Viscoelastic Impedance Adapter User Manual

Product Number: VIA7991

ViVitro Labs Viscoelastic Impedance Adapter System
Designed and Distributed by ViVitro Labs Inc., BC, Canada

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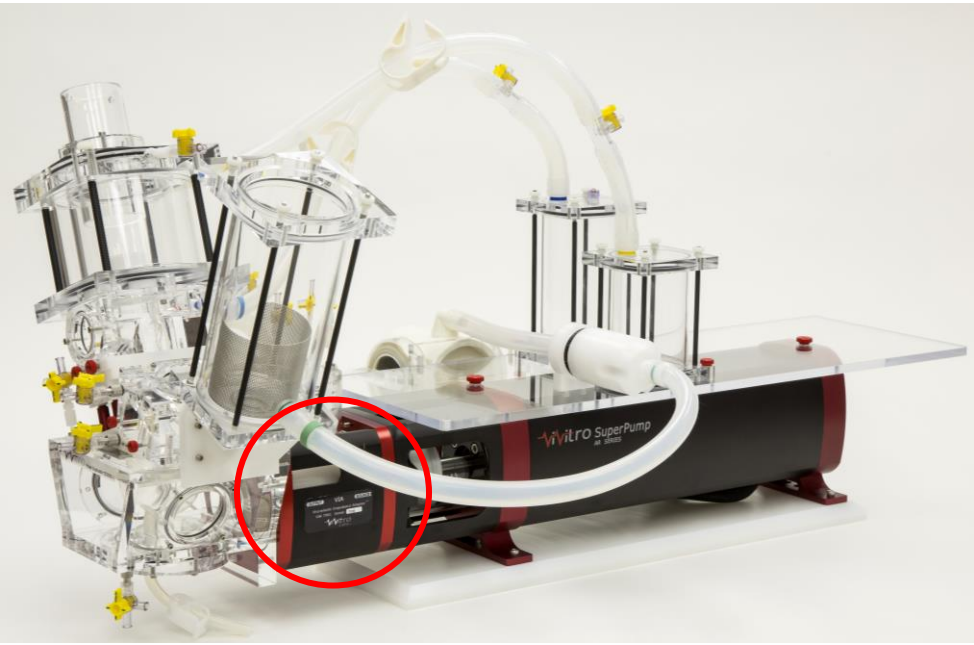
1 INTRODUCTION

The Viscoelastic Impedance Adapter (VIA) is used to produce more physiological ventricular pressures in a Pulse Duplicator system. It consists of a fixed resistive element and two adjustable compliance chambers, simulating ventricular viscoelastic behavior. In prosthetic heart valve studies, ventricle pressures with physiological pressure change in time (dp/dt) can be achieved using the VIA. Without a VIA, Pulse Duplicator systems tend to generate high frequency pressure and flow oscillations during closure of the aortic and mitral valve. The influence of the VIA on pressure and flow waveforms has been described in a publication by Jennings et al.[a]

The VIA is installed at the interface between a flow source and a load such as a ViVitro Labs SuperPump (10647) and Model Left Heart (SD2001-1).



