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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<sup>®</sup> 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 2.41cm<sup>2</sup> for the 25mm stentless to a low of 2.18cm<sup>2</sup> for the 25mm stented bioprosthesis. The mean EOA for the stented bioprostheses was 1.94cm<sup>2</sup> and 2.06cm<sup>2</sup> 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**

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APPROVAL PAGE

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THE STENTED AND STENTLESS  
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# CHAPTER 1

## INTRODUCTION

### 1.1 Background Information

The stent, Delrin<sup>®</sup> 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<sup>®</sup> 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 flange<sup>1</sup>.

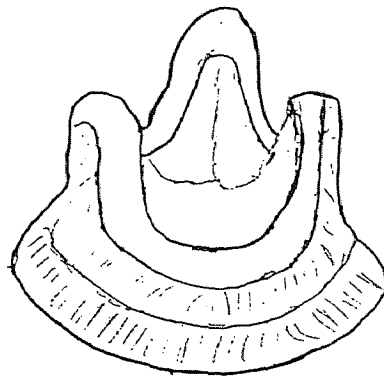
#### 2.2 Stentless Bioprosthesis

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.

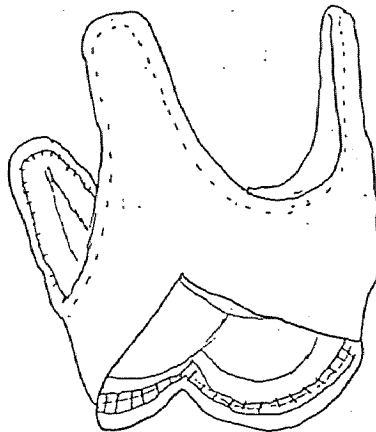
The Shelhigh stentless aortic valve can resist significant distortion. The two-suture-

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)<sup>1</sup>.



**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 orifice<sup>2</sup>.

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 dimensions<sup>3</sup>. 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  $\rho$  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  $A_o$  ( $\text{cm}^2$ ),

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

where  $\Delta p$  (mm Hg) =  $p_i - p_j$ , and  $K$  is a scale or a conversion factor. This expression constitutes the basis of Gorlin's Hydraulic formula<sup>4</sup>.

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  $j$  gives<sup>5</sup>:

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

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

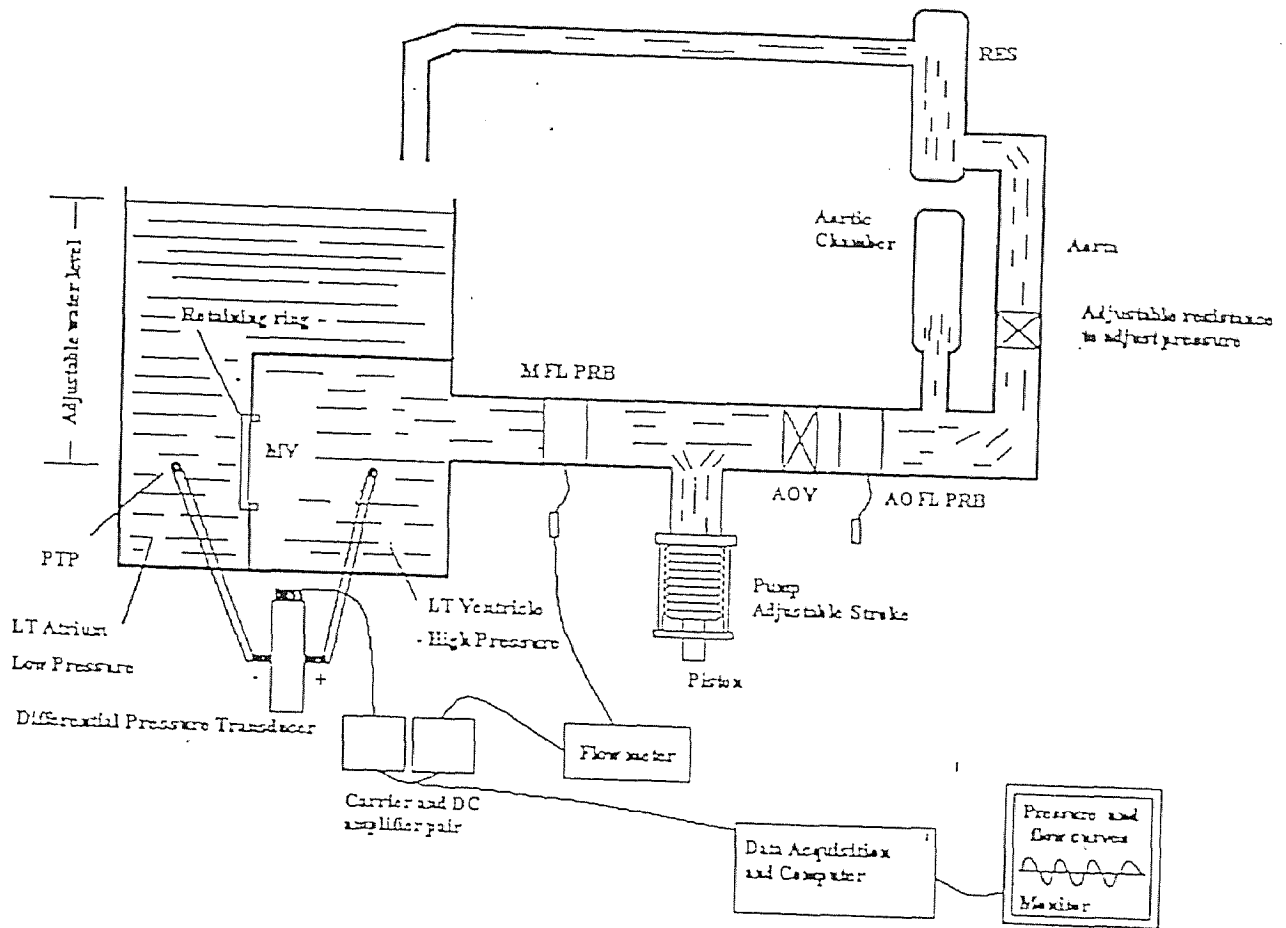
### 4.2.1 The Pulse Duplicator

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 amplifier<sup>6</sup>.

**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  $t$ -test<sup>7</sup>.

### 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  $\pm 5$  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 1<sup>2</sup>. 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 cm<sup>2</sup> while the 25mm stented valve provided an EOA of 2.18 cm<sup>2</sup>. The 23mm stentless valve provided an average EOA of 2.13 cm<sup>2</sup> while the 25mm stented valve provided an EOA of 1.91 cm<sup>2</sup>. 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 <sup>2</sup> )	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	0.49	0.14	0.26	0.19	0.03	1.70	

**Table 8**  
Pulse Rate: 110 BPM

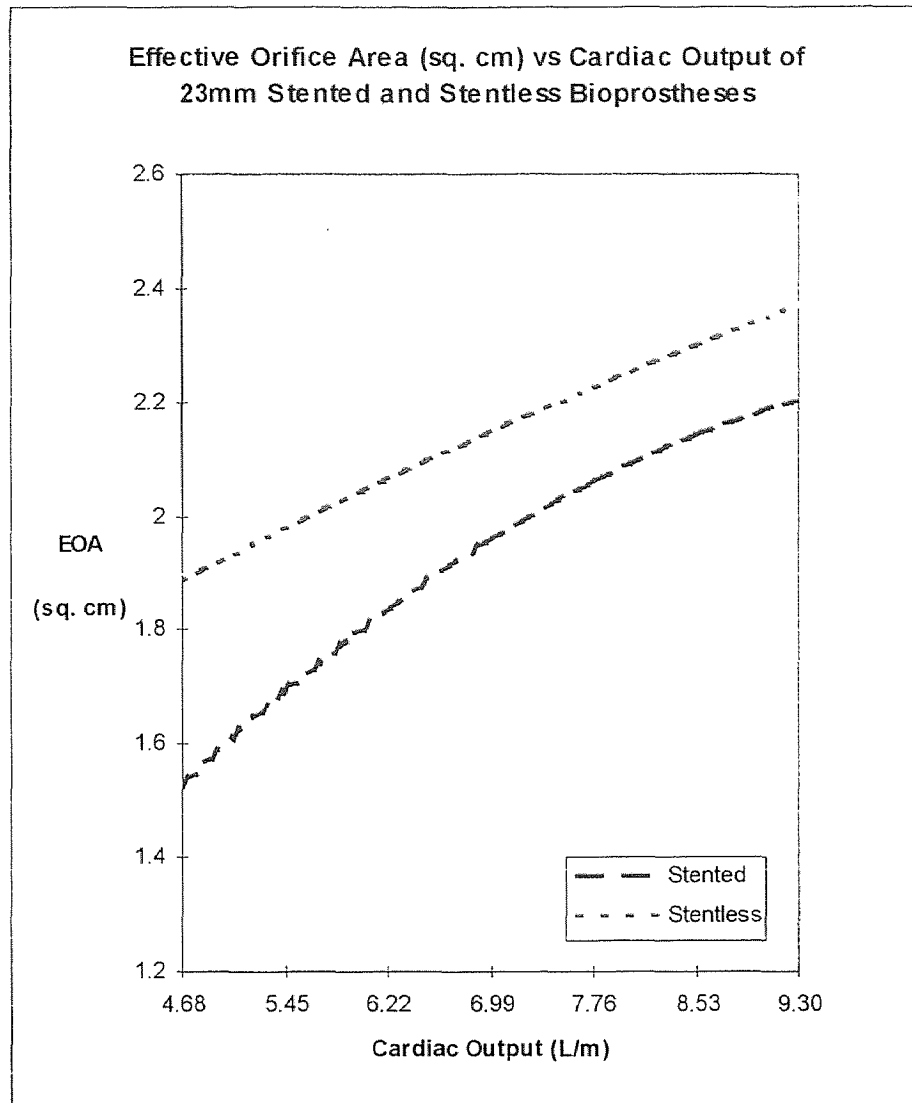
Run #	CO (L/m)	Flow RMS (L/m)	Flow mean (L/m)	Pressure mean (mm Hg)	EOA (sq. cm)	Leakage Volume (percent)*	Size (mm)
1	7.96	17.36	7.14	7.14	2.10	0.03	23
2	8.74	18.19	12.53	6.76	2.26	1.41	
3	8.83	18.03	12.62	7.72	2.10	1.21	
4	-----	-----	-----	-----	-----	-----	
mean	8.51	17.86	10.76	7.21	2.15	0.88	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	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	25
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	
$\sigma_x$	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	
$\sigma_x$	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	
$\sigma_x$	0.32	0.30	0.03	0.13	0.04	2.15	

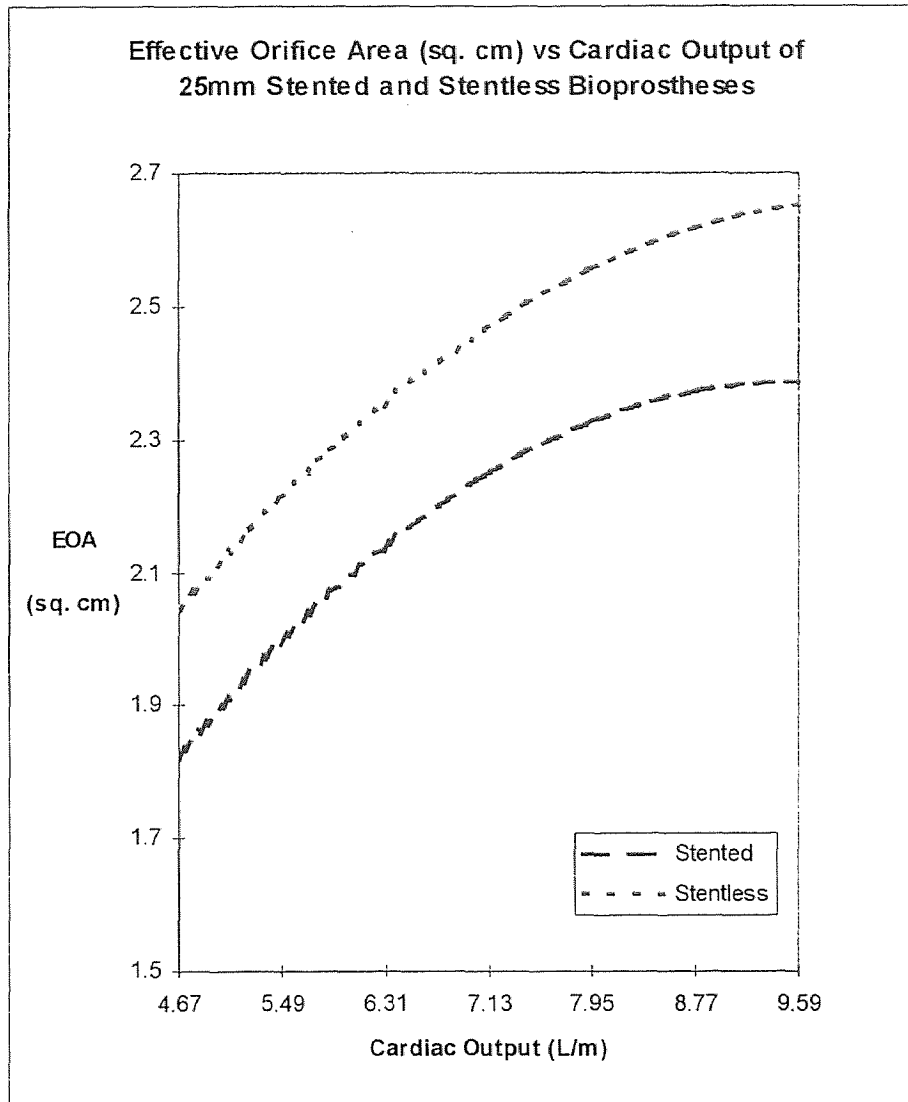
## Tables 3-9

\* 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 2.32cm<sup>2</sup> with stentless valves and 1.06 to 2.28cm<sup>2</sup> 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 size<sup>8</sup>.

**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 cm<sup>2</sup> 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 cm<sup>2</sup> as compared to the Shelhigh 25 mm stented valves with an EOA of 2.18 cm<sup>2</sup>. 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 cm<sup>2</sup> and 1.48 cm<sup>2</sup>, stentless and stented valves respectively. The cause of the 0.03 cm<sup>2</sup> 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<sup>®</sup> 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

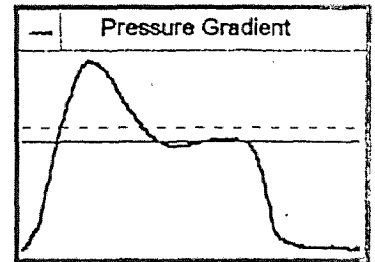
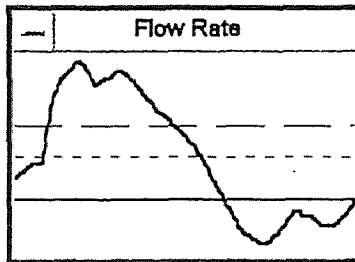
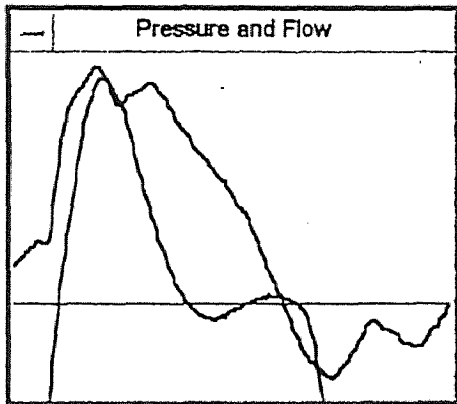
System Parameters: Heart Rate: 61.22 bpm  
 Stroke Volume: 75.21 ml  
 Cardiac Output: 4.60 L/m  
 Duration of valve cycle: 0.98 sec.  
 Forward Flow Phase: 0.60 sec. 61.44 %

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

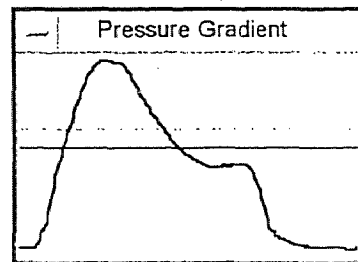
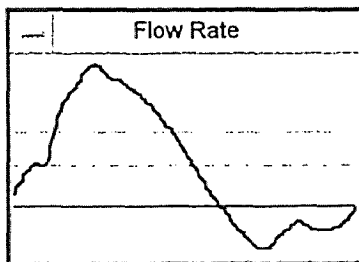
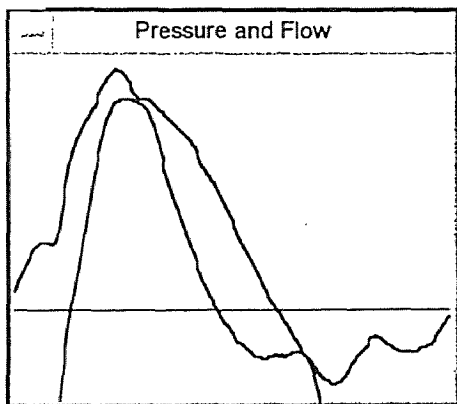
System Parameters: Heart Rate: 75.38 bpm  
 Stroke Volume: 73.23 ml  
 Cardiac Output: 5.52 L/m  
 Duration of valve cycle: 0.80 sec.  
 Forward Flow Phase: 0.48 sec. 60.71 %

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

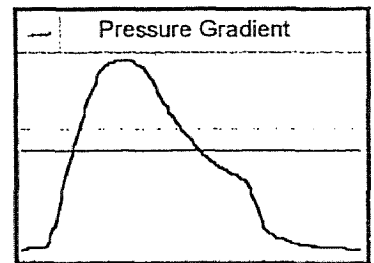
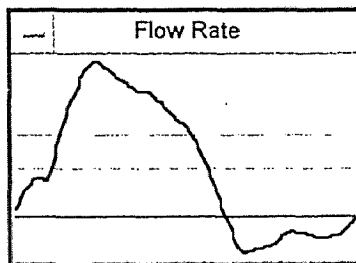
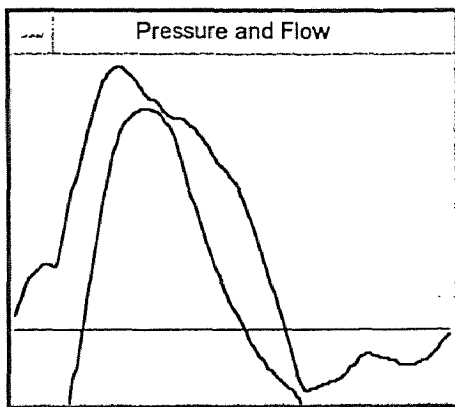
System Parameters: Heart Rate: 84.75 bpm  
 Stroke Volume: 79.54 ml  
 Cardiac Output: 6.74 L/m  
 Duration of valve cycle: 0.71 sec.  
 Forward Flow Phase: 0.44 sec. 62.21 %

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

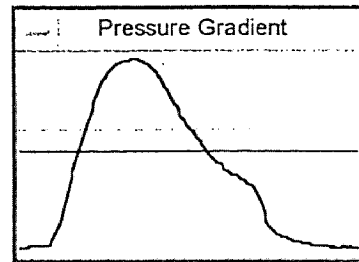
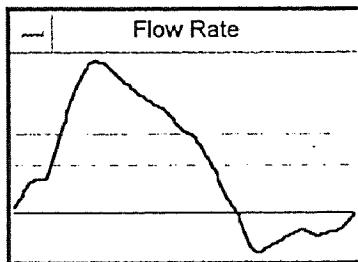
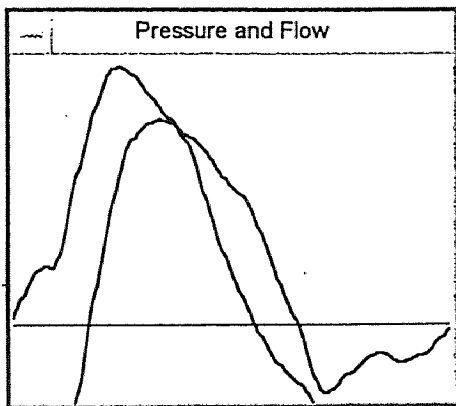
System Parameters: Heart Rate: 92.59 bpm  
 Stroke Volume: 79.64 ml  
 Cardiac Output: 7.37 L/m  
 Duration of valve cycle: 0.65 sec.  
 Forward Flow Phase: 0.42 sec. 65.41 %

