial No. **3955** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

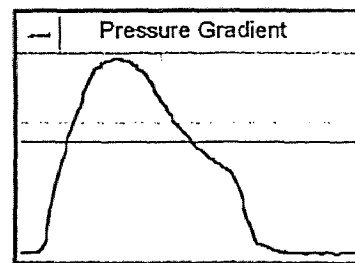
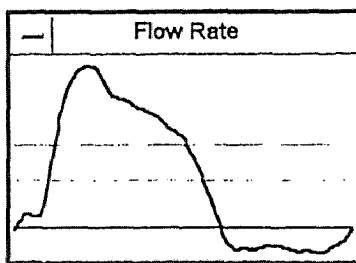
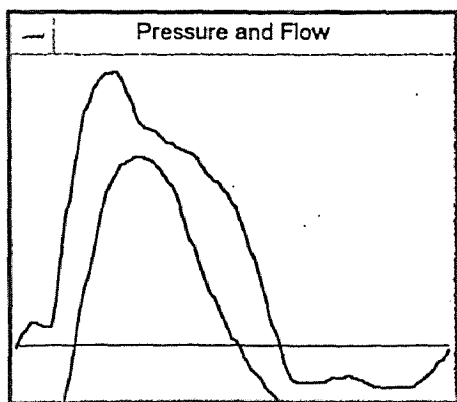
System Parameters: Heart Rate: 93.17 bpm
 Stroke Volume: 76.56 ml
 Cardiac Output: 7.13 L/m
 Duration of valve cycle: 0.64 sec.
 Forward Flow Phase: 0.39 sec. 60.49 %

Measured Flow (L/m): RMS: 17.19 L/m
 Mean: 11.65 L/m
 Peak: 20.93 L/m

Measured Pressures (mm Hg): Mean: 5.56 mm Hg
 Peak Pressure: 14.47 mm Hg
 Pressure at max flow: 13.12 mm Hg

Valve Parameters Closing Volume: 10.94 ml, 14.29 %
 Leakage Volume: 0.02 ml, 0.03 %
 Regurgitant Fraction: 14.32 %

Effective Orifice Area (sq cm.): Peak: 2.87 Discharge Coefficient: 0.750
 Mean: 1.60 Performance Index: 0.480
 RMS: 2.36 Efficiency Index: 0.411



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 83 Valve Type: **SHELHIGH** Serial No. **3955** Valve size: **25 mm** Mitral Positi
 Operator: E. Sean Parker

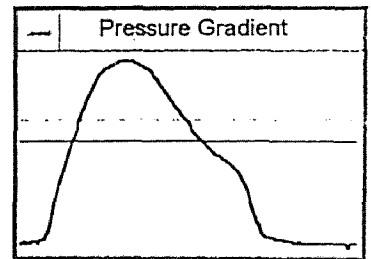
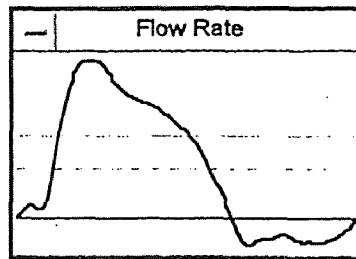
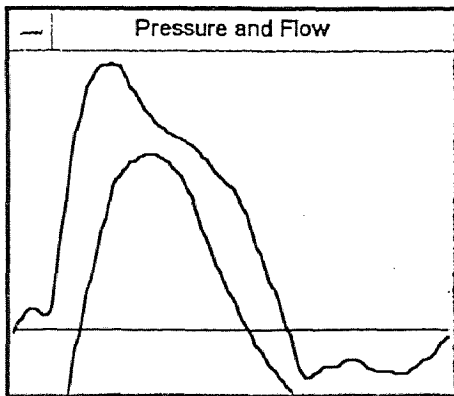
System Parameters: Heart Rate: 97.40 bpm
 Stroke Volume: 79.60 ml
 Cardiac Output: 7.75 L/m
 Duration of valve cycle: 0.62 sec.
 Forward Flow Phase: 0.38 sec. 62.50 %

Measured Flow (L/m): RMS: 17.90 L/m
 Mean: 12.24 L/m
 Peak: 22.16 L/m

Measured Pressures (mm Hg): Mean: 5.72 mm Hg
 Peak Pressure: 14.75 mm Hg
 Pressure at max flow: 11.32 mm Hg

Valve Parameters Closing Volume: 5.30 ml, 6.66 %
 Leakage Volume: 5.50 ml, 6.91 %
 Regurgitant Fraction: 13.57 %

Effective Orifice Area (sq cm.): Peak: 2.99 Discharge Coefficient: 0.769
 Mean: 1.65 Performance Index: 0.492
 RMS: 2.42 Efficiency Index: 0.425



SHELHIGH Inc. Millburn, NJ 07041

** SHELHIGH Pulse Duplicator System **

Test No. 85 Valve Type: **SHELHIGH** Serial No. **3955** Valve size: **25 mm** Mitral Position
 Operator: E. Sean Parker