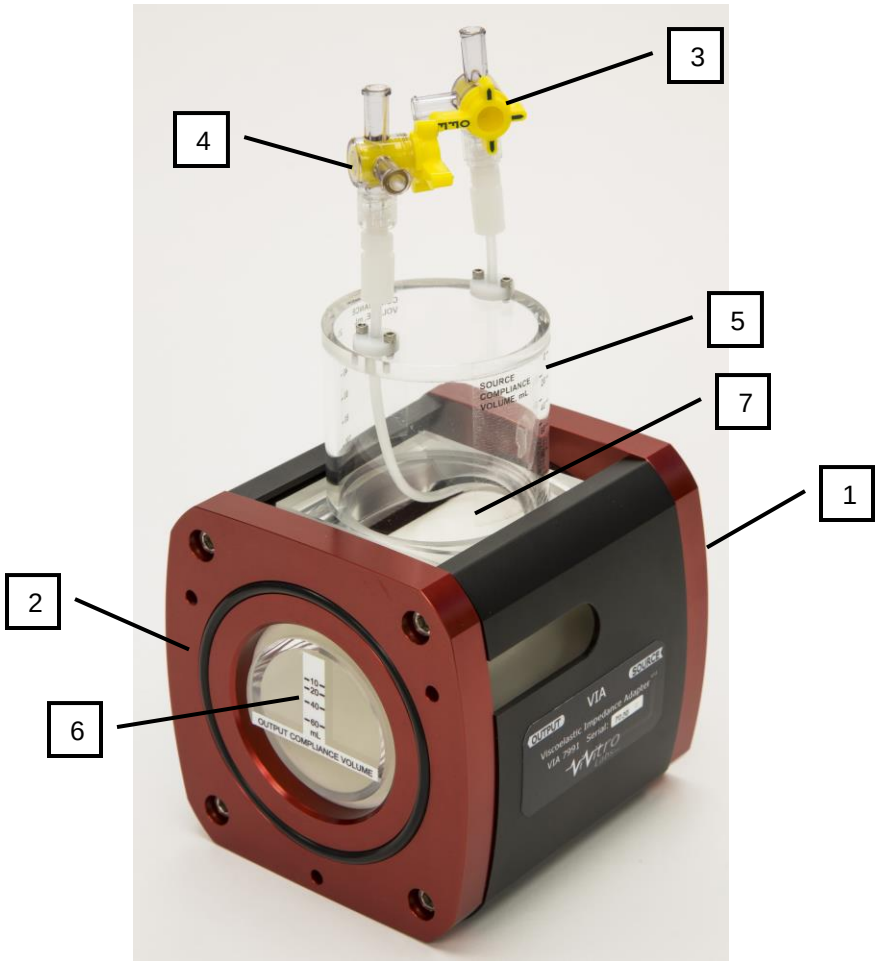
A Pulse Duplicator with a VIA installed

[a] LM, Butterfield M, Walker PG, Watterson KG and Fisher J. The influence of ventricular input impedance on the hydrodynamic performance of bioprosthetic aortic roots in vitro. *J Heart Valve Dis.* Vol10 No. 2, 269-275, 2001.

2 FEATURES

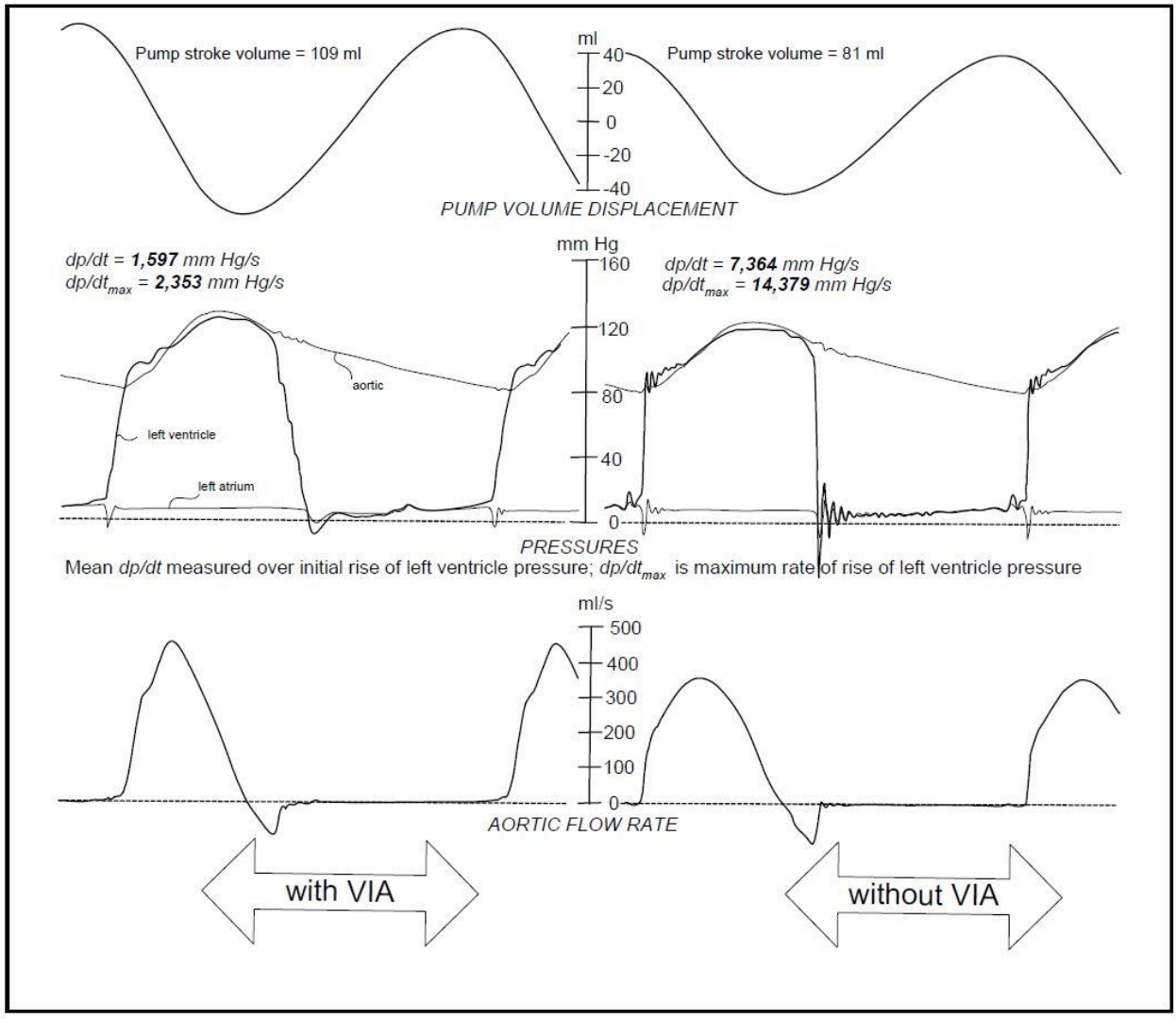
The key features of the VIA are as follows:

1. Source: Interface between the SuperPump hydraulic chamber and VIA
2. Output: Interface between VIA and load (e.g., Model Left Heart)
3. Source volume stopcock
4. Output volume stopcock
5. Source compliance chamber (labelled with air volume markings)
6. Output compliance chamber (labelled with air volume markings)
7. Fixed resistive element



3 PERFORMANCE

The performance of the VIA will be dependent on the pump, load, valves and operating conditions. Pump stroke volumes and pressures, both with and without the VIA between the pump and the load, are shown below.



The test parameters for the data shown above are as follows:

VIA Source Compliance Volume	120 mL
VIA Output Compliance Volume	50 mL
Aortic Valve	29mm Tri-Leaflet Pericardial
Mitral Valve	29mm Bileaflet Mechanical
Cycle Rate	70 BPM
Cardiac Output	5 LPM
Waveform	Sine 40% Systolic

Test Fluid	Glycerin-Saline, Viscosity: 3.2

4 UNPACKING

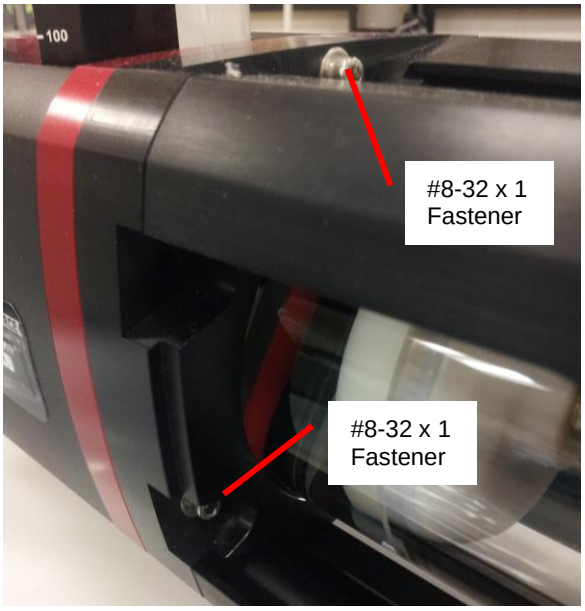
Inspect the shipping container for damage. If there is any evidence of damage contact the carrier, initiate a damage claim and inform ViVitro Labs. Unpack the VIA, hardware, and accessories in preparation for installation.