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

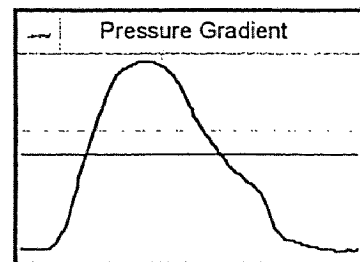
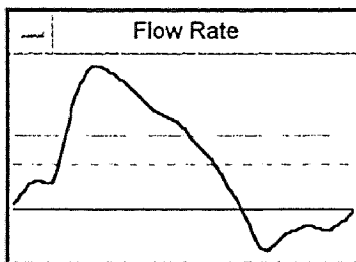
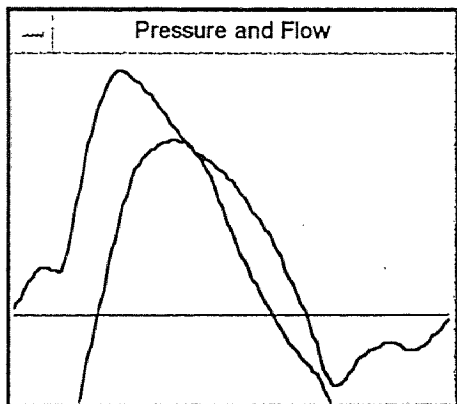
System Parameters: Heart Rate: 102.04 bpm  
 Stroke Volume: 79.61 ml  
 Cardiac Output: 8.12 L/m  
 Duration of valve cycle: 0.59 sec.  
 Forward Flow Phase: 0.39 sec. 67.12 %

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

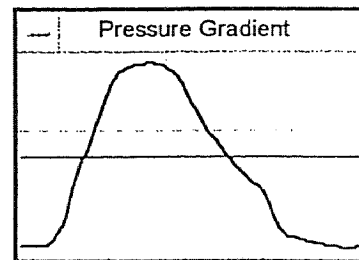
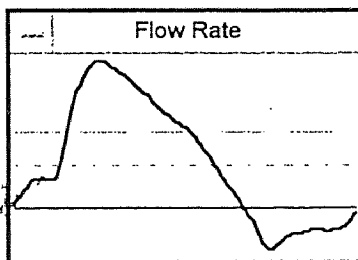
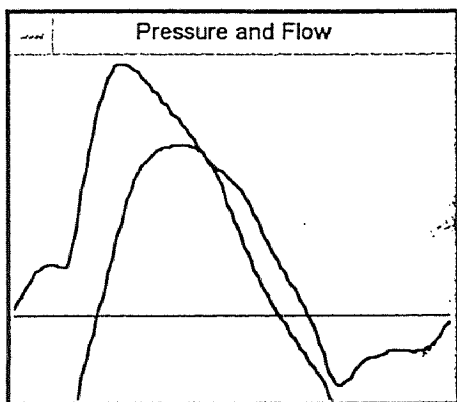
System Parameters: Heart Rate: 111.11 bpm  
 Stroke Volume: 77.06 ml  
 Cardiac Output: 8.56 L/m  
 Duration of valve cycle: 0.54 sec.  
 Forward Flow Phase: 0.36 sec. 67.41 %

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

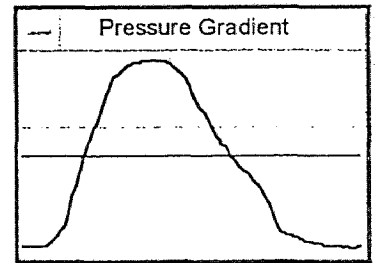
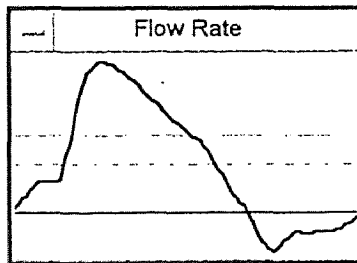
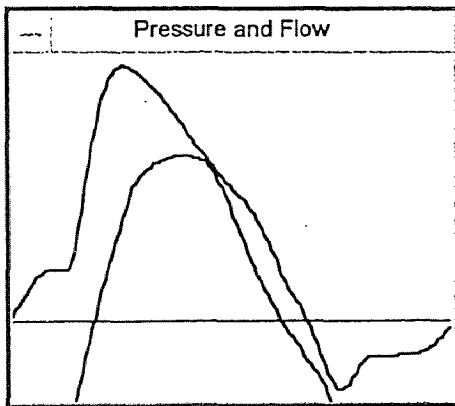
System Parameters: Heart Rate: 118.11 bpm  
Stroke Volume: 76.96 ml  
Cardiac Output: 9.09 L/m  
Duration of valve cycle: 0.51 sec.  
Forward Flow Phase: 0.34 sec. 67.72 %

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

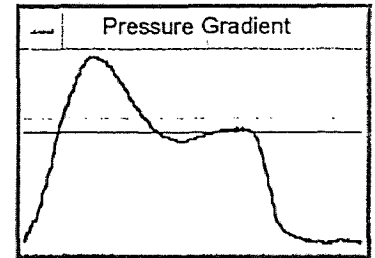
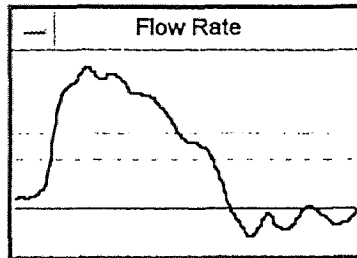
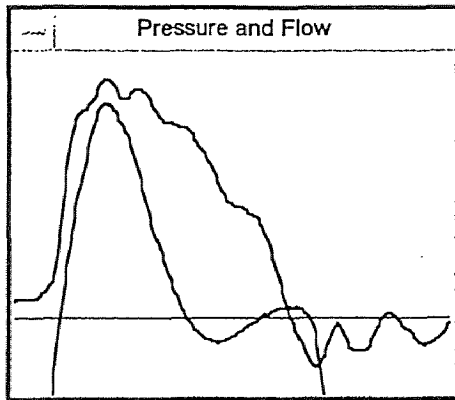
System Parameters: Heart Rate: 61.73 bpm  
 Stroke Volume: 77.44 ml  
 Cardiac Output: 4.78 L/m  
 Duration of valve cycle: 0.97 sec.  
 Forward Flow Phase: 0.65 sec. 66.82 %

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

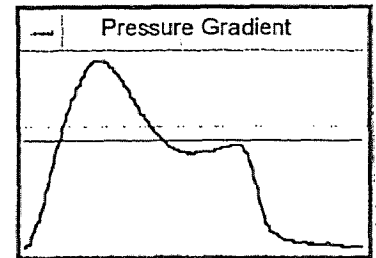
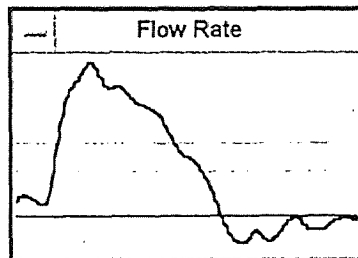
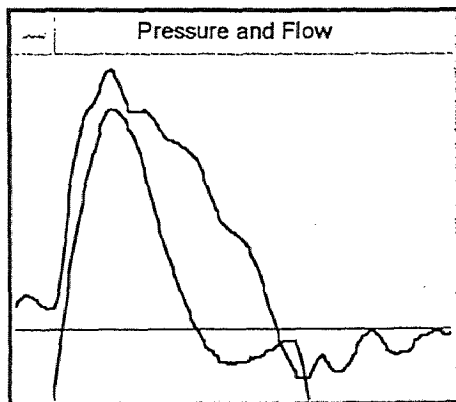
System Parameters: Heart Rate: 69.44 bpm  
 Stroke Volume: 70.61 ml  
 Cardiac Output: 4.90 L/m  
 Duration of valve cycle: 0.86 sec.  
 Forward Flow Phase: 0.52 sec. 59.91 %

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

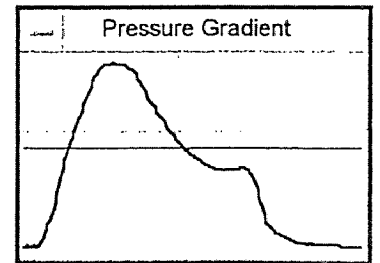
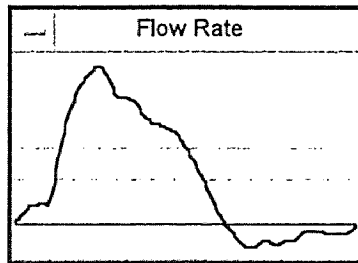
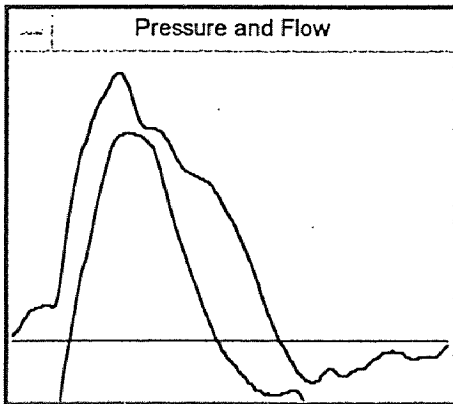
System Parameters: Heart Rate: 81.52 bpm  
 Stroke Volume: 73.08 ml  
 Cardiac Output: 5.96 L/m  
 Duration of valve cycle: 0.74 sec.  
 Forward Flow Phase: 0.45 sec. 61.11 %

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

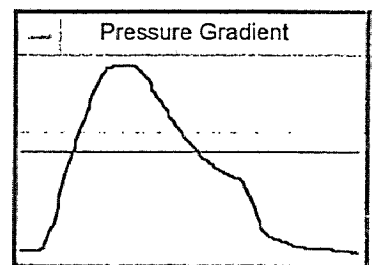
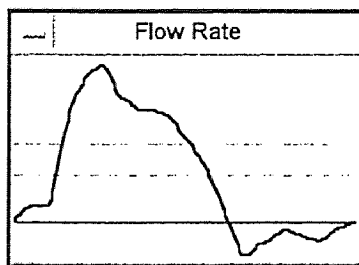
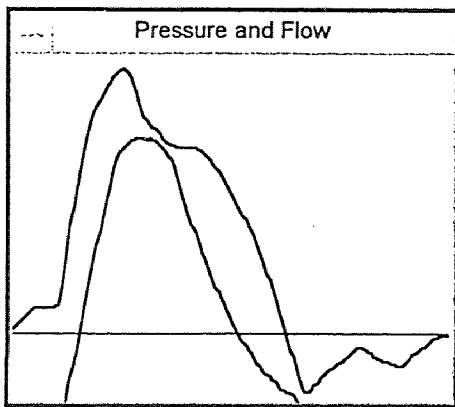
System Parameters: Heart Rate: 88.24 bpm  
 Stroke Volume: 76.16 ml  
 Cardiac Output: 6.72 L/m  
 Duration of valve cycle: 0.68 sec.  
 Forward Flow Phase: 0.43 sec. 63.03 %

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

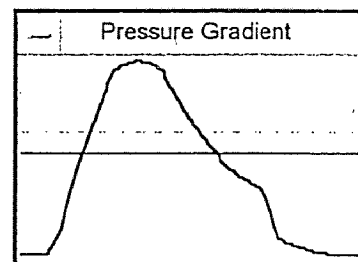
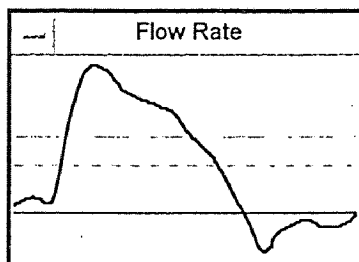
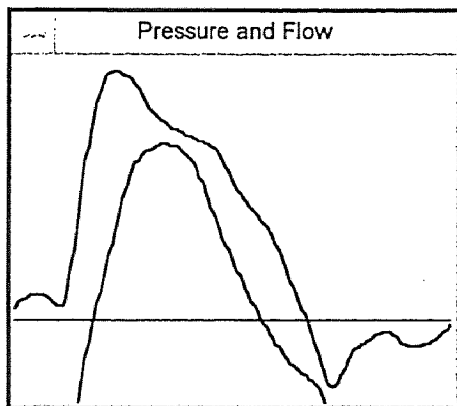
System Parameters: Heart Rate: 96.77 bpm  
 Stroke Volume: 80.40 ml  
 Cardiac Output: 7.78 L/m  
 Duration of valve cycle: 0.62 sec.  
 Forward Flow Phase: 0.42 sec. 67.11 %

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

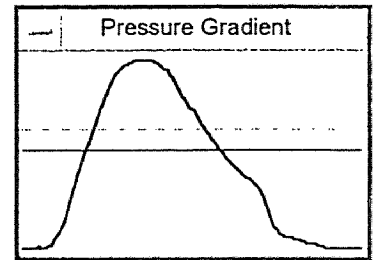
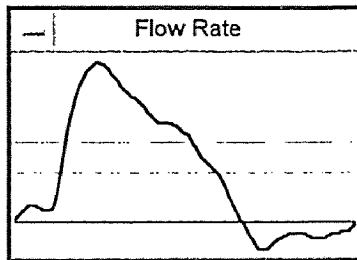
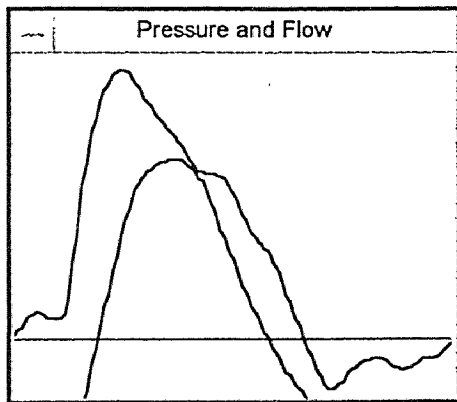
System Parameters: Heart Rate: 104.90 bpm  
 Stroke Volume: 76.67 ml  
 Cardiac Output: 8.04 L/m  
 Duration of valve cycle: 0.57 sec.  
 Forward Flow Phase: 0.38 sec. 66.20 %

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

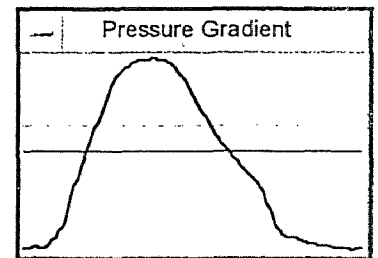
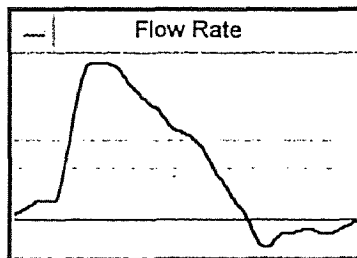
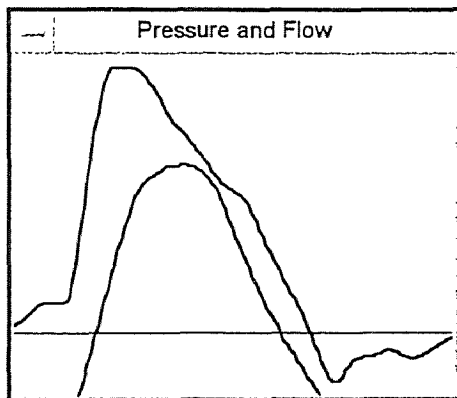
System Parameters: Heart Rate: 115.38 bpm  
Stroke Volume: 77.86 ml  
Cardiac Output: 8.98 L/m  
Duration of valve cycle: 0.52 sec.  
Forward Flow Phase: 0.35 sec. 67.72 %

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

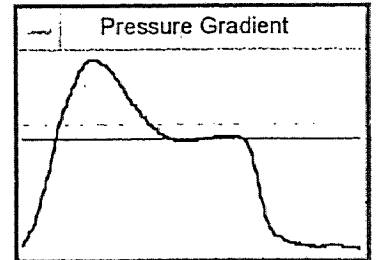
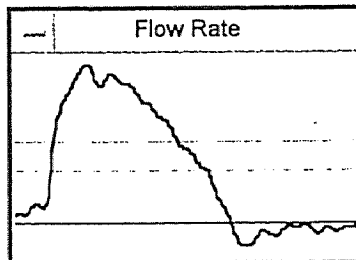
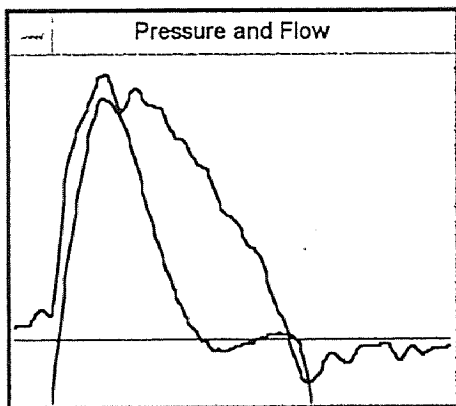
System Parameters: Heart Rate: 63.56 bpm  
 Stroke Volume: 74.14 ml  
 Cardiac Output: 4.71 L/m  
 Duration of valve cycle: 0.94 sec.  
 Forward Flow Phase: 0.60 sec. 63.06 %

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

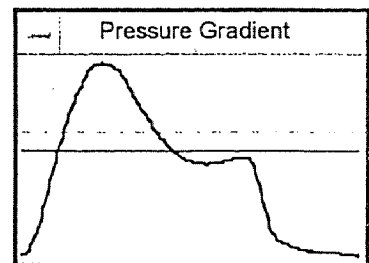
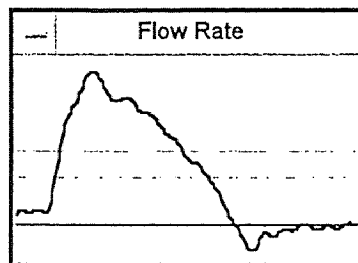
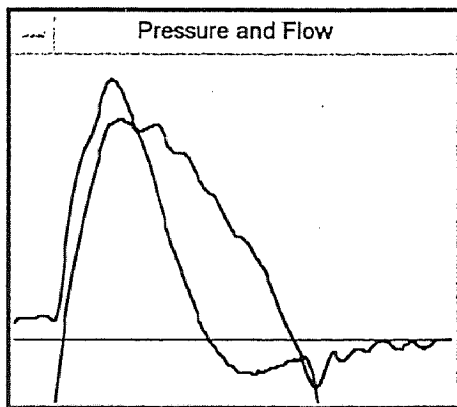
System Parameters: Heart Rate: 71.77 bpm  
 Stroke Volume: 75.62 ml  
 Cardiac Output: 5.43 L/m  
 Duration of valve cycle: 0.84 sec.  
 Forward Flow Phase: 0.54 sec. 64.29 %

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

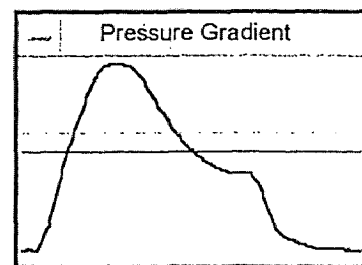
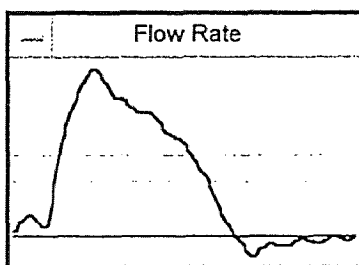
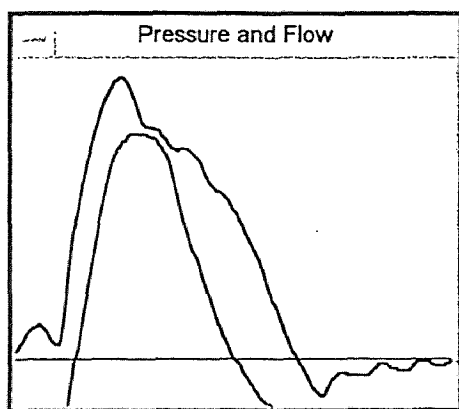
System Parameters: Heart Rate: 81.97 bpm  
 Stroke Volume: 77.79 ml  
 Cardiac Output: 6.38 L/m  
 Duration of valve cycle: 0.73 sec.  
 Forward Flow Phase: 0.48 sec. 65.12 %

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

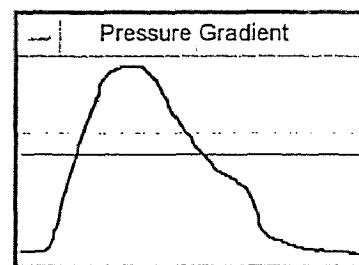
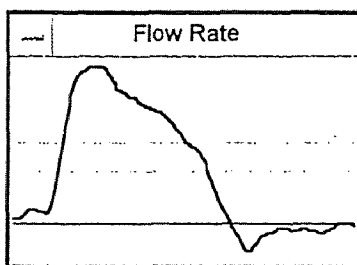
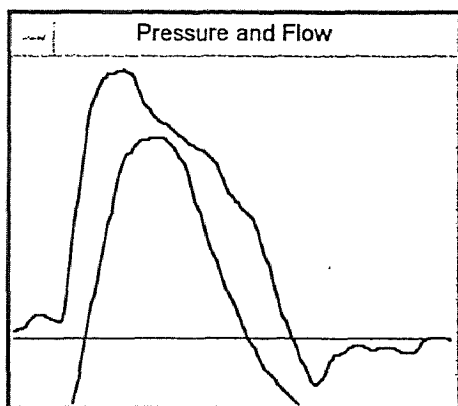
System Parameters: Heart Rate: 96.15 bpm  
 Stroke Volume: 76.19 ml  
 Cardiac Output: 7.33 L/m  
 Duration of valve cycle: 0.62 sec.  
 Forward Flow Phase: 0.41 sec. 66.46 %