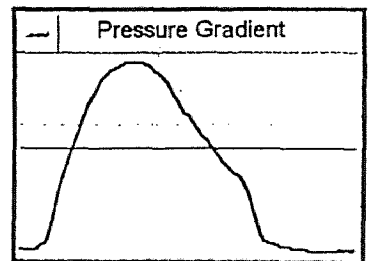
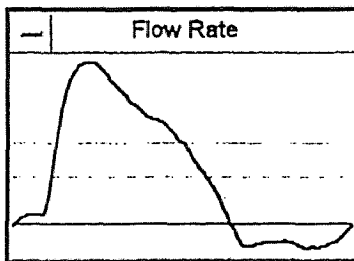
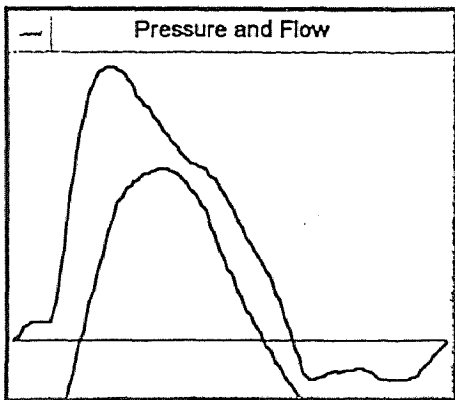
System Parameters: Heart Rate: 110.29 bpm
 Stroke Volume: 77.44 ml
 Cardiac Output: 8.54 L/m
 Duration of valve cycle: 0.54 sec.
 Forward Flow Phase: 0.35 sec. 63.97 %

Measured Flow (L/m): RMS: 19.35 L/m
 Mean: 13.16 L/m
 Peak: 24.98 L/m

Measured Pressures (mm Hg): Mean: 6.54 mm Hg
 Peak Pressure: 15.72 mm Hg
 Pressure at max flow: 9.90 mm Hg

Valve Parameters Closing Volume: 9.15 ml, 11.82 %
 Leakage Volume: 0.01 ml, 0.02 %
 Regurgitant Fraction: 11.84 %

Effective Orifice Area (sq cm.): Peak: 3.16 Discharge Coefficient: 0.778
 Mean: 1.66 Performance Index: 0.498
 RMS: 2.44 Efficiency Index: 0.439



SHELHIGH Inc. Millburn, NJ 07041

**** SHELHIGH Pulse Duplicator System ****

Test No. 84 Valve Type: **SHELHIGH** Serial No. **3955** Valve size: **25 mm** Mitral Positic
 Operator: E. Sean Parker

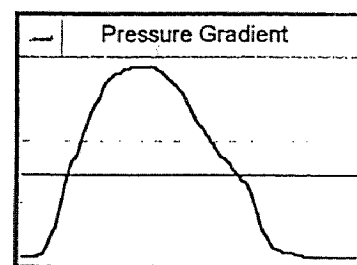
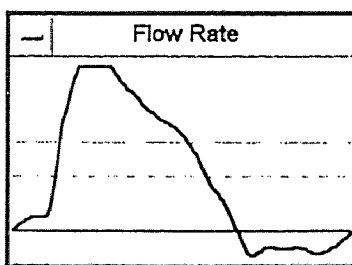
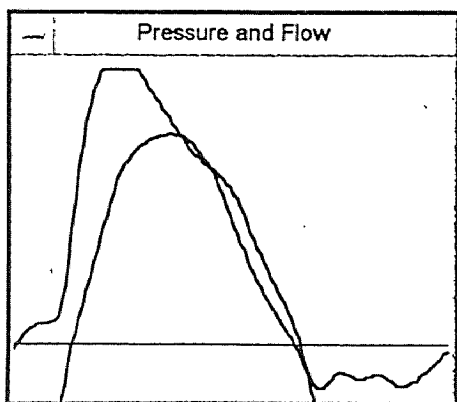
System Parameters: Heart Rate: 119.05 bpm
 Stroke Volume: 78.56 ml
 Cardiac Output: 9.35 L/m
 Duration of valve cycle: 0.50 sec.
 Forward Flow Phase: 0.33 sec. 65.35 %

Measured Flow (L/m): RMS: 20.56 L/m
 Mean: 14.09 L/m
 Peak: 25.98 L/m

Measured Pressures (mm Hg): Mean: 9.65 mm Hg
 Peak Pressure: 19.87 mm Hg
 Pressure at max flow: 11.32 mm Hg

Valve Parameters Closing Volume: 4.82 ml, 6.14 %
 Leakage Volume: 3.38 ml, 4.30 %
 Regurgitant Fraction: 10.44 %

Effective Orifice Area (sq cm.): Peak: 2.70 Discharge Coefficient: 0.680
 Mean: 1.46 Performance Index: 0.435
 RMS: 2.14 Efficiency Index: 0.390



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