Mounting hardware and accessories supplied with the VIA include:

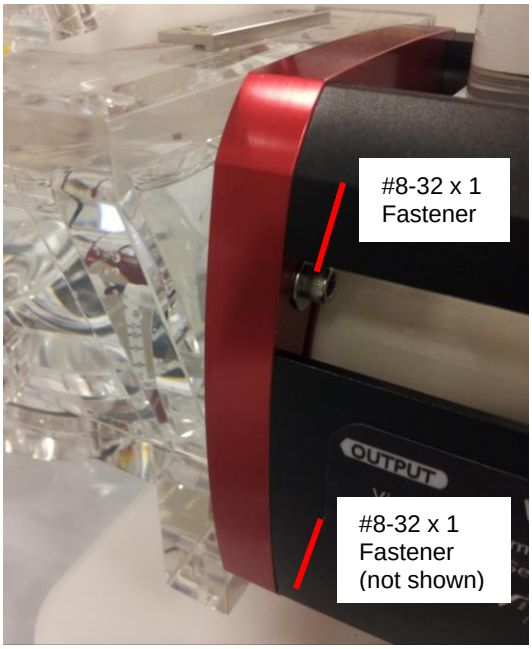
- 2x 3-Way Stopcocks
- 3x #8-32 x 1 inch Socket Head Cap Screws, 316 Stainless Steel
- 3x #8 Flat Washers, 316 Stainless Steel

5 INSTALLATION

1. Orient the VIA as shown below. The Source end of the VIA should be bolted to the SuperPump using three #8-32 x 1 inch socket head cap screws and #8 flat washers. Refer to the decal on the side of the VIA for the location of the Source end.



2. The Output end of the VIA should be bolted to the hydraulic chamber of the Pulse Duplicator using three #8-32 x 1 inch socket head cap screws and #8 flat washers.



3. Attach the two stopcocks provided to the luer fittings on the top of the VIA.

4. Fill the VIA with distilled water. This can be done by injecting fluid at the Output port with the Source stopcock open to release air. A bacteriostat such as Cosmocil CQ

/Biguanide20[b] or Proclin[c] can be used to prevent biological growth. Be sure that the bacteriostat selected will not harm any of the wetted materials of the VIA (Acrylic, Polycarbonate, Delrin, Nylon, Polyethylene, Stainless Steel, Viton). Saline is not recommended for use in the VIA as it can damage the resistive element and the SuperPump piston seal.

6 ADJUSTMENT

The VIA consists of one fixed resistive element and two adjustable compliance chambers. Using a syringe, a measured volume of air at atmospheric pressure can be inserted or withdrawn from the Source and Output stopcocks shown above to adjust system compliance. The Source air volume can be adjusted from 0 to 120 mL. The Output air volume can be adjusted from 0 to 60 mL. Air volumes can be set to simulate different Viscoelastic properties.

When adjusting the compliance volumes of the VIA, take into consideration the two effects:

1. When air is added to the VIA, the attached Model Left Heart ventricle will decrease in volume by the same amount as the volume added. To prevent ventricle collapse, an equal volume of fluid should be removed from the hydraulic chamber to obtain a neutral relaxed ventricle volume.

[b] http://www.lotioncrafter.com/Biguanide-20.html
[c] http://www.sigmaaldrich.com/catalog/product/sial/48171u?lang=en&region=CA

2. As the compliant air volumes in the VIA are increased, the transmitted stroke volume of the SuperPump will be reduced due to compression of the compliant air volume.

As compliance volume is added to the VIA, the high frequency pressure oscillations in the fluid system are attenuated.

7 MAINTENANCE

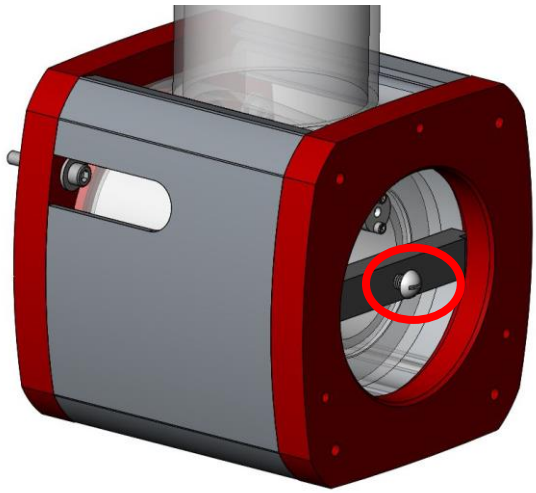
To clean the VIA, remove the four #10-32 x 4 inch bolts from the red anodized end plate. Disassemble the aluminum and acrylic components. Handle the acrylic chamber with care as it is fragile.