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

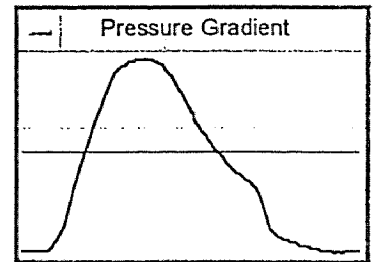
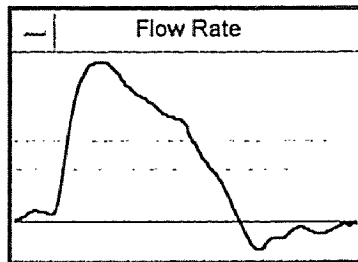
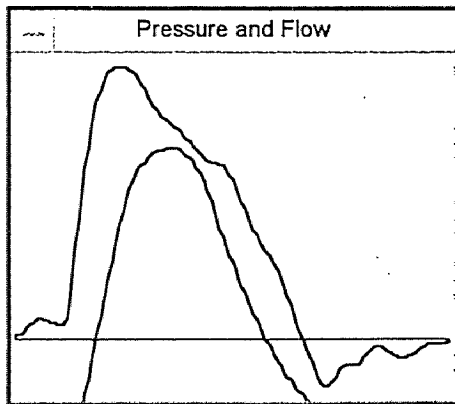
System Parameters: Heart Rate: 102.74 bpm  
 Stroke Volume: 77.99 ml  
 Cardiac Output: 8.01 L/m  
 Duration of valve cycle: 0.58 sec.  
 Forward Flow Phase: 0.39 sec. 66.67 %

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

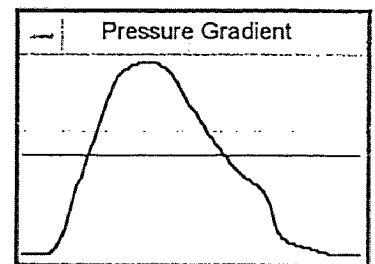
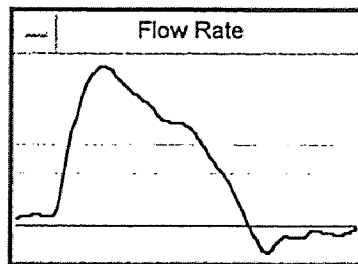
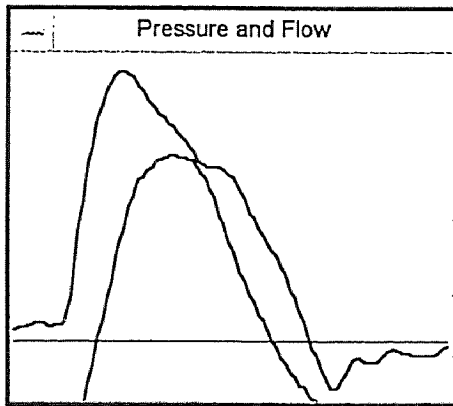
System Parameters: Heart Rate: 104.17 bpm  
 Stroke Volume: 79.79 ml  
 Cardiac Output: 8.31 L/m  
 Duration of valve cycle: 0.58 sec.  
 Forward Flow Phase: 0.39 sec. 68.57 %

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

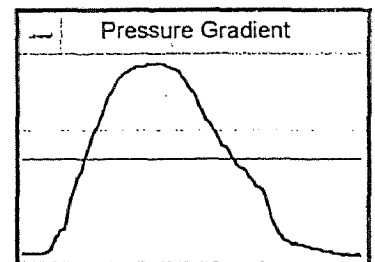
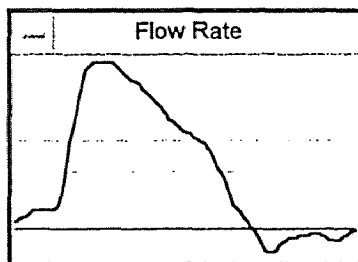
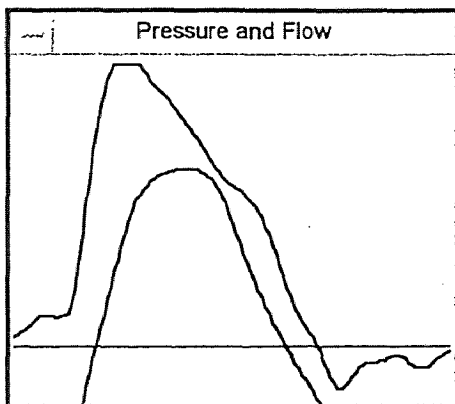
System Parameters: Heart Rate: 118.11 bpm  
 Stroke Volume: 80.55 ml  
 Cardiac Output: 9.51 L/m  
 Duration of valve cycle: 0.51 sec.  
 Forward Flow Phase: 0.35 sec. 69.67 %

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

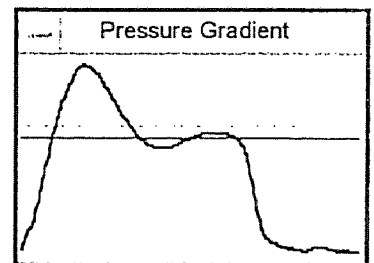
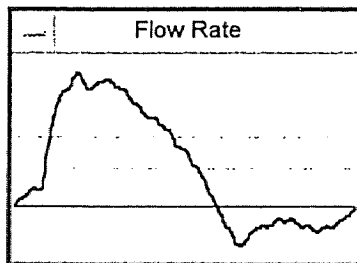
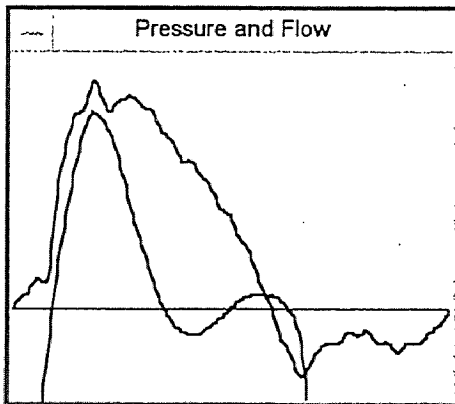
System Parameters: Heart Rate: 61.48 bpm  
 Stroke Volume: 68.71 ml  
 Cardiac Output: 4.22 L/m  
 Duration of valve cycle: 0.98 sec.  
 Forward Flow Phase: 0.58 sec. 58.94 %

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

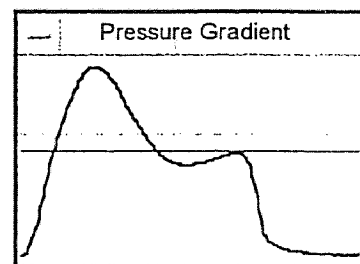
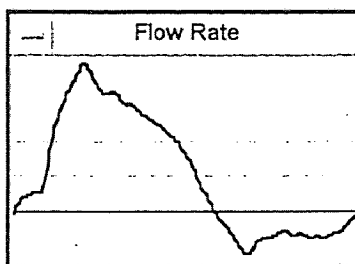
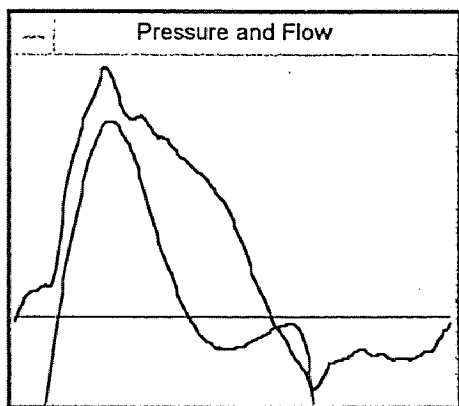
System Parameters: Heart Rate: 75.38 bpm  
 Stroke Volume: 70.88 ml  
 Cardiac Output: 5.34 L/m  
 Duration of valve cycle: 0.80 sec.  
 Forward Flow Phase: 0.46 sec. 58.25 %

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

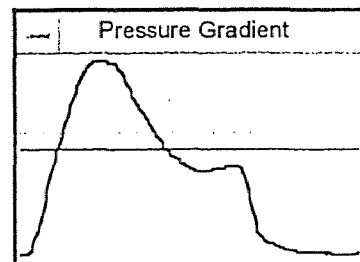
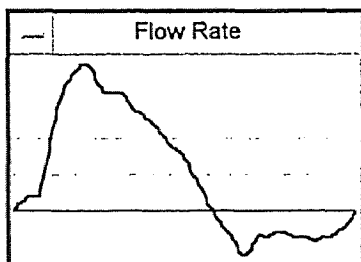
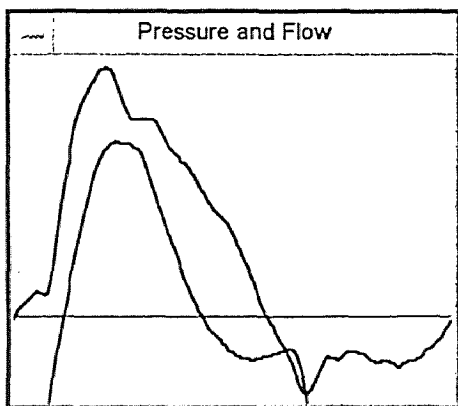
System Parameters: Heart Rate: 80.21 bpm  
 Stroke Volume: 76.76 ml  
 Cardiac Output: 6.16 L/m  
 Duration of valve cycle: 0.75 sec.  
 Forward Flow Phase: 0.43 sec. 57.22 %

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

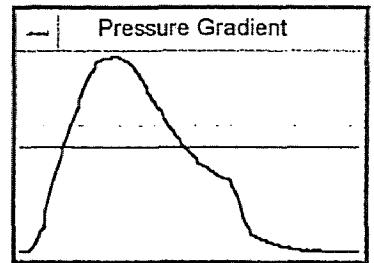
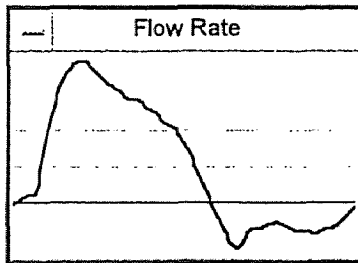
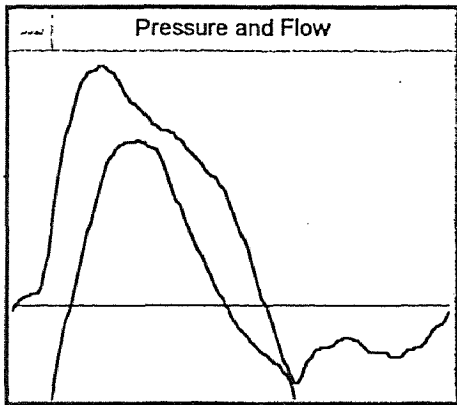
System Parameters: Heart Rate: 92.02 bpm  
 Stroke Volume: 75.59 ml  
 Cardiac Output: 6.96 L/m  
 Duration of valve cycle: 0.65 sec.  
 Forward Flow Phase: 0.38 sec. 57.67 %

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

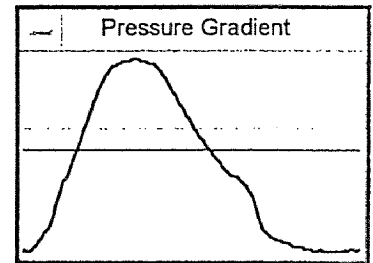
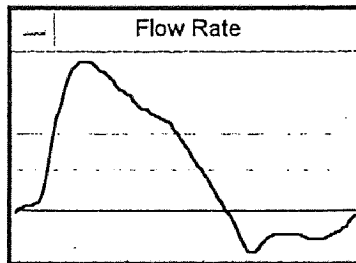
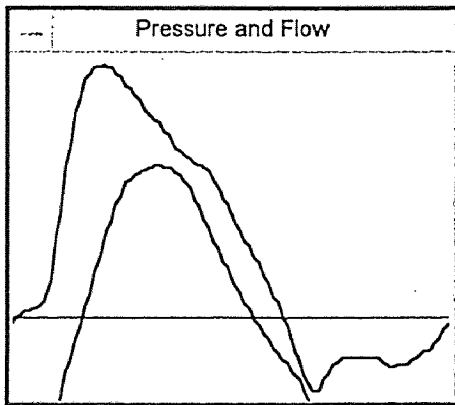
System Parameters: Heart Rate: 108.70 bpm  
 Stroke Volume: 76.63 ml  
 Cardiac Output: 8.33 L/m  
 Duration of valve cycle: 0.55 sec.  
 Forward Flow Phase: 0.34 sec. 61.87 %

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

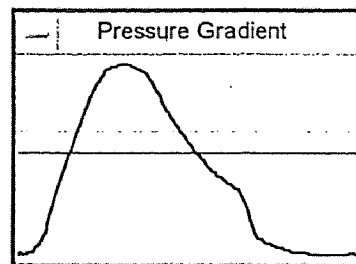
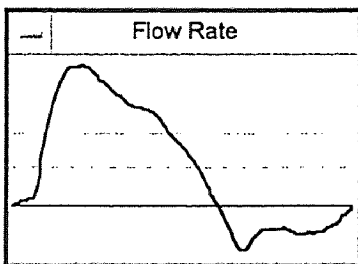
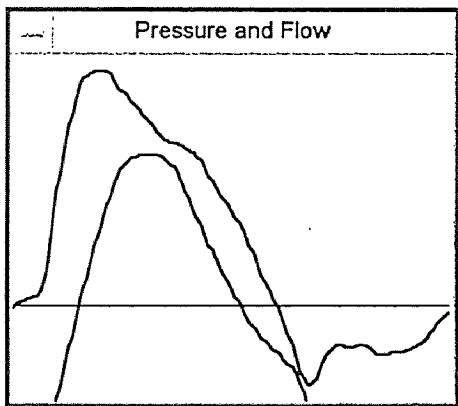
System Parameters: Heart Rate: 102.04 bpm  
 Stroke Volume: 75.48 ml  
 Cardiac Output: 7.70 L/m  
 Duration of valve cycle: 0.59 sec.  
 Forward Flow Phase: 0.36 sec. 60.40 %

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

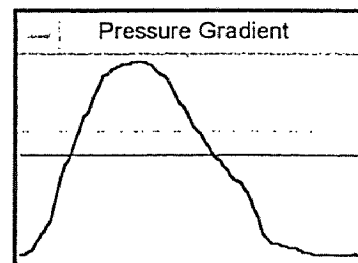
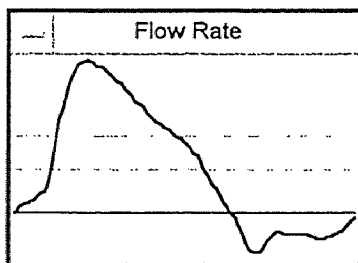
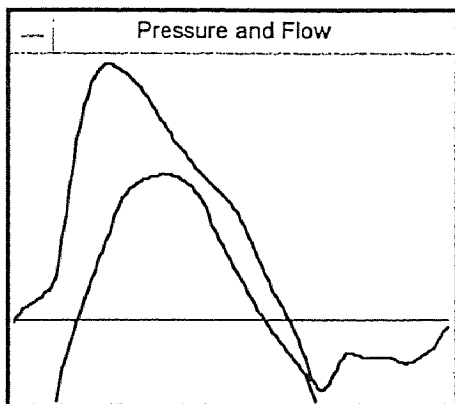
System Parameters: Heart Rate: 120.00 bpm  
 Stroke Volume: 78.09 ml  
 Cardiac Output: 9.37 L/m  
 Duration of valve cycle: 0.50 sec.  
 Forward Flow Phase: 0.31 sec. 62.40 %

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

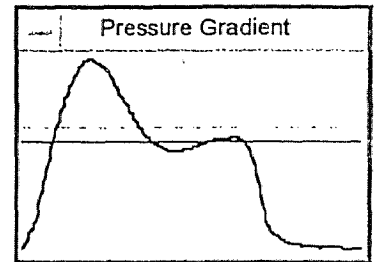
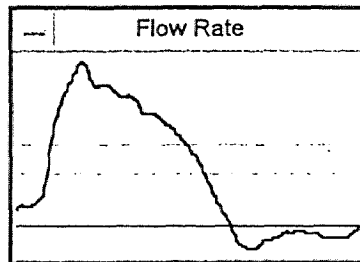
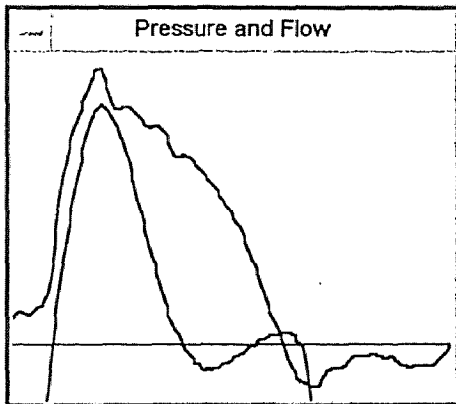
System Parameters: Heart Rate: 66.67 bpm  
 Stroke Volume: 79.07 ml  
 Cardiac Output: 5.27 L/m  
 Duration of valve cycle: 0.90 sec.  
 Forward Flow Phase: 0.56 sec. 61.93 %

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

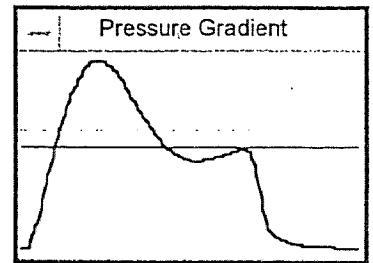
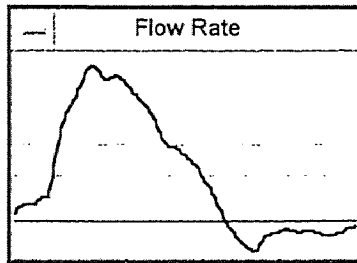
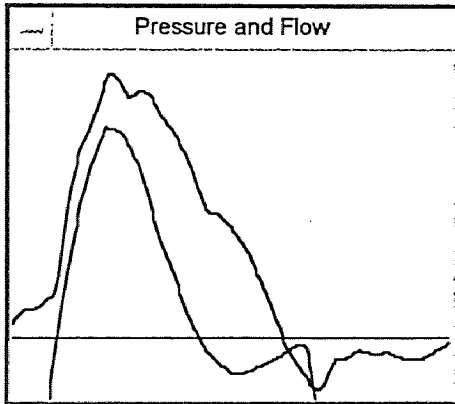
System Parameters: Heart Rate: 72.46 bpm  
 Stroke Volume: 80.73 ml  
 Cardiac Output: 5.85 L/m  
 Duration of valve cycle: 0.83 sec.  
 Forward Flow Phase: 0.51 sec. 62.00 %

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

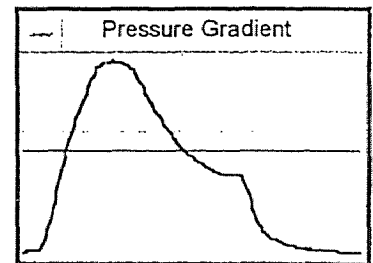
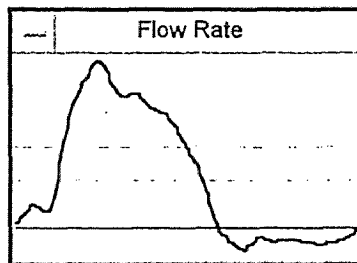
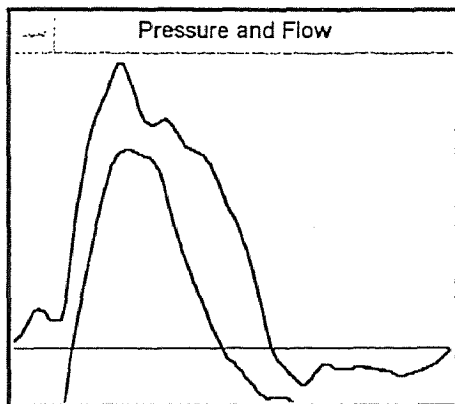
System Parameters: Heart Rate: 83.80 bpm  
 Stroke Volume: 81.40 ml  
 Cardiac Output: 6.82 L/m  
 Duration of valve cycle: 0.72 sec.  
 Forward Flow Phase: 0.42 sec. 58.99 %

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

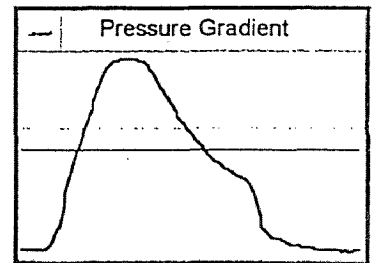
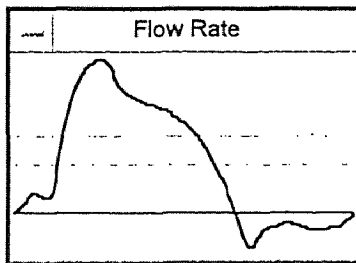
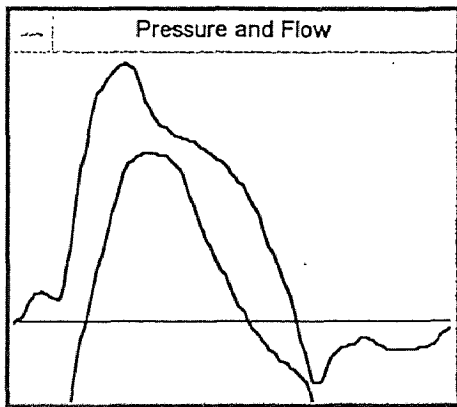
System Parameters: Heart Rate: 96.77 bpm  
 Stroke Volume: 83.19 ml  
 Cardiac Output: 8.05 L/m  
 Duration of valve cycle: 0.62 sec.  
 Forward Flow Phase: 0.40 sec. 64.52 %

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

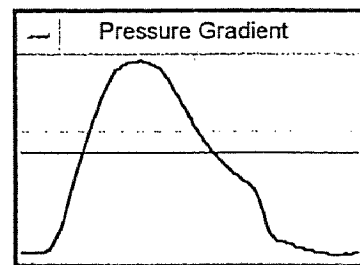
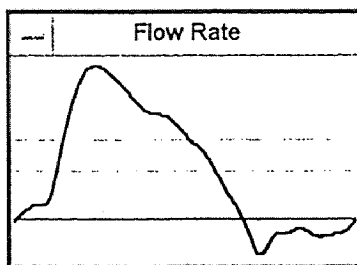
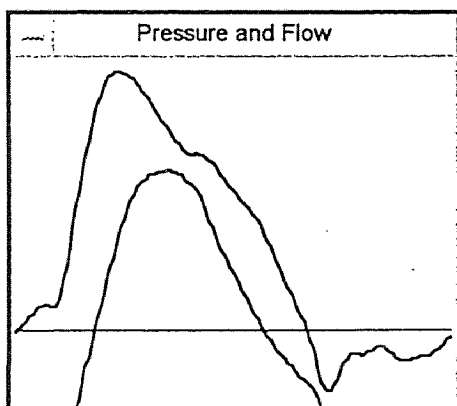
System Parameters: Heart Rate: 103.45 bpm  
 Stroke Volume: 85.05 ml  
 Cardiac Output: 8.80 L/m  
 Duration of valve cycle: 0.58 sec.  
 Forward Flow Phase: 0.39 sec. 66.67 %

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

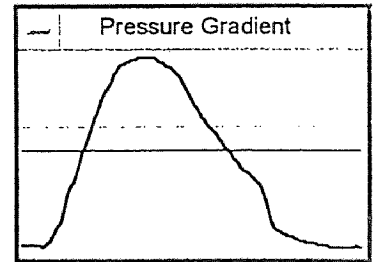
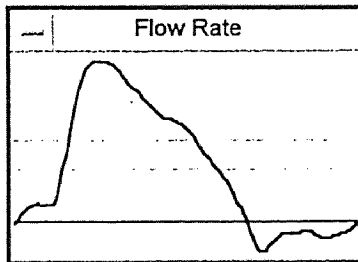
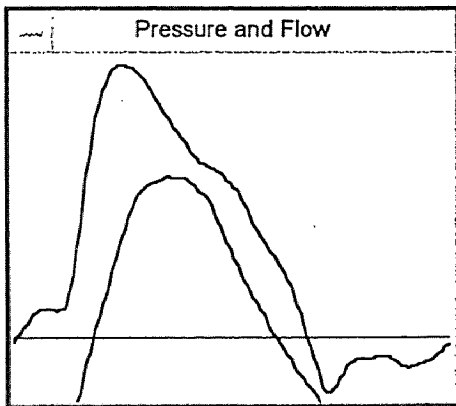
System Parameters: Heart Rate: 111.94 bpm  
 Stroke Volume: 84.22 ml  
 Cardiac Output: 9.43 L/m  
 Duration of valve cycle: 0.54 sec.  
 Forward Flow Phase: 0.36 sec. 66.92 %

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

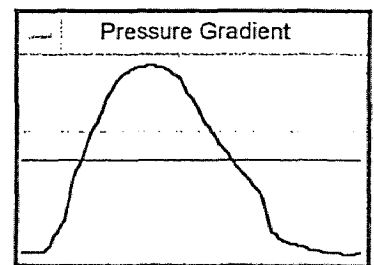
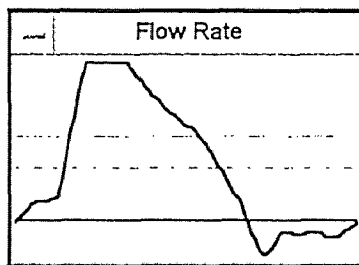
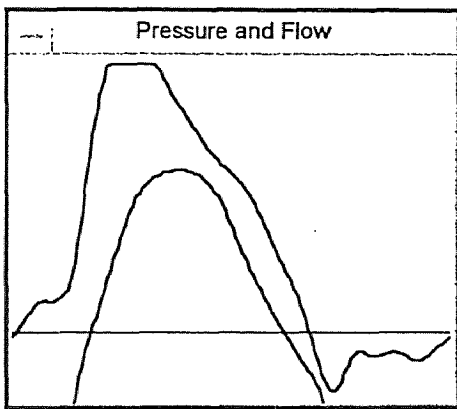
System Parameters: Heart Rate: 123.97 bpm  
 Stroke Volume: 81.58 ml  
 Cardiac Output: 10.11 L/m  
 Duration of valve cycle: 0.48 sec.  
 Forward Flow Phase: 0.33 sec. 67.21 %

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

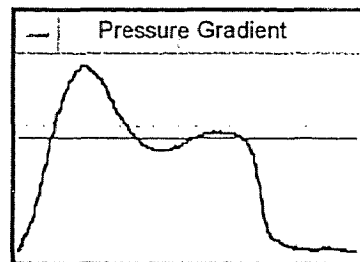
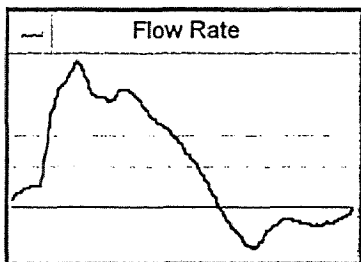
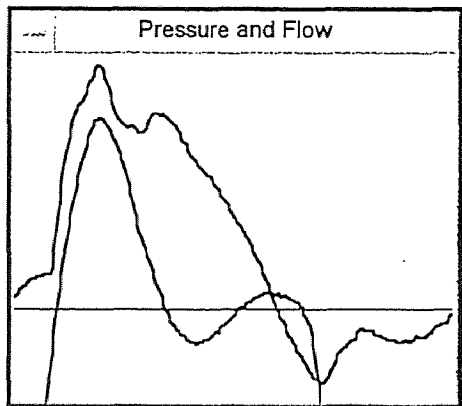
System Parameters: Heart Rate: 62.24 bpm  
 Stroke Volume: 70.74 ml  
 Cardiac Output: 4.40 L/m  
 Duration of valve cycle: 0.96 sec.  
 Forward Flow Phase: 0.58 sec. 60.43 %

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

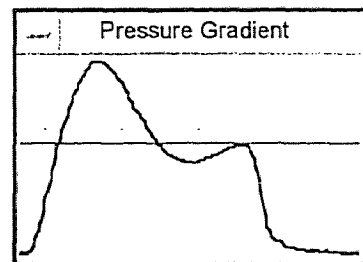
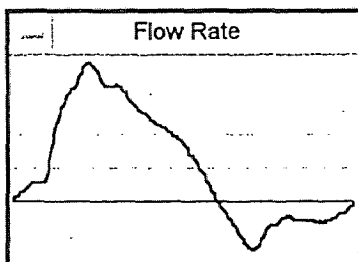
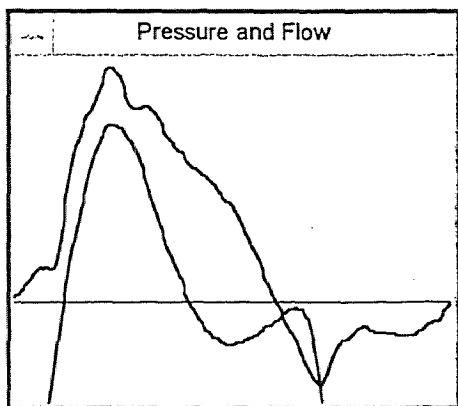
System Parameters: Heart Rate: 72.46 bpm  
 Stroke Volume: 70.40 ml  
 Cardiac Output: 5.10 L/m  
 Duration of valve cycle: 0.83 sec.  
 Forward Flow Phase: 0.50 sec. 60.00 %

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

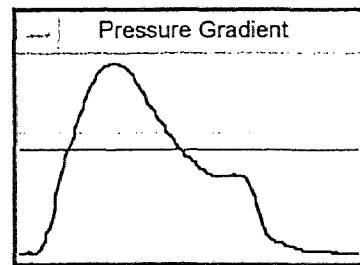
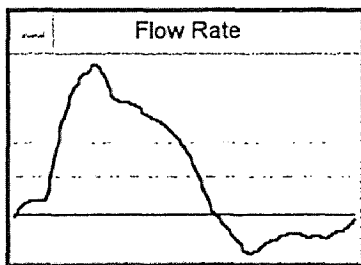
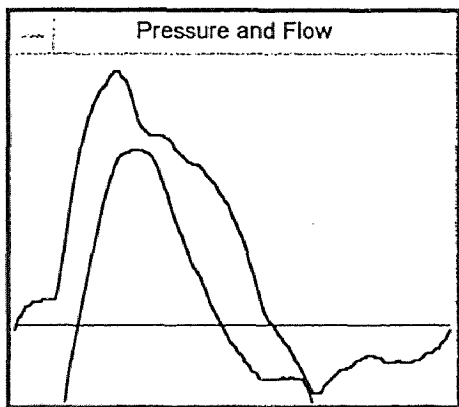
System Parameters: Heart Rate: 85.23 bpm  
Stroke Volume: 72.38 ml  
Cardiac Output: 6.17 L/m  
Duration of valve cycle: 0.70 sec.  
Forward Flow Phase: 0.41 sec. 58.19 %

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

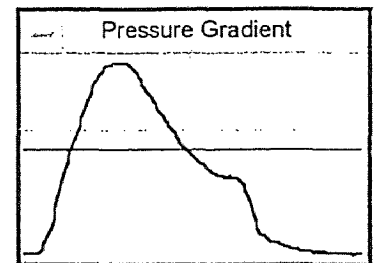
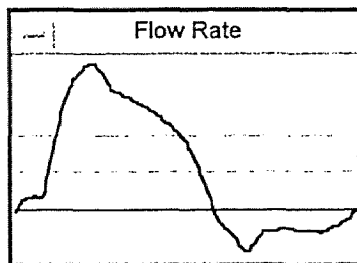
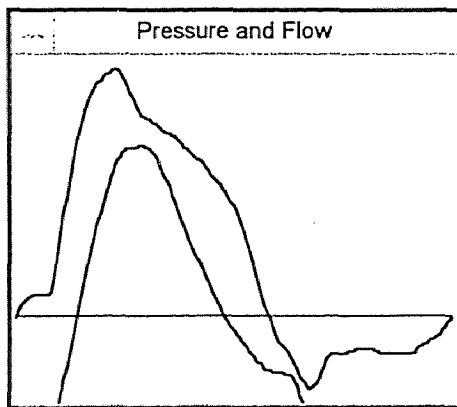
System Parameters: Heart Rate: 88.76 bpm  
 Stroke Volume: 73.00 ml  
 Cardiac Output: 6.48 L/m  
 Duration of valve cycle: 0.68 sec.  
 Forward Flow Phase: 0.39 sec. 57.65 %

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

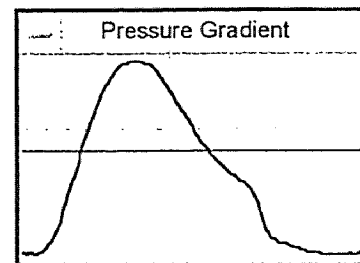
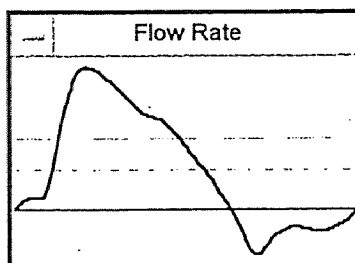
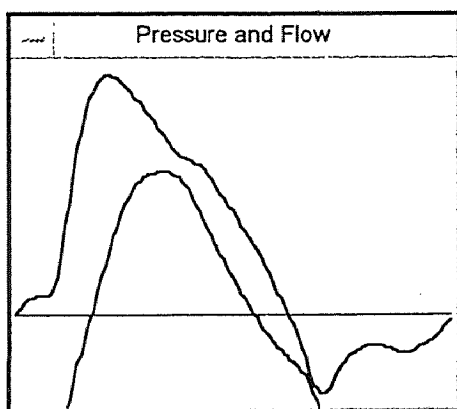
System Parameters: Heart Rate: 102.04 bpm  
 Stroke Volume: 76.70 ml  
 Cardiac Output: 7.83 L/m  
 Duration of valve cycle: 0.59 sec.  
 Forward Flow Phase: 0.37 sec. 62.33 %

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

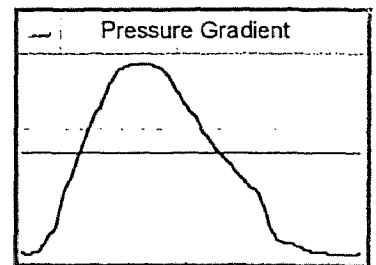
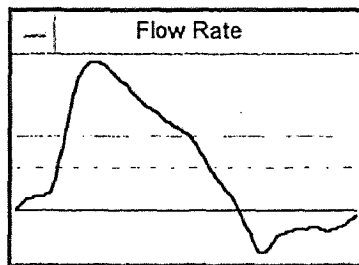
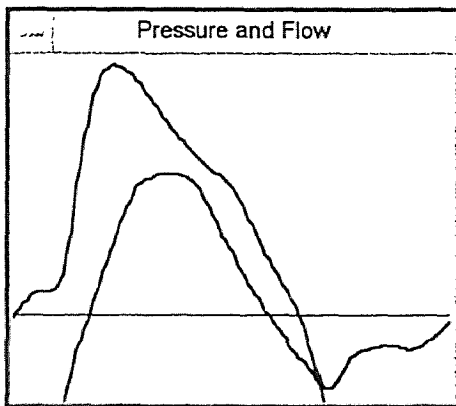
System Parameters: Heart Rate: 112.78 bpm  
Stroke Volume: 77.92 ml  
Cardiac Output: 8.79 L/m  
Duration of valve cycle: 0.53 sec.  
Forward Flow Phase: 0.34 sec. 64.39 %

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

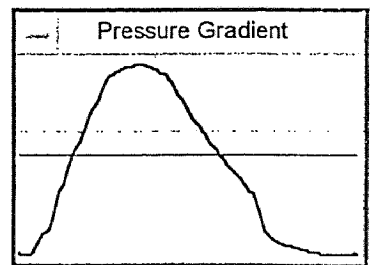
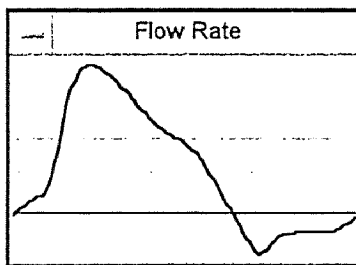
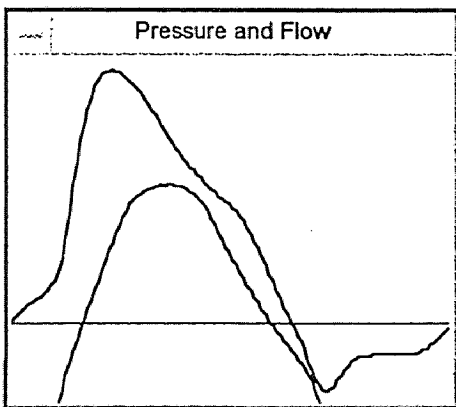
System Parameters: Heart Rate: 120.97 bpm  
 Stroke Volume: 78.48 ml  
 Cardiac Output: 9.49 L/m  
 Duration of valve cycle: 0.50 sec.  
 Forward Flow Phase: 0.31 sec. 63.41 %

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

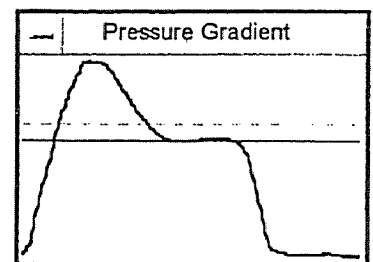
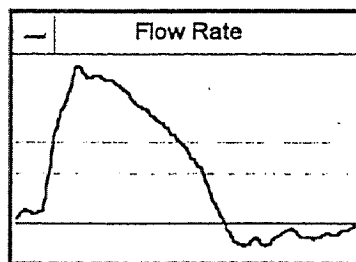
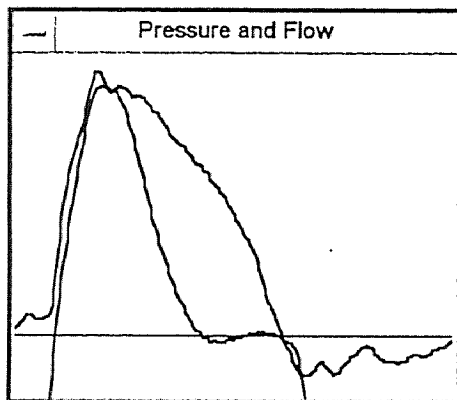
System Parameters: Heart Rate: 61.22 bpm  
 Stroke Volume: 74.18 ml  
 Cardiac Output: 4.54 L/m  
 Duration of valve cycle: 0.98 sec.  
 Forward Flow Phase: 0.60 sec. 61.44 %

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

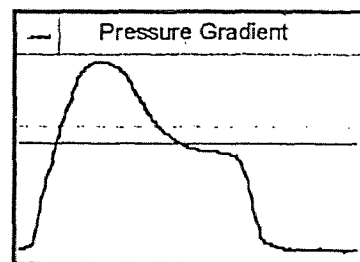
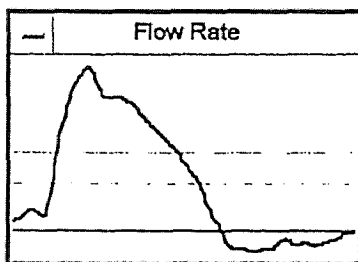
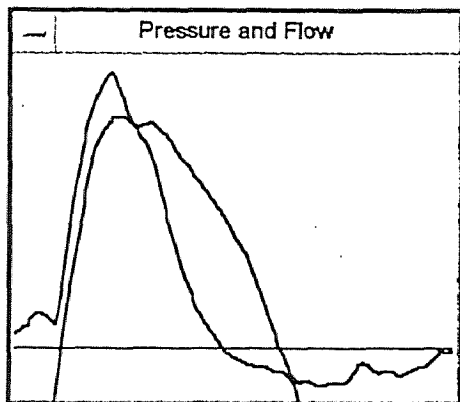
System Parameters: Heart Rate: 74.26 bpm  
 Stroke Volume: 72.52 ml  
 Cardiac Output: 5.39 L/m  
 Duration of valve cycle: 0.81 sec.  
 Forward Flow Phase: 0.49 sec. 60.80 %