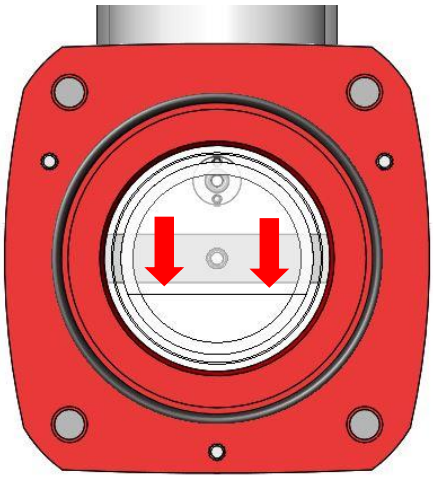
DO NOT clean the cylindrical white porous resistive element with anything but fresh water. Contaminants may block the pores of the element and alter its resistive properties.

DO NOT use alcohol, abrasives or solvents to clean the acrylic components of VIA as it will damage the material and could compromise the seal of the VIA.

Clean all other components with warm soapy water.

When re-assembling, ensure the tension of the white plastic screw is adjusted to prevent movement of the Output compliance and that the Output compliance chamber is level (see images below).





8 VISCOELASTIC IMPEDANCE ADAPTER SPECIFICATIONS

Fixed resistance	200 c.g.s. units
Source Compliance Air Volume	0-120 mL (Syringe adjustable)
Output Compliance Air Volume	0-60 mL (Syringe adjustable)
Total Liquid Volume	500 mL (with zero compliance air volumes)
Working Fluid	Distilled water (bacteriostat optional)
Materials	• Acrylic • Delrin • Nylon • Polycarbonate • Polyethylene • Stainless Steel • Viton
Length	11.7cm (4.61in)
Width	11.2cm (4.41in)
Height	23.0cm (9.06in)
Weight	1kg (2.2lbs)

Mounting Flange	**Inside Ø cm (in)**	**Bolt Pitch Circle Ø 3 holes, Equally Spaced.**
Source	7.37 (2.90)	10.23 (4.026) Threaded #8-32
Output	5.97 (2.35)	10.23 (4.026) Clearance, Ø 0.45 (Ø 0.177)