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

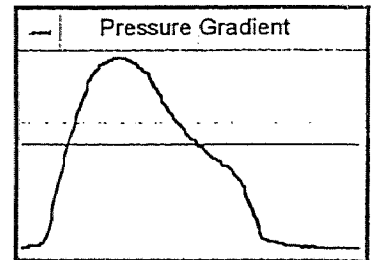
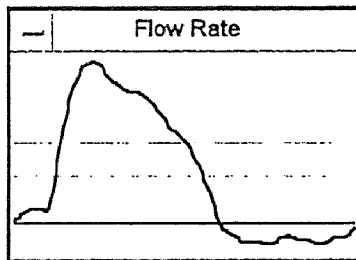
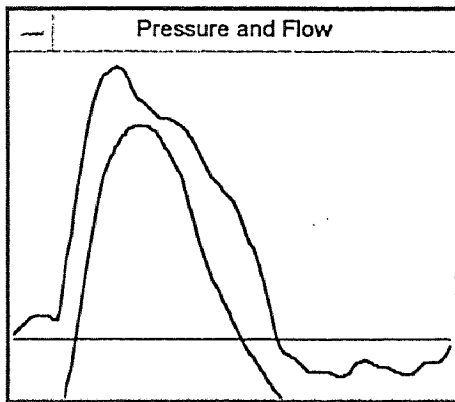
System Parameters: Heart Rate: 86.21 bpm  
 Stroke Volume: 73.57 ml  
 Cardiac Output: 6.34 L/m  
 Duration of valve cycle: 0.70 sec.  
 Forward Flow Phase: 0.42 sec. 60.23 %

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

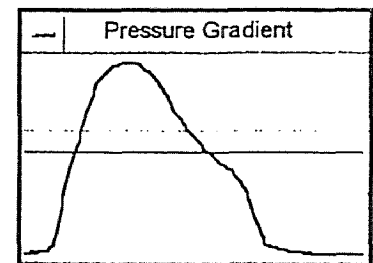
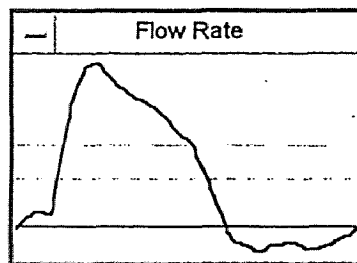
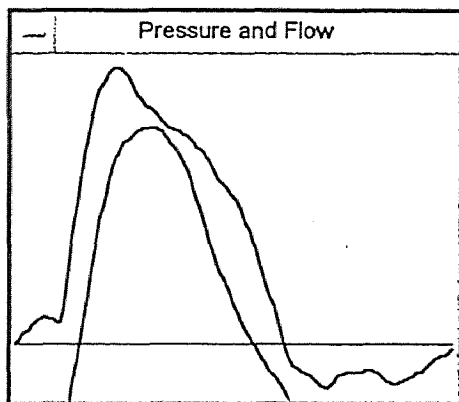
System Parameters: Heart Rate: 90.36 bpm  
 Stroke Volume: 74.83 ml  
 Cardiac Output: 6.76 L/m  
 Duration of valve cycle: 0.66 sec.  
 Forward Flow Phase: 0.41 sec. 61.21 %

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

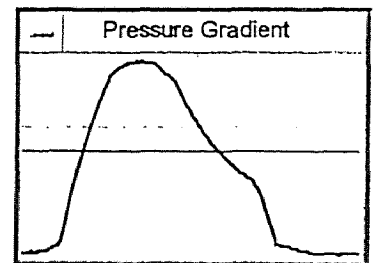
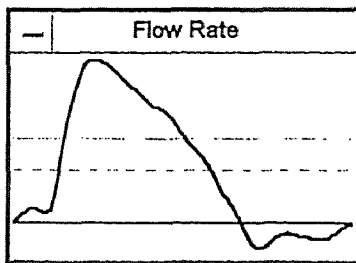
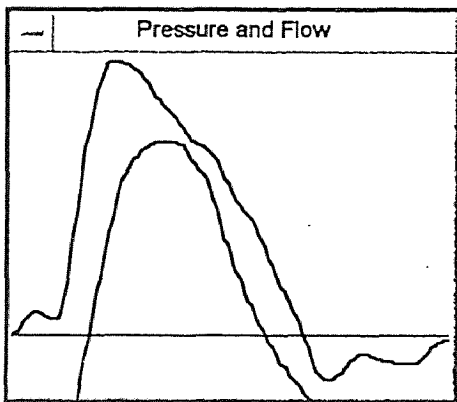
System Parameters: Heart Rate: 101.35 bpm  
 Stroke Volume: 77.43 ml  
 Cardiac Output: 7.85 L/m  
 Duration of valve cycle: 0.59 sec.  
 Forward Flow Phase: 0.39 sec. 66.21 %

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

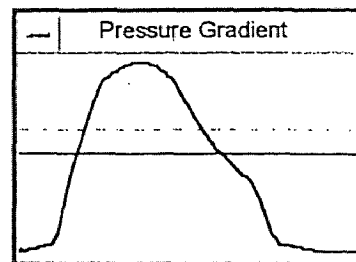
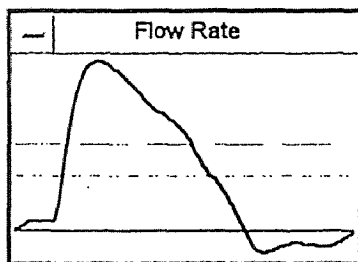
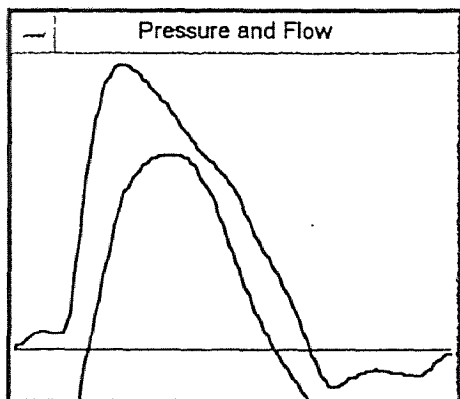
System Parameters: Heart Rate: 110.29 bpm  
 Stroke Volume: 76.89 ml  
 Cardiac Output: 8.48 L/m  
 Duration of valve cycle: 0.54 sec.  
 Forward Flow Phase: 0.37 sec. 67.88 %

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

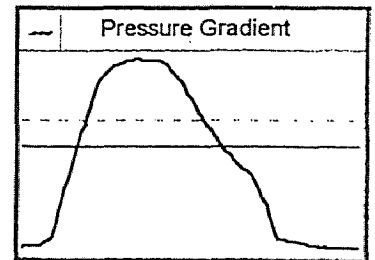
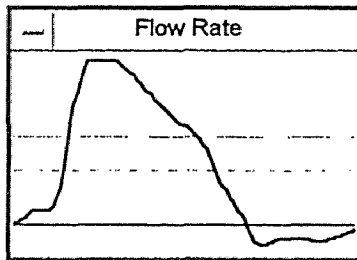
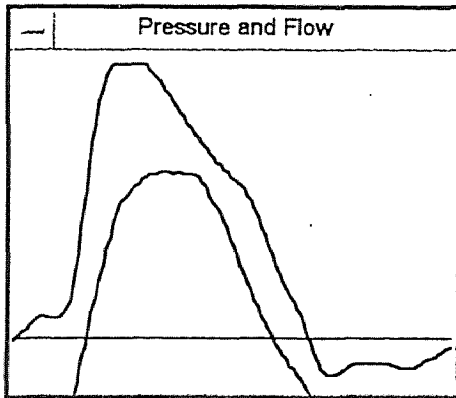
System Parameters: Heart Rate: 121.95 bpm  
 Stroke Volume: 76.59 ml  
 Cardiac Output: 9.34 L/m  
 Duration of valve cycle: 0.49 sec.  
 Forward Flow Phase: 0.33 sec. 66.94 %

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

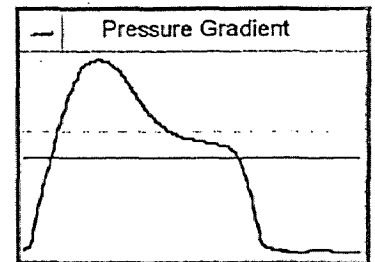
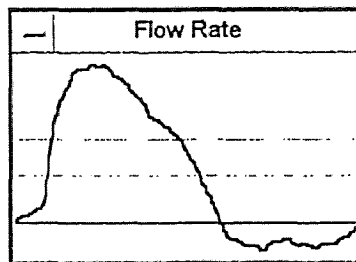
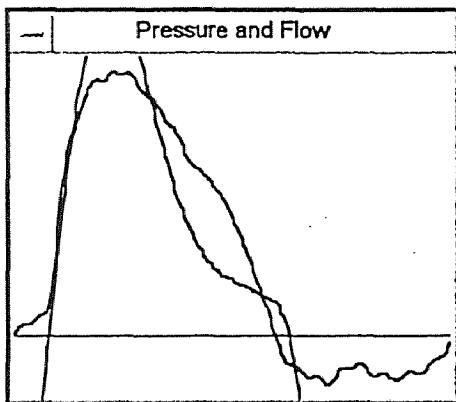
System Parameters: Heart Rate: 63.29 bpm  
 Stroke Volume: 73.45 ml  
 Cardiac Output: 4.65 L/m  
 Duration of valve cycle: 0.95 sec.  
 Forward Flow Phase: 0.57 sec. 60.09 %

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

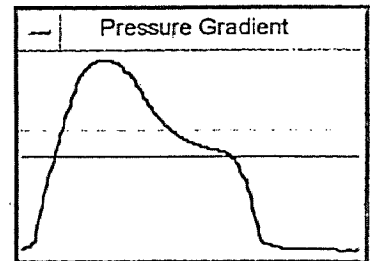
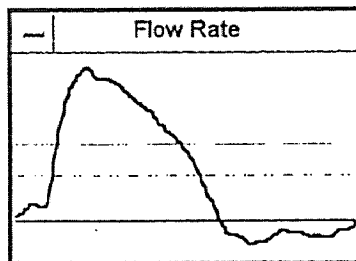
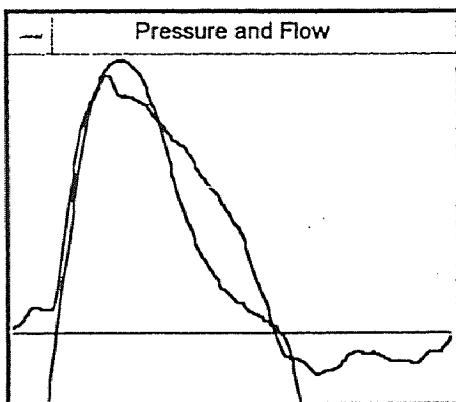
System Parameters: Heart Rate: 73.53 bpm  
 Stroke Volume: 71.81 ml  
 Cardiac Output: 5.28 L/m  
 Duration of valve cycle: 0.82 sec.  
 Forward Flow Phase: 0.49 sec. 60.20 %

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

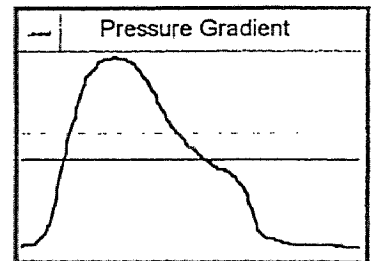
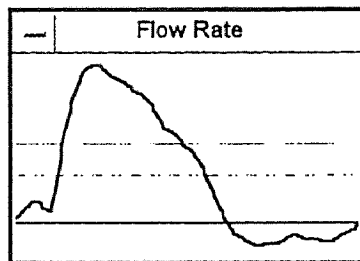
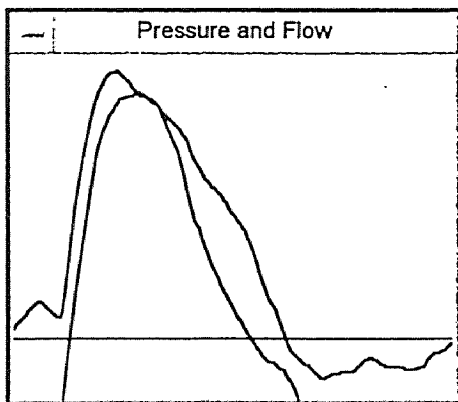
System Parameters: Heart Rate: 83.80 bpm  
 Stroke Volume: 71.71 ml  
 Cardiac Output: 6.01 L/m  
 Duration of valve cycle: 0.72 sec.  
 Forward Flow Phase: 0.44 sec. 61.58 %

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

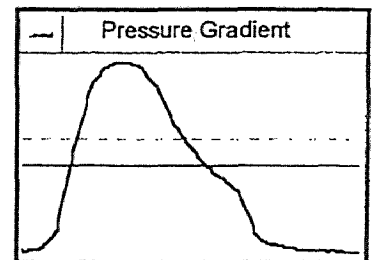
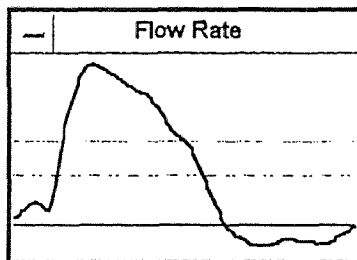
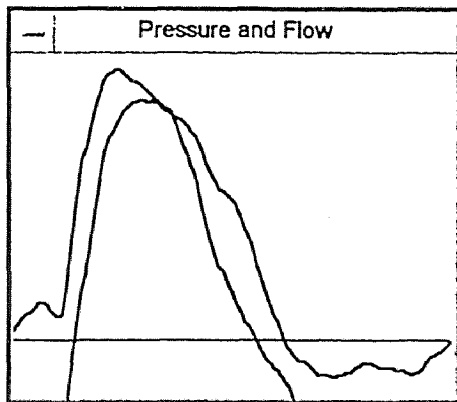
System Parameters: Heart Rate: 89.29 bpm  
 Stroke Volume: 72.35 ml  
 Cardiac Output: 6.46 L/m  
 Duration of valve cycle: 0.67 sec.  
 Forward Flow Phase: 0.41 sec. 61.68 %

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

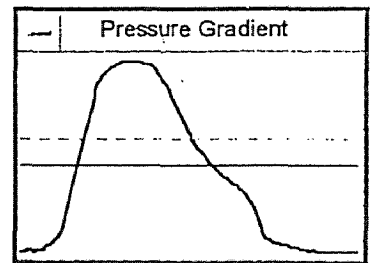
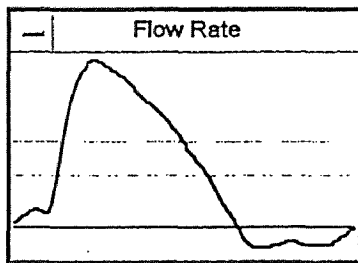
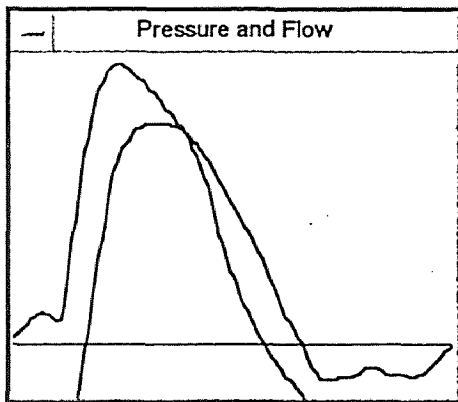
System Parameters: Heart Rate: 99.34 bpm  
 Stroke Volume: 74.12 ml  
 Cardiac Output: 7.36 L/m  
 Duration of valve cycle: 0.60 sec.  
 Forward Flow Phase: 0.40 sec. 66.00 %

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

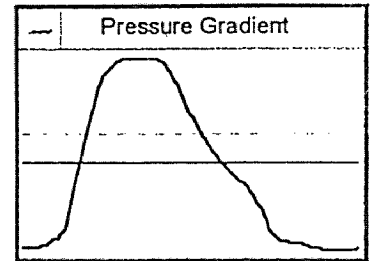
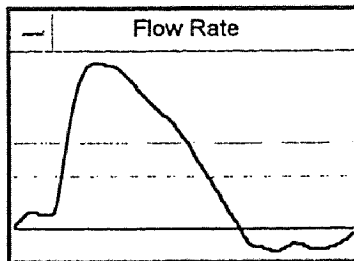
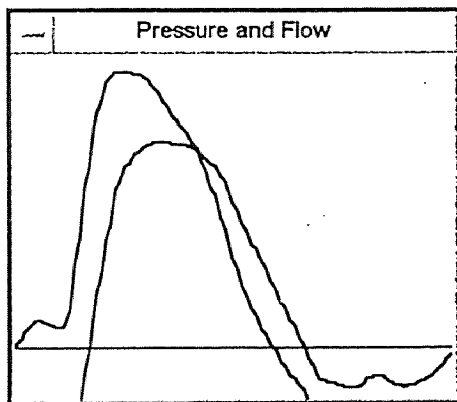
System Parameters: Heart Rate: 107.91 bpm  
 Stroke Volume: 73.80 ml  
 Cardiac Output: 7.96 L/m  
 Duration of valve cycle: 0.56 sec.  
 Forward Flow Phase: 0.37 sec. 66.67 %

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

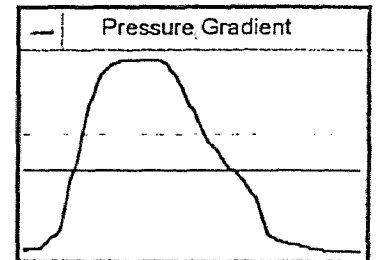
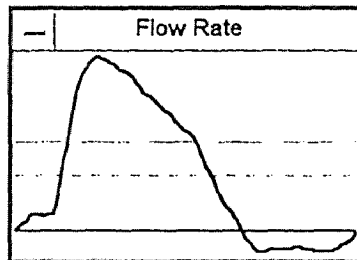
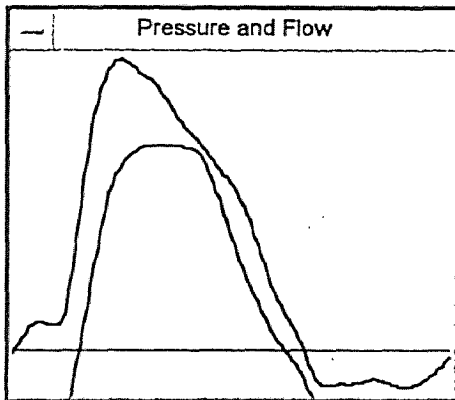
System Parameters: Heart Rate: 118.11 bpm  
Stroke Volume: 74.96 ml  
Cardiac Output: 8.85 L/m  
Duration of valve cycle: 0.51 sec.  
Forward Flow Phase: 0.33 sec. 65.87 %

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

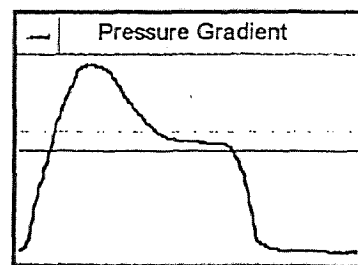
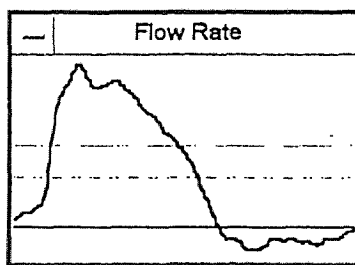
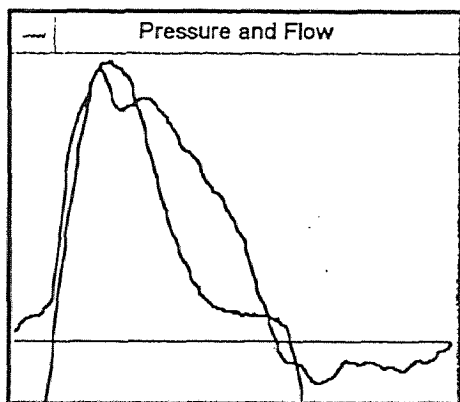
System Parameters: Heart Rate: 66.96 bpm  
 Stroke Volume: 72.74 ml  
 Cardiac Output: 4.87 L/m  
 Duration of valve cycle: 0.90 sec.  
 Forward Flow Phase: 0.54 sec. 59.91 %

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

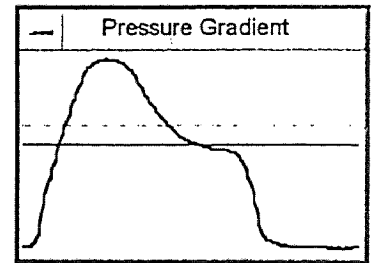
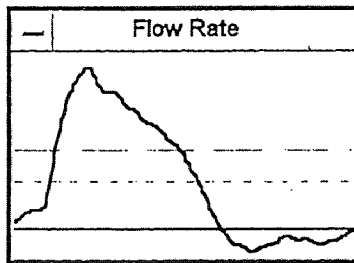
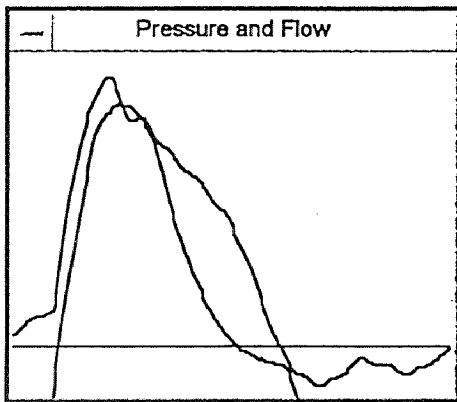
System Parameters: Heart Rate: 74.63 bpm  
Stroke Volume: 72.46 ml  
Cardiac Output: 5.41 L/m  
Duration of valve cycle: 0.80 sec.  
Forward Flow Phase: 0.49 sec. 61.11 %

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

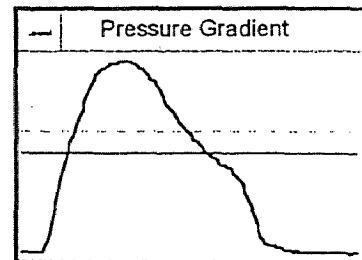
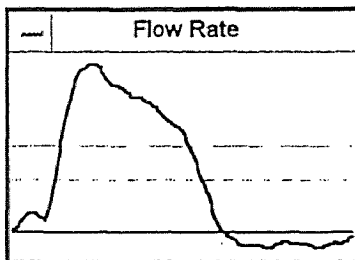
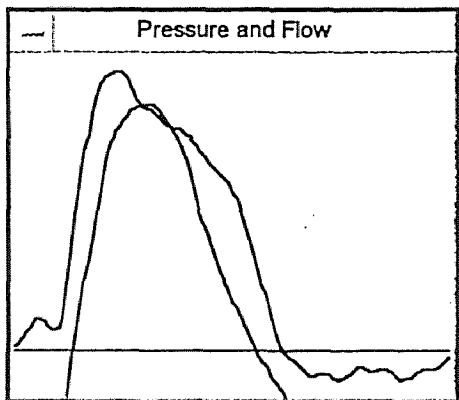
System Parameters: Heart Rate: 86.71 bpm  
 Stroke Volume: 74.90 ml  
 Cardiac Output: 6.49 L/m  
 Duration of valve cycle: 0.69 sec.  
 Forward Flow Phase: 0.43 sec. 61.90 %

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

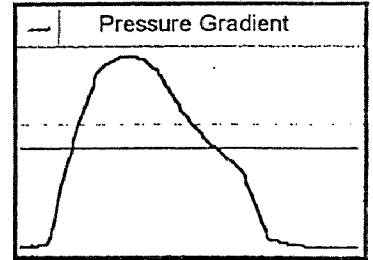
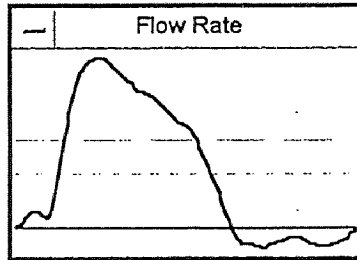
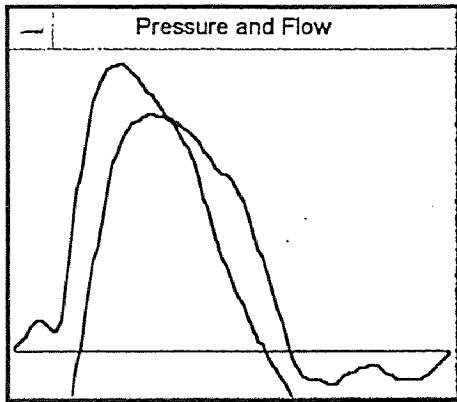
System Parameters: Heart Rate: 92.59 bpm  
 Stroke Volume: 77.27 ml  
 Cardiac Output: 7.15 L/m  
 Duration of valve cycle: 0.65 sec.  
 Forward Flow Phase: 0.41 sec. 63.52 %

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

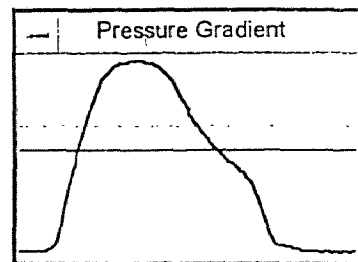
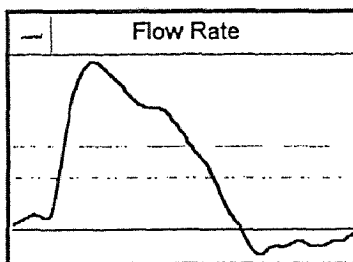
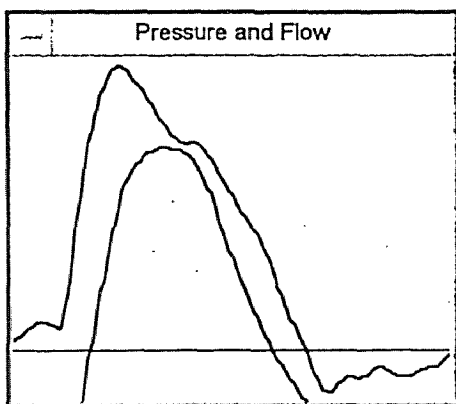
System Parameters: Heart Rate: 101.35 bpm  
 Stroke Volume: 77.16 ml  
 Cardiac Output: 7.82 L/m  
 Duration of valve cycle: 0.59 sec.  
 Forward Flow Phase: 0.40 sec. 67.12 %

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

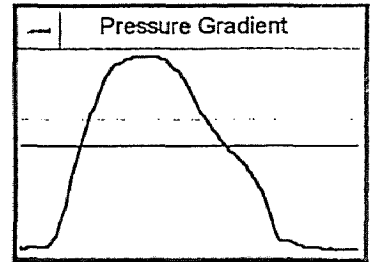
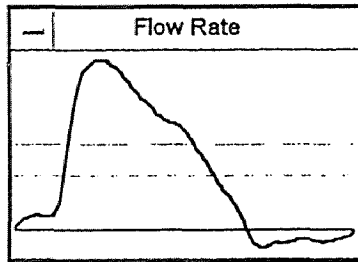
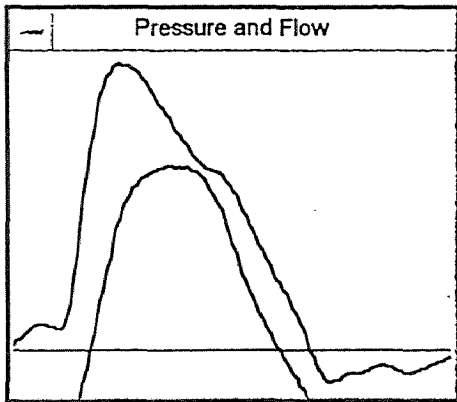
System Parameters: Heart Rate: 113.64 bpm  
Stroke Volume: 76.87 ml  
Cardiac Output: 8.74 L/m  
Duration of valve cycle: 0.53 sec.  
Forward Flow Phase: 0.36 sec. 68.70 %

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

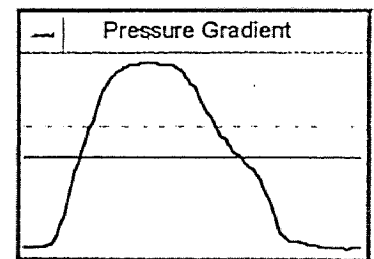
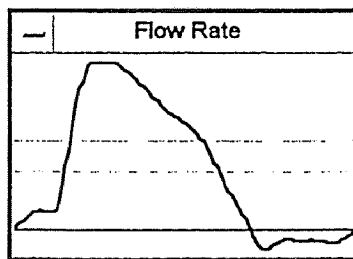
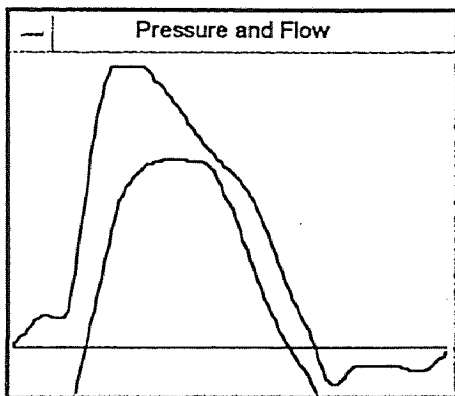
System Parameters: Heart Rate: 122.95 bpm  
 Stroke Volume: 79.82 ml  
 Cardiac Output: 9.81 L/m  
 Duration of valve cycle: 0.49 sec.  
 Forward Flow Phase: 0.34 sec. 69.17 %

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

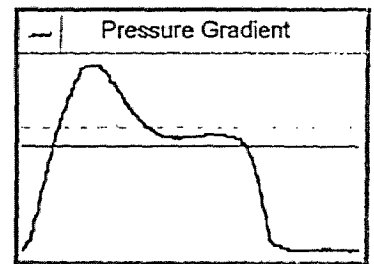
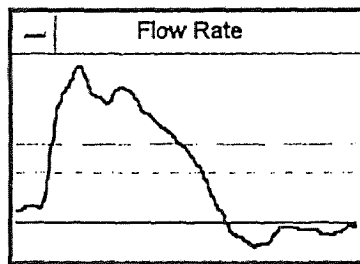
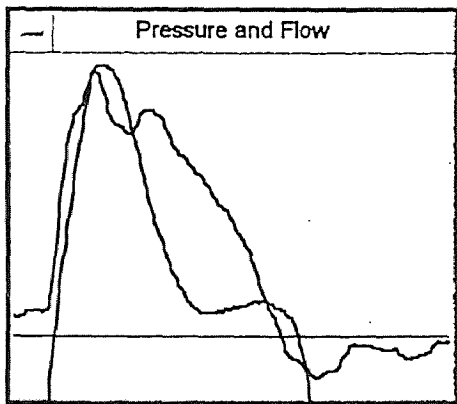
System Parameters: Heart Rate: 60.48 bpm  
 Stroke Volume: 73.98 ml  
 Cardiac Output: 4.47 L/m  
 Duration of valve cycle: 0.99 sec.  
 Forward Flow Phase: 0.61 sec. 61.60 %

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

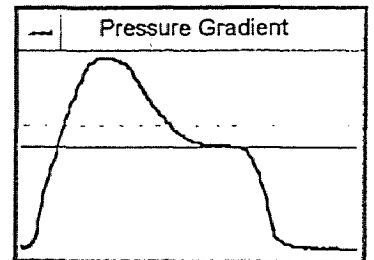
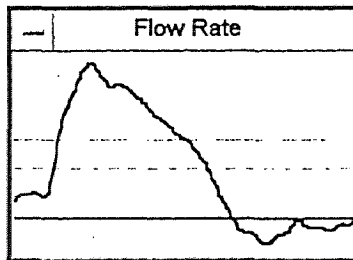
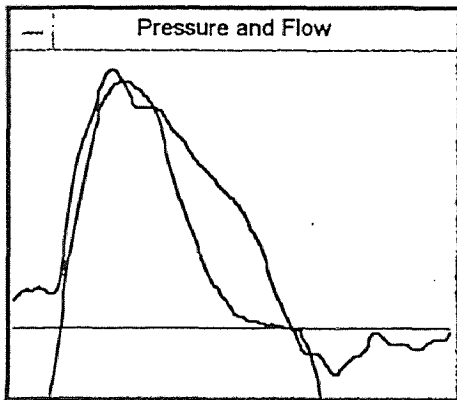
System Parameters: Heart Rate: 71.43 bpm  
 Stroke Volume: 77.75 ml  
 Cardiac Output: 5.55 L/m  
 Duration of valve cycle: 0.84 sec.  
 Forward Flow Phase: 0.54 sec. 63.78 %

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

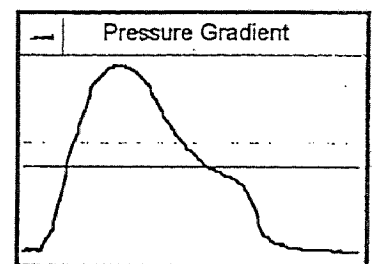
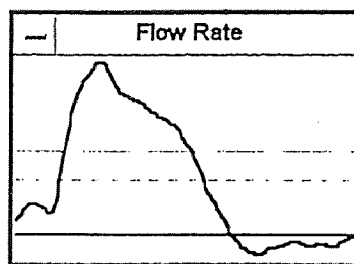
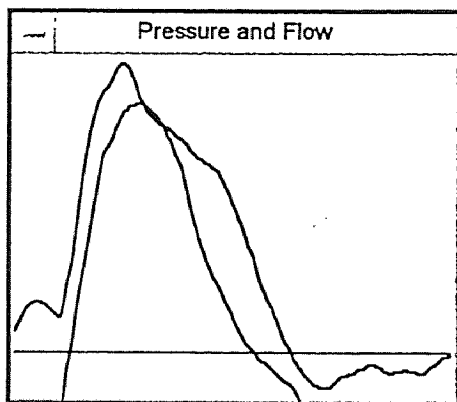
System Parameters: Heart Rate: 84.75 bpm  
 Stroke Volume: 77.41 ml  
 Cardiac Output: 6.56 L/m  
 Duration of valve cycle: 0.71 sec.  
 Forward Flow Phase: 0.45 sec. 63.16 %

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

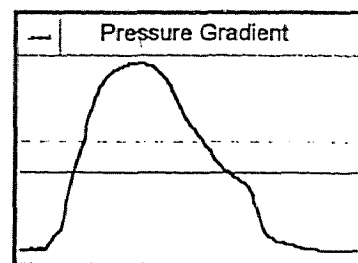
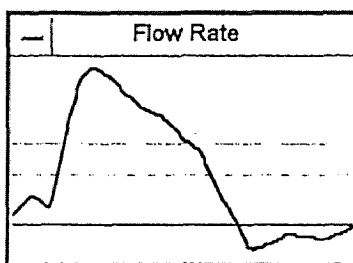
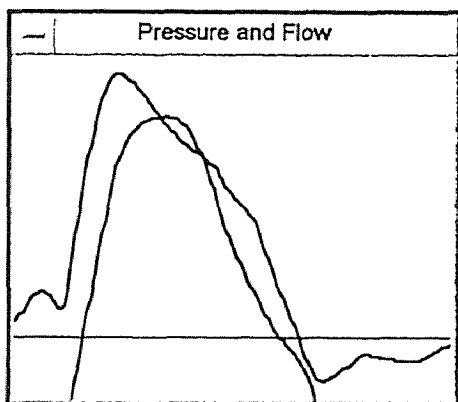
System Parameters: Heart Rate: 96.77 bpm  
Stroke Volume: 78.98 ml  
Cardiac Output: 7.64 L/m  
Duration of valve cycle: 0.62 sec.  
Forward Flow Phase: 0.41 sec. 65.56 %

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

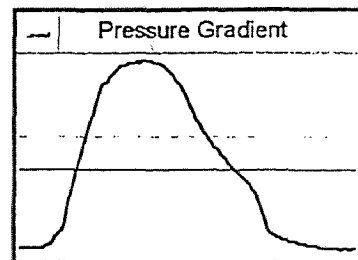
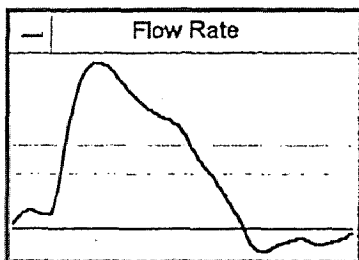
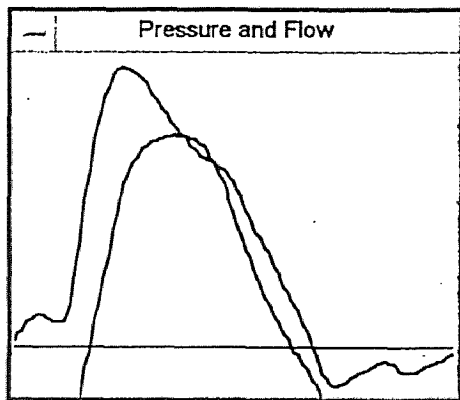
System Parameters: Heart Rate: 107.14 bpm  
 Stroke Volume: 78.40 ml  
 Cardiac Output: 8.40 L/m  
 Duration of valve cycle: 0.56 sec.  
 Forward Flow Phase: 0.38 sec. 67.88 %

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

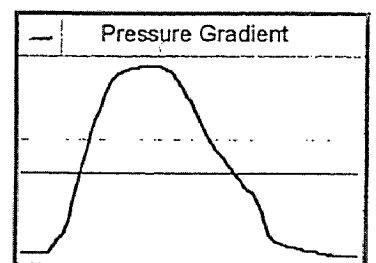
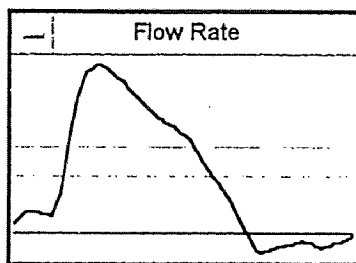
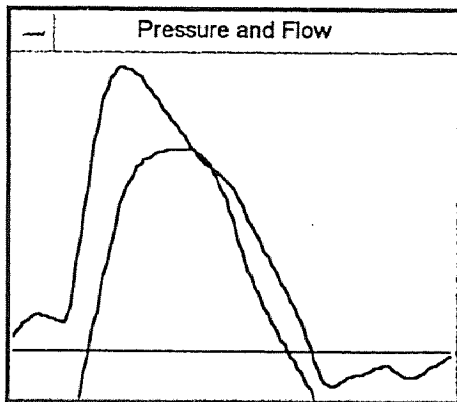
System Parameters: Heart Rate: 111.11 bpm  
 Stroke Volume: 79.47 ml  
 Cardiac Output: 8.83 L/m  
 Duration of valve cycle: 0.54 sec.  
 Forward Flow Phase: 0.37 sec. 68.94 %

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

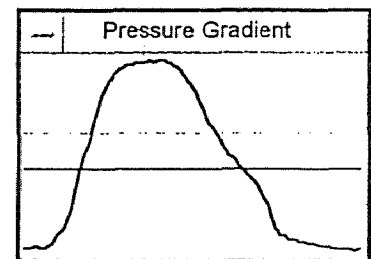
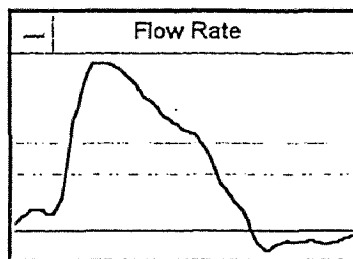
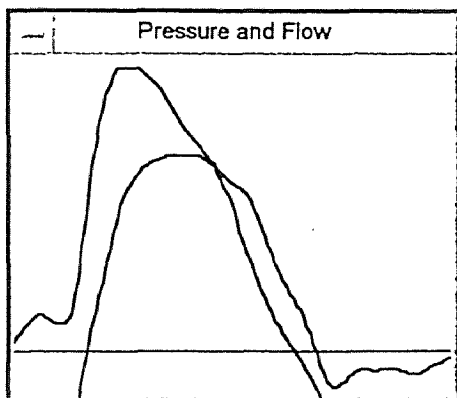
System Parameters: Heart Rate: 119.05 bpm  
 Stroke Volume: 79.52 ml  
 Cardiac Output: 9.47 L/m  
 Duration of valve cycle: 0.50 sec.  
 Forward Flow Phase: 0.35 sec. 69.35 %

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



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

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

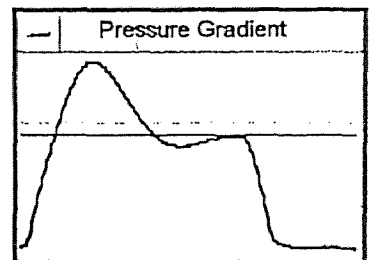
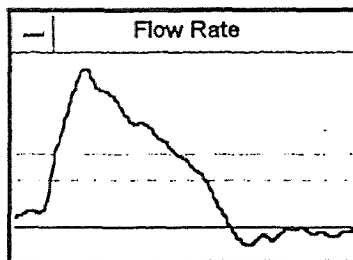
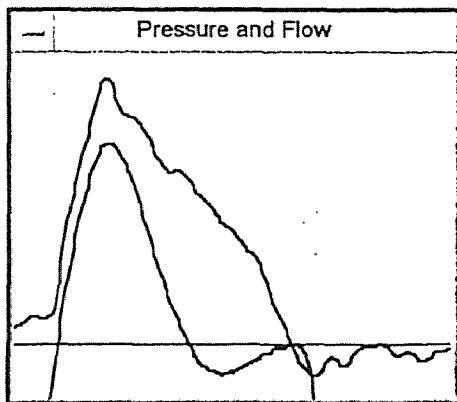
System Parameters: Heart Rate: 65.50 bpm  
 Stroke Volume: 76.83 ml  
 Cardiac Output: 5.03 L/m  
 Duration of valve cycle: 0.92 sec.  
 Forward Flow Phase: 0.60 sec. 65.28 %