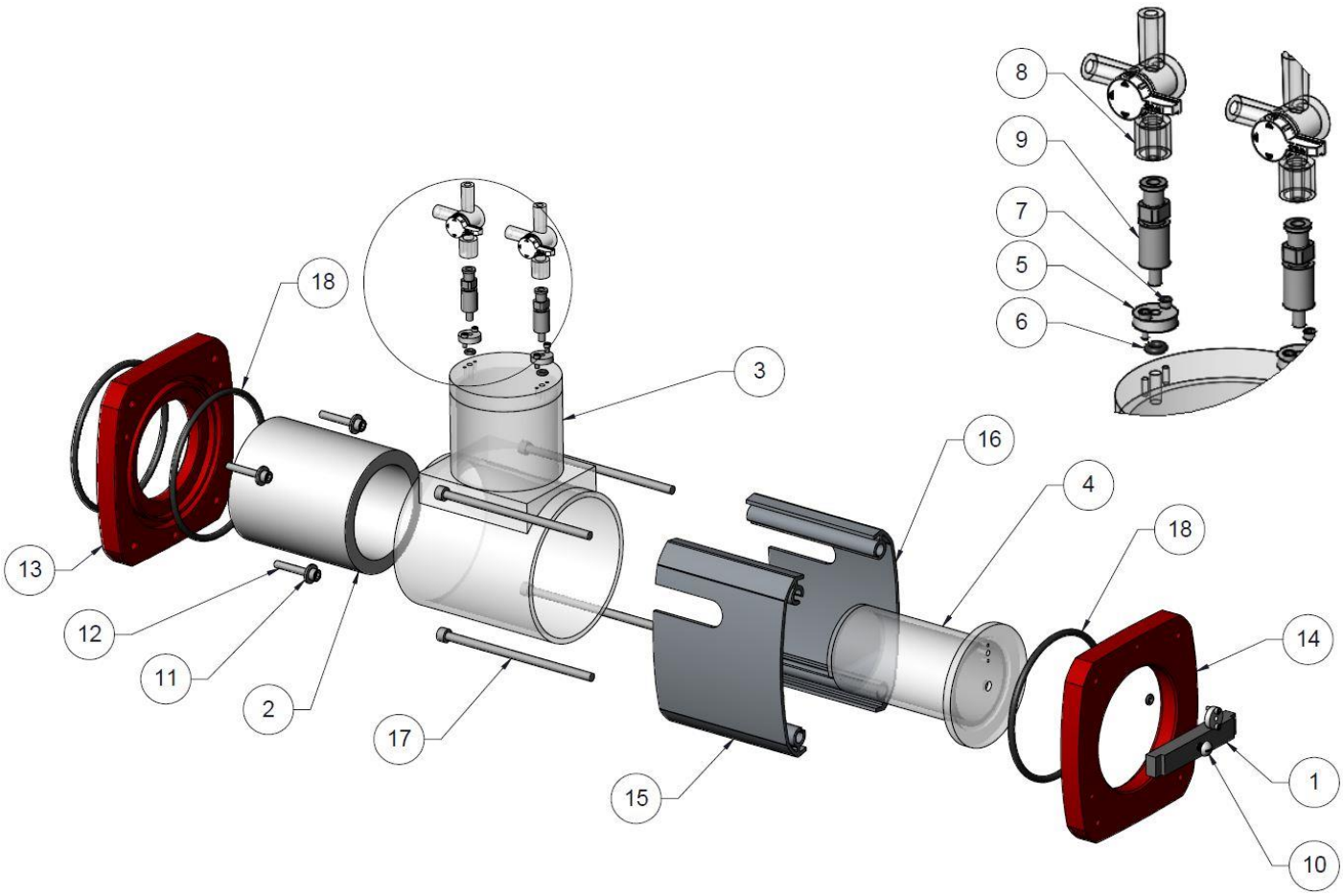
9 SERVICE AND WARRANTY

Should you experience problems with this product, contact ViVitro Labs at techsupport@vivitrolabs.com or (250) 388-3531 and we will give you directions for obtaining service.

ViVitro Labs warrants all parts of its own manufacture to be free from defects in material and workmanship under normal use and service in a suitable environment for the period of one year after delivery. ViVitro Labs is limited to repairing, or at its option, replacing without charge, any part which in the sole opinion of ViVitro Labs proves to be defective within the scope of this warranty. Unauthorized modifications or tampering of the apparatus voids the warranty.

UNDER NO CIRCUMSTANCES SHALL VIVITRO LABS BE LIABLE TO THE BUYER OR USER FOR ANY SPECIAL INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, EXPENSES, LOSSES, OR DELAYS HOWEVER CAUSED.

10 APPENDIX A - PARTS LIST



ITEM NO.	PART NO.	DESCRIPTION	QTY.
1	VIA002	VIA CLAMP	1
2	VIA012	VIA, RESISTANCE TUBE	1
3	05797	VIA, BODY AND CHIMNEY	1
4	05810	VIA, COMPLIANCE TUBE ASSEMBLY	1
5	SDA008.1	CATHETER CLAMP	3
6	18029	O RING DASH 006	3
7	HCM090	#2-56 x 1/4" SS SHCS	6
8	SDA009.1	3-WAY LUER STOPCOCK	2
9	SDA010.1	LUER LOK ADAPTER & HIGH PRESSURE CONNECTING HOSE	2

ITEM NO.	PART NO.	DESCRIPTION	QTY.
10	05816	10-32 X 3/4" NYLON	1
11	HCM071.1	#8 FLAT WASHER SS	3
12	HCM089	#8-32 x 1" SHCS SS 316	3
13	12049	VIA, OUTLET MOUNTING FLANGE	1
14	12051	VIA, INLET MOUNTING FLANGE	1
15	12479	VIA, EXTRUSION - LEFT	1
16	12112	VIA, EXTRUSION - RIGHT	1
17	12052	#10-32 x 4" SHCS SS	4
18	18024	O-RING DASH 236	3

APPENDIX B - COMPLIANCE MODELING

Tissue compliance is simulated in the Pulse Duplicator by using contained air volumes. These air volumes are adjustable and cover a physiologic range for simulating left ventricle, aortic root and systemic arterial compliance.

Compliance is defined as the ratio of volume change to pressure difference as follows:

$$\text{Compliance} = \frac{\Delta V\left[cm^3\right]}{\Delta P\left[mmHg\right] \bullet 1333.2\left[\frac{\left[\frac{Dynes}{cm^2}\right]}{mmHg}\right]}$$

Where:
ΔV = change in contained air volume in mL
ΔP = change in pressure (mmHg) caused by volume change ΔV
$\Delta P = P_2 - P_1$ [mmHg]
P_1 = initial static pressure in mmHg
P_2 = final static pressure in mmHg
Conversion factor: 1 mmHg = 1333.2 $\frac{Dynes}{cm^2}$