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

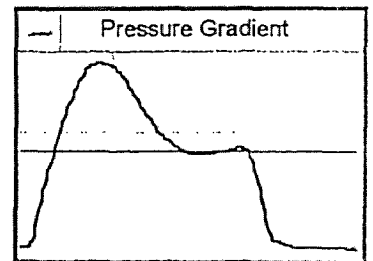
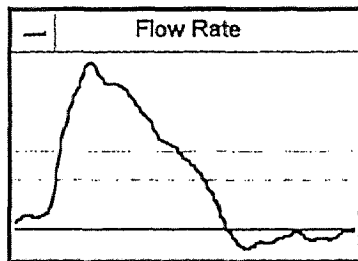
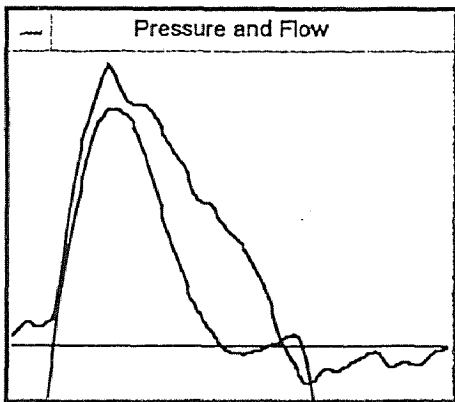
System Parameters: Heart Rate: 72.12 bpm  
 Stroke Volume: 76.25 ml  
 Cardiac Output: 5.50 L/m  
 Duration of valve cycle: 0.83 sec.  
 Forward Flow Phase: 0.52 sec. 62.31 %

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

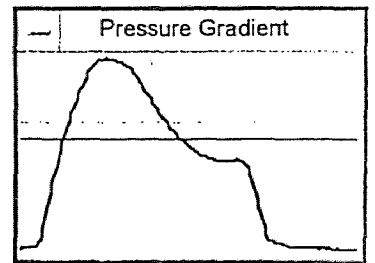
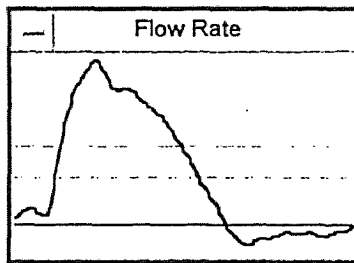
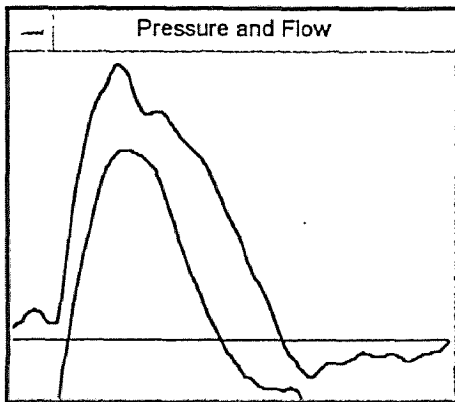
System Parameters: Heart Rate: 81.08 bpm  
 Stroke Volume: 76.08 ml  
 Cardiac Output: 6.17 L/m  
 Duration of valve cycle: 0.74 sec.  
 Forward Flow Phase: 0.46 sec. 61.88 %

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



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

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

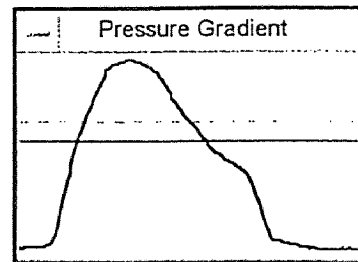
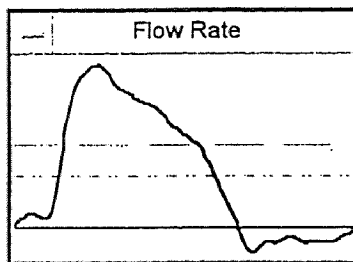
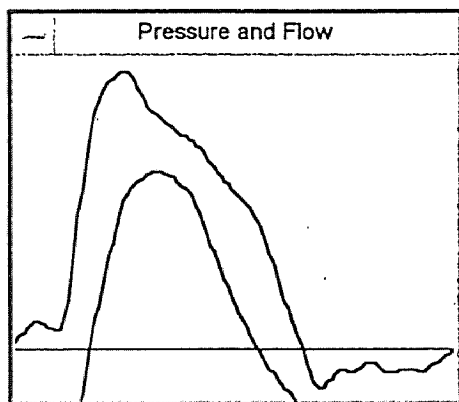
System Parameters: Heart Rate: 96.15 bpm  
 Stroke Volume: 81.03 ml  
 Cardiac Output: 7.79 L/m  
 Duration of valve cycle: 0.62 sec.  
 Forward Flow Phase: 0.41 sec. 66.01 %

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





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

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

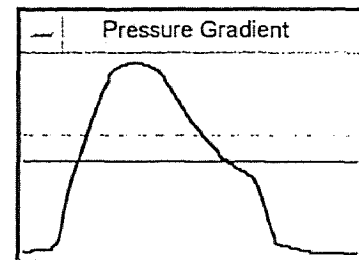
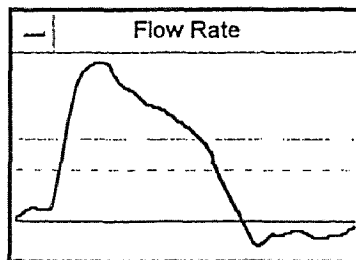
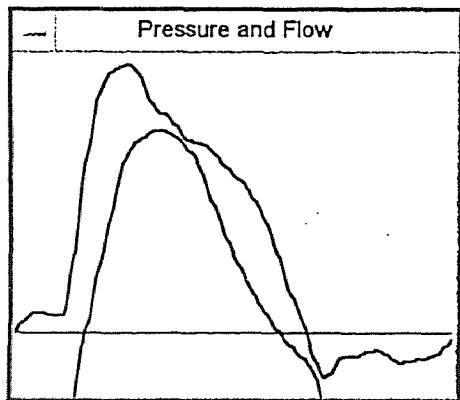
System Parameters: Heart Rate: 101.35 bpm  
 Stroke Volume: 78.73 ml  
 Cardiac Output: 7.98 L/m  
 Duration of valve cycle: 0.59 sec.  
 Forward Flow Phase: 0.40 sec. 67.11 %

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



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

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

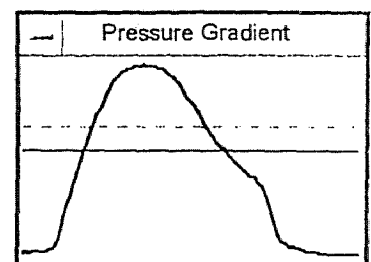
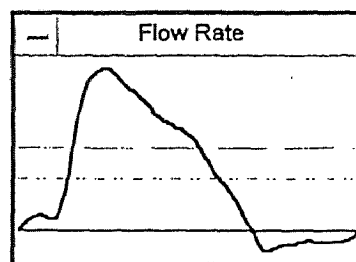
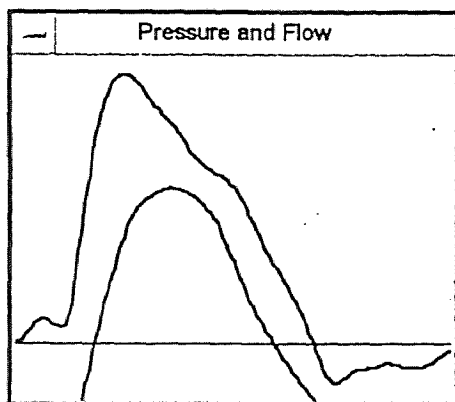
System Parameters: Heart Rate: 112.78 bpm  
 Stroke Volume: 79.66 ml  
 Cardiac Output: 8.98 L/m  
 Duration of valve cycle: 0.53 sec.  
 Forward Flow Phase: 0.36 sec. 68.18 %

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



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

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

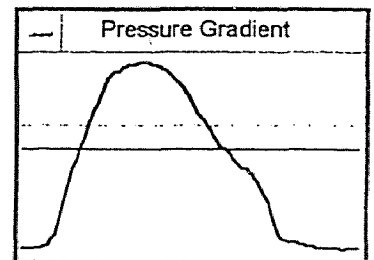
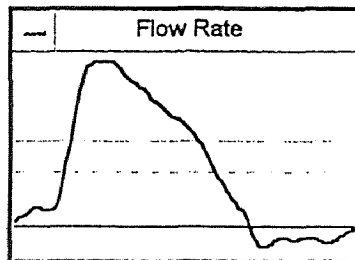
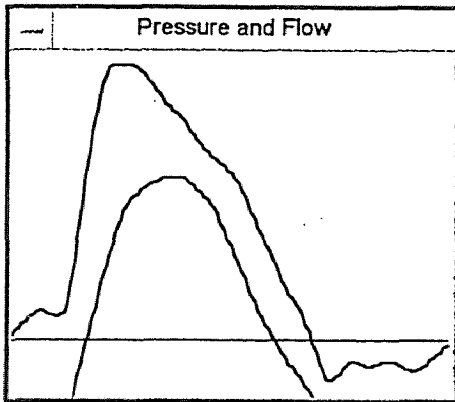
System Parameters: Heart Rate: 118.11 bpm  
 Stroke Volume: 79.43 ml  
 Cardiac Output: 9.38 L/m  
 Duration of valve cycle: 0.51 sec.  
 Forward Flow Phase: 0.35 sec. 68.50 %

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



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

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

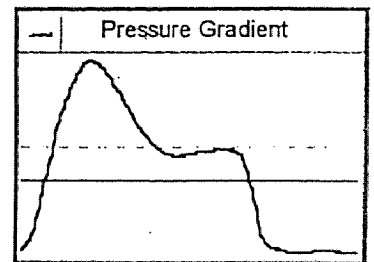
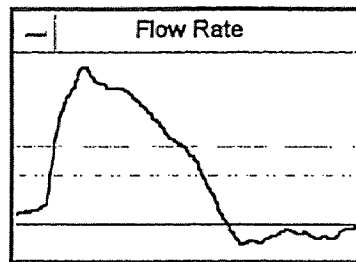
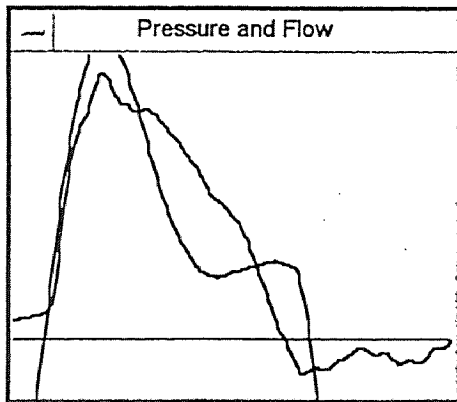
System Parameters: Heart Rate: 64.10 bpm  
 Stroke Volume: 74.30 ml  
 Cardiac Output: 4.76 L/m  
 Duration of valve cycle: 0.94 sec.  
 Forward Flow Phase: 0.58 sec. 62.11 %

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



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

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

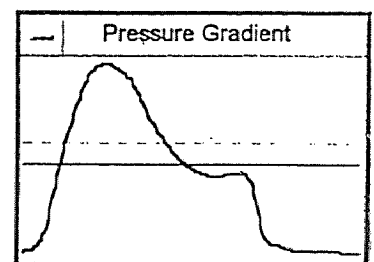
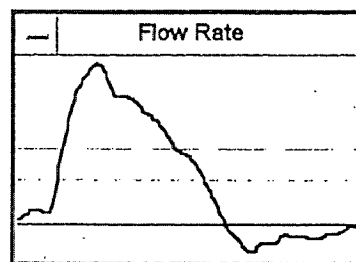
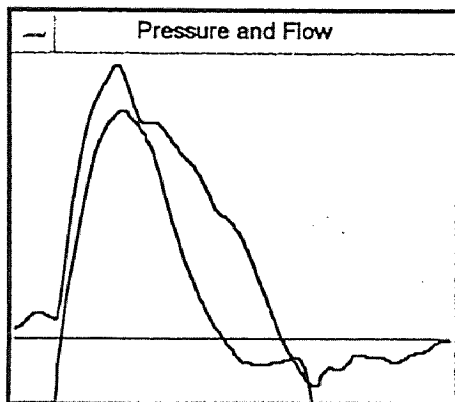
System Parameters: Heart Rate: 78.13 bpm  
 Stroke Volume: 73.25 ml  
 Cardiac Output: 5.72 L/m  
 Duration of valve cycle: 0.77 sec.  
 Forward Flow Phase: 0.47 sec. 61.17 %

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



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

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

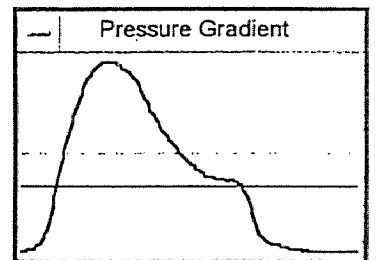
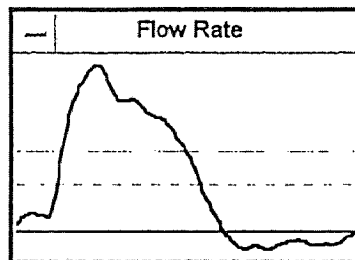
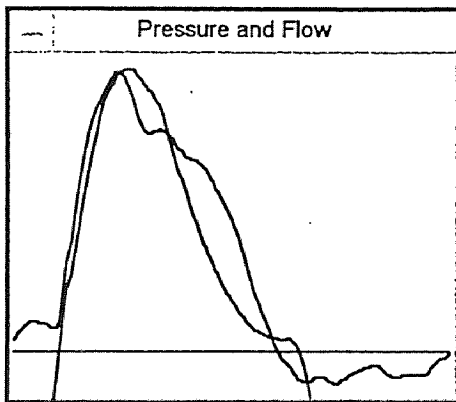
System Parameters: Heart Rate: 82.42 bpm  
 Stroke Volume: 73.59 ml  
 Cardiac Output: 6.07 L/m  
 Duration of valve cycle: 0.73 sec.  
 Forward Flow Phase: 0.44 sec. 60.89 %

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



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

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

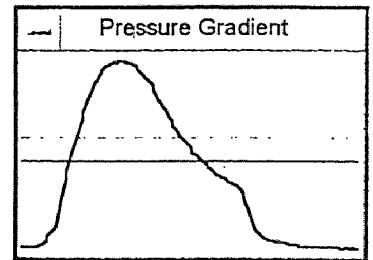
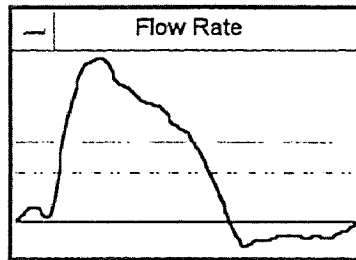
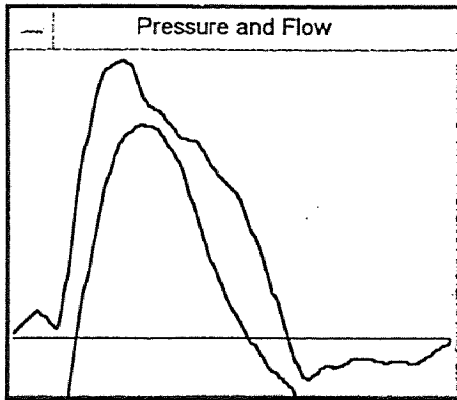
System Parameters: Heart Rate: 91.46 bpm  
 Stroke Volume: 74.98 ml  
 Cardiac Output: 6.86 L/m  
 Duration of valve cycle: 0.66 sec.  
 Forward Flow Phase: 0.41 sec. 62.96 %

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



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

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

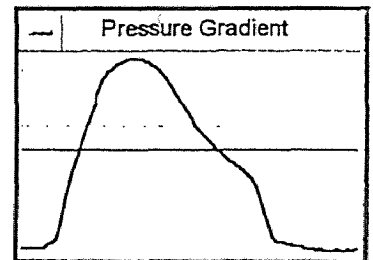
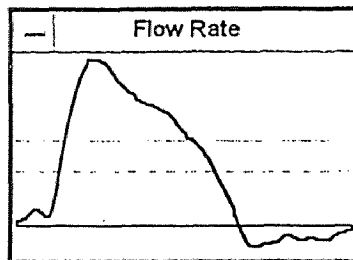
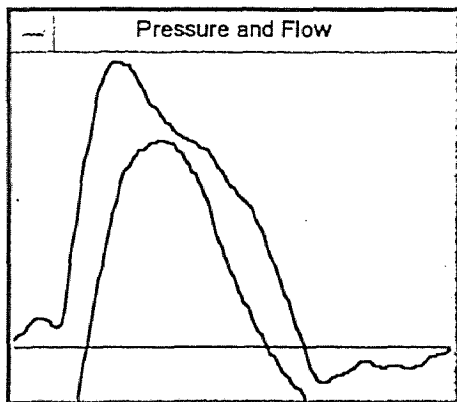
System Parameters: Heart Rate: 96.15 bpm  
 Stroke Volume: 82.70 ml  
 Cardiac Output: 7.95 L/m  
 Duration of valve cycle: 0.62 sec.  
 Forward Flow Phase: 0.42 sec. 66.67 %

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





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

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

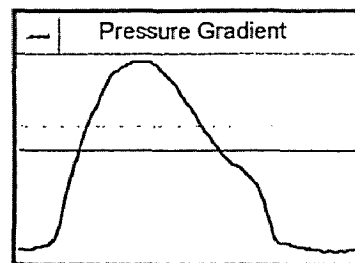
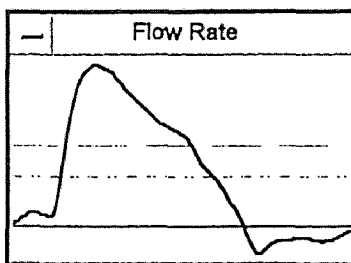
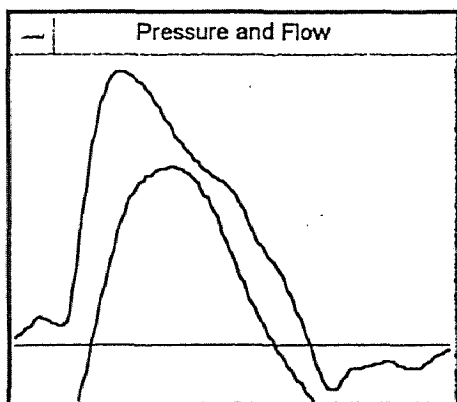
System Parameters: Heart Rate: 109.49 bpm  
 Stroke Volume: 78.02 ml  
 Cardiac Output: 8.54 L/m  
 Duration of valve cycle: 0.55 sec.  
 Forward Flow Phase: 0.37 sec. 67.65 %

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

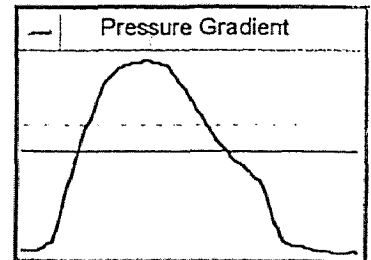
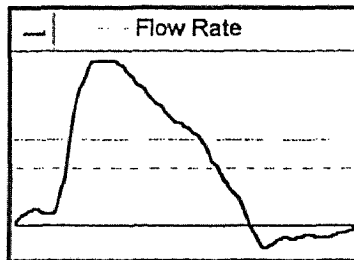
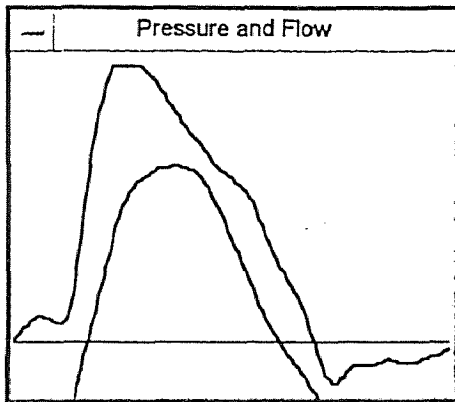
System Parameters: Heart Rate: 119.05 bpm  
 Stroke Volume: 79.00 ml  
 Cardiac Output: 9.40 L/m  
 Duration of valve cycle: 0.50 sec.  
 Forward Flow Phase: 0.35 sec. 68.80 %

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

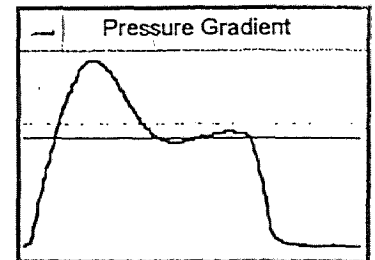
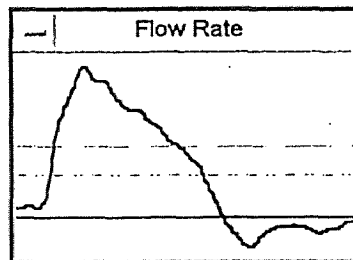
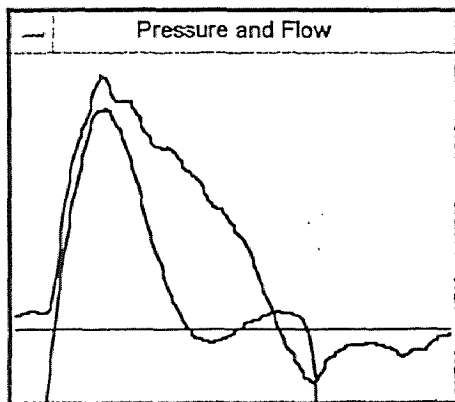
System Parameters: Heart Rate: 64.66 bpm  
 Stroke Volume: 73.45 ml  
 Cardiac Output: 4.75 L/m  
 Duration of valve cycle: 0.93 sec.  
 Forward Flow Phase: 0.56 sec. 60.62 %

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

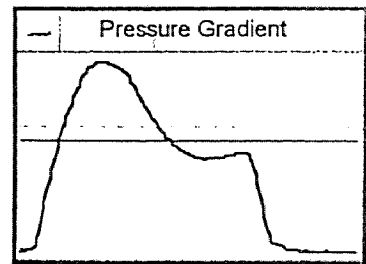
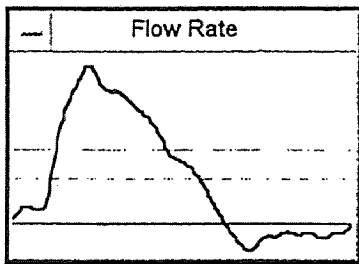
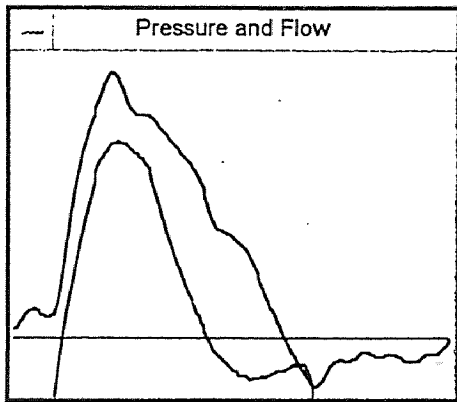
System Parameters: Heart Rate: 76.53 bpm  
 Stroke Volume: 76.78 ml  
 Cardiac Output: 5.88 L/m  
 Duration of valve cycle: 0.78 sec.  
 Forward Flow Phase: 0.49 sec. 62.83 %

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

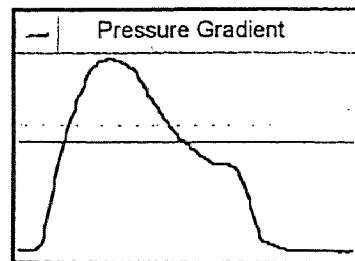
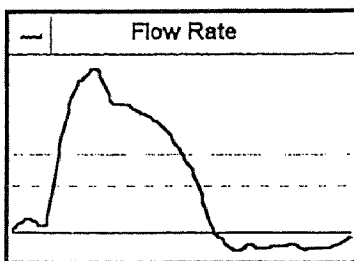
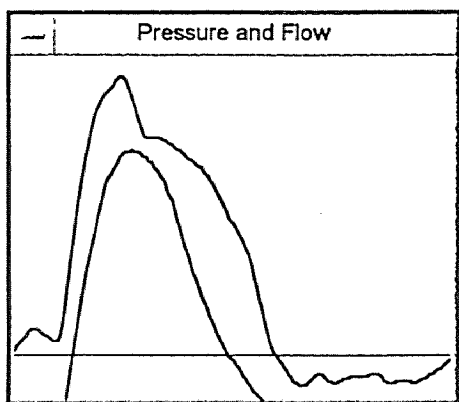
System Parameters: Heart Rate: 84.27 bpm  
 Stroke Volume: 74.38 ml  
 Cardiac Output: 6.27 L/m  
 Duration of valve cycle: 0.71 sec.  
 Forward Flow Phase: 0.43 sec. 60.23 %

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

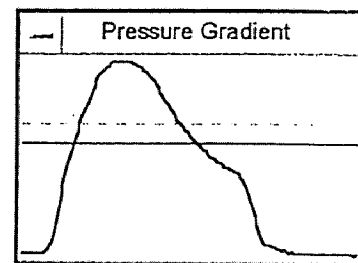
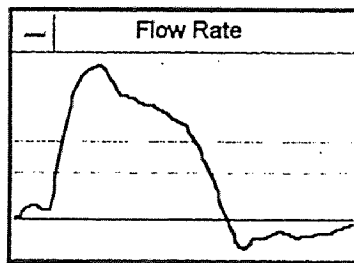
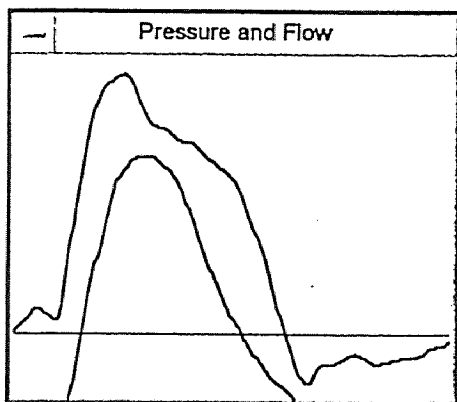
System Parameters: Heart Rate: 90.91 bpm  
 Stroke Volume: 78.16 ml  
 Cardiac Output: 7.11 L/m  
 Duration of valve cycle: 0.66 sec.  
 Forward Flow Phase: 0.41 sec. 62.20 %

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

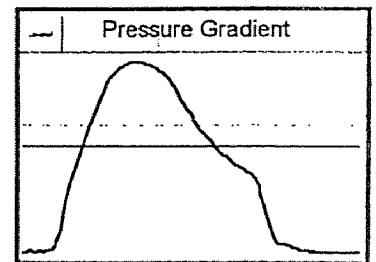
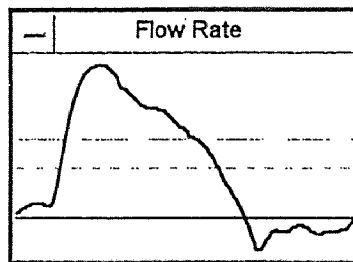
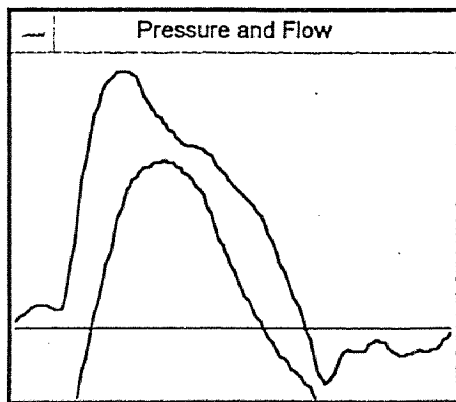
System Parameters: Heart Rate: 100.00 bpm  
 Stroke Volume: 80.23 ml  
 Cardiac Output: 8.02 L/m  
 Duration of valve cycle: 0.60 sec.  
 Forward Flow Phase: 0.40 sec. 66.89 %

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

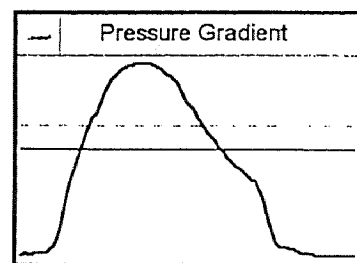
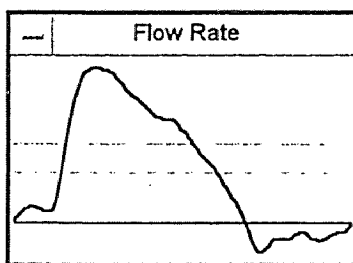
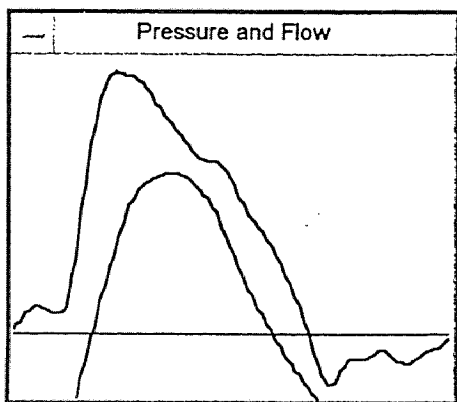
System Parameters: Heart Rate: 109.49 bpm  
 Stroke Volume: 79.92 ml  
 Cardiac Output: 8.75 L/m  
 Duration of valve cycle: 0.55 sec.  
 Forward Flow Phase: 0.37 sec. 68.38 %

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

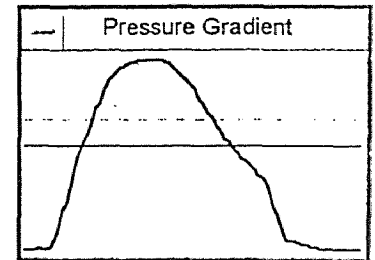
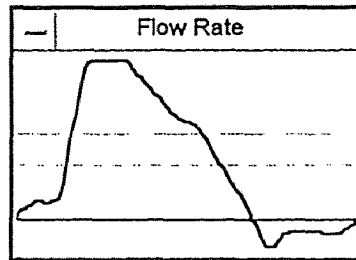
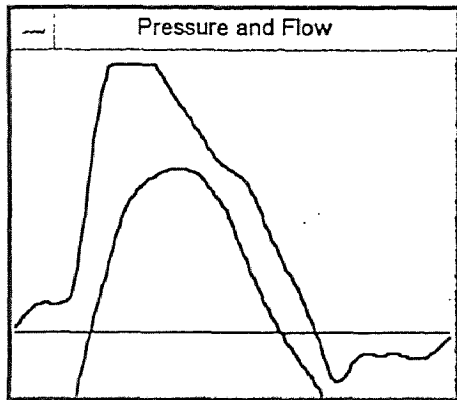
System Parameters: Heart Rate: 121.95 bpm  
 Stroke Volume: 79.26 ml  
 Cardiac Output: 9.67 L/m  
 Duration of valve cycle: 0.49 sec.  
 Forward Flow Phase: 0.34 sec. 68.85 %

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

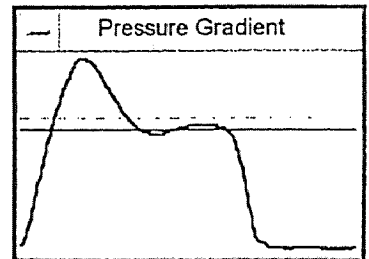
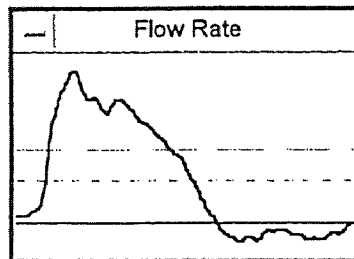
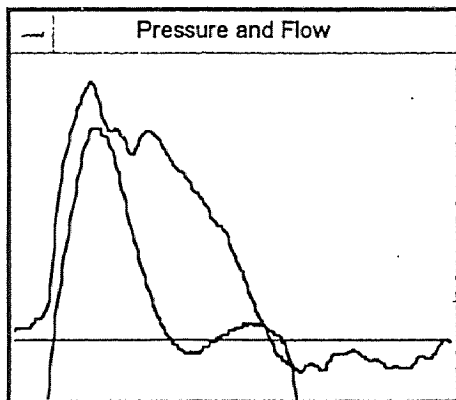
System Parameters: Heart Rate: 60.24 bpm  
Stroke Volume: 70.70 ml  
Cardiac Output: 4.26 L/m  
Duration of valve cycle: 1.00 sec.  
Forward Flow Phase: 0.59 sec. 58.96 %

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

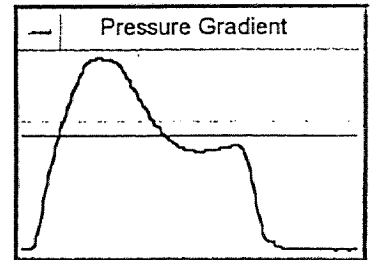
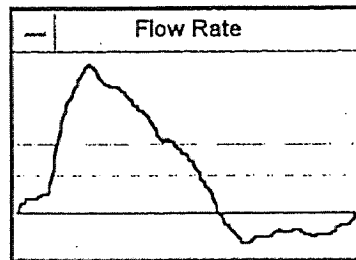
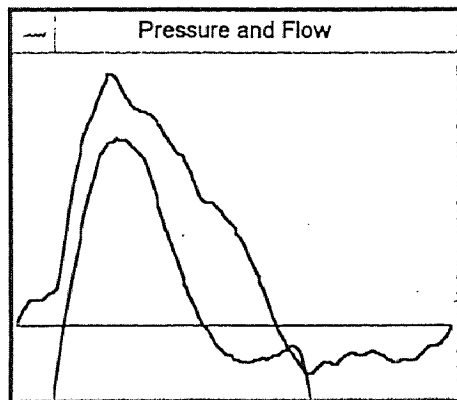
System Parameters: Heart Rate: 74.26 bpm  
 Stroke Volume: 74.12 ml  
 Cardiac Output: 5.50 L/m  
 Duration of valve cycle: 0.81 sec.  
 Forward Flow Phase: 0.48 sec. 60.00 %

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

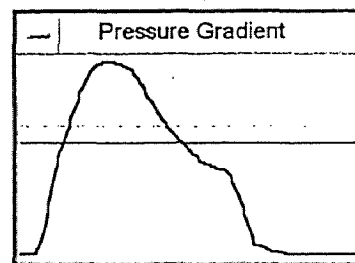
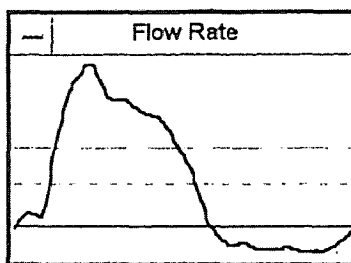
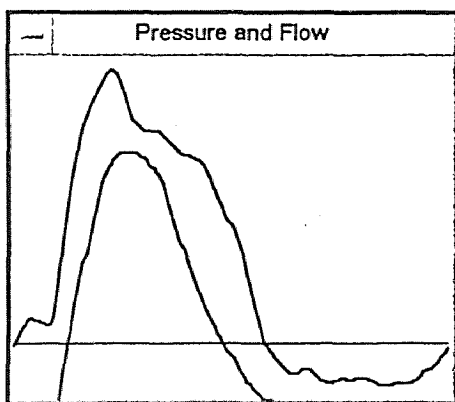
System Parameters: Heart Rate: 86.21 bpm  
 Stroke Volume: 74.32 ml  
 Cardiac Output: 6.41 L/m  
 Duration of valve cycle: 0.70 sec.  
 Forward Flow Phase: 0.40 sec. 58.05 %

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

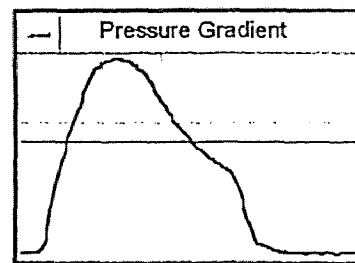
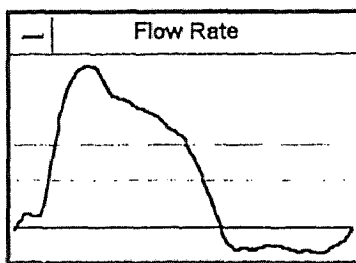
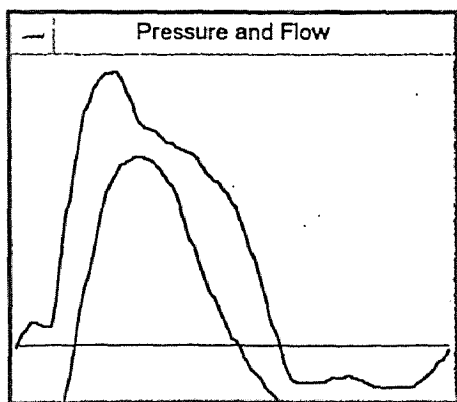
System Parameters: Heart Rate: 93.17 bpm  
 Stroke Volume: 76.56 ml  
 Cardiac Output: 7.13 L/m  
 Duration of valve cycle: 0.64 sec.  
 Forward Flow Phase: 0.39 sec. 60.49 %

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

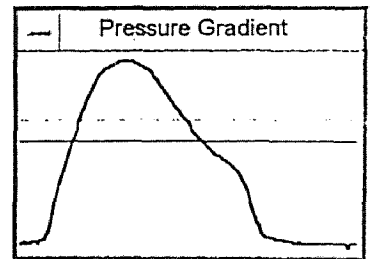
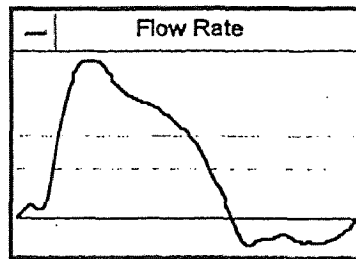
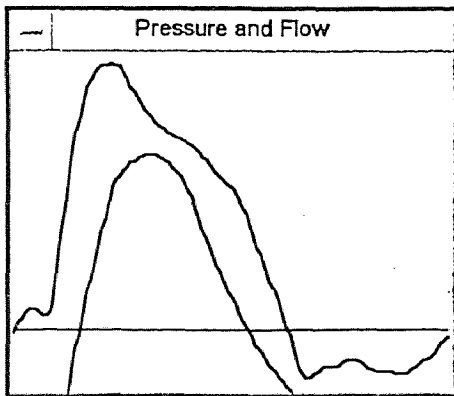
System Parameters: Heart Rate: 97.40 bpm  
 Stroke Volume: 79.60 ml  
 Cardiac Output: 7.75 L/m  
 Duration of valve cycle: 0.62 sec.  
 Forward Flow Phase: 0.38 sec. 62.50 %

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

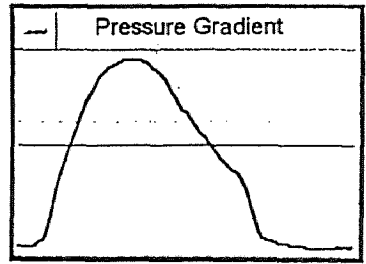
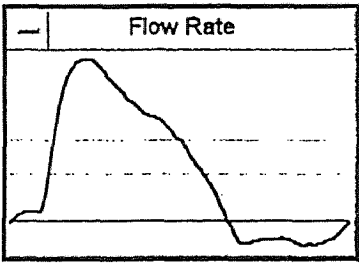
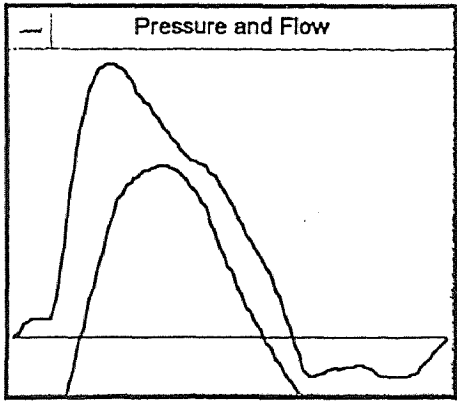
System Parameters: Heart Rate: 110.29 bpm  
 Stroke Volume: 77.44 ml  
 Cardiac Output: 8.54 L/m  
 Duration of valve cycle: 0.54 sec.  
 Forward Flow Phase: 0.35 sec. 63.97 %

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

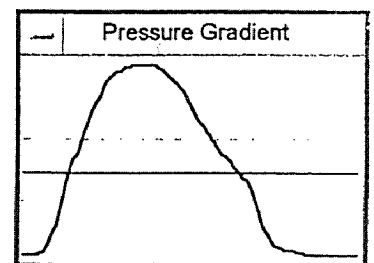
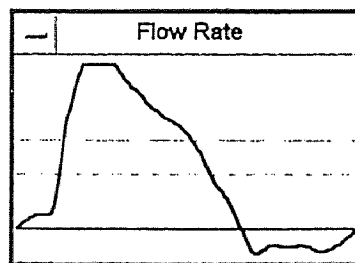
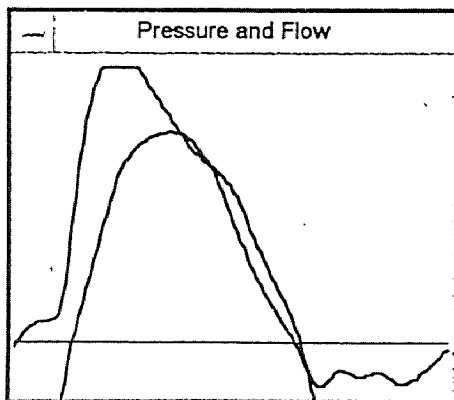
System Parameters: Heart Rate: 119.05 bpm  
 Stroke Volume: 78.56 ml  
 Cardiac Output: 9.35 L/m  
 Duration of valve cycle: 0.50 sec.  
 Forward Flow Phase: 0.33 sec. 65.35 %

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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