

ABIOMED, Inc.

BVS[®] 5000

Quick Reference Guide

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These are recommended guidelines. For complete instructions please refer to the Atrial/Arterial Cannulae Instructions For Use, Blood Pump Instructions for Use, and the Operator's Manual.

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6. ***Opening a Stuck Inflow Valve***

In rare cases, the inflow valve of the BVS[®] Blood Pump will not open during the priming process. This is because surface tension on the adjacent leaflets of the inflow valve assembly causes them to stick together. Applying additional pressure across the valve during priming will separate these leaflets, and the pump is safe to use after the valve has been opened. If the inflow valve opens freely during the priming process, proceed to Step 4. If the inflow valve does not open, the following steps may be used to open a stuck valve.

- a. Raise the inverted pump so that the inflow valve is at the same level as the fluid level in the cardiotomy reservoir.
- b. Place a clamp on the outflow of the blood pump.
- c. Connect the stopcock of an IV pressure bag to the luer connector of the cardiotomy reservoir using either a length of male-to-male IV tubing or a suitable combination of tubing and luer adapters.
- d. Clamp off the line used to prime the reservoir. Ensure all other ports on the reservoir are capped and sealed.
- e. With the stopcock open in all directions, pressurize the bag using the bulb until the stuck valve opens. It may require 250 to 300 mmHg to open the valve.
- f. After the valve has opened, the pressure bag may be deflated and the pump can be de-aired in the usual manner.
- g. Visually verify that the valve opens and closes normally when circulating the priming solution.

(Over)

4

Check for Air Bubbles

1. Rotate the blood pump back and forth to evacuate any trapped air. Carefully inspect both valve sinus areas and the inflow and outflow lines at the blood pump (gentle tapping may help release bubbles).
2. After bubbles have been evacuated, allow the BVS to circulate the priming solution for approximately 5 minutes. This should eliminate microbubbles and permit a check for proper BVS operation. Do not expect flows >3.0 L/min during the priming procedure.
3. Stop pumping when ready for patient connection.
(A scrub nurse must perform the next steps.)
4. Clamp the blood pump and silicone tubing with the line clamps. **(Fig.2)**
5. Remove the silicone tubing by rolling it off. **(Fig.3)**
Once the silicone is separated from the blood pump, the tubing is ready to be connected to the primed cannula. **(Fig.4)***

Tip:

Keep the priming circuit intact and in the sterile field until the case is completed. This saves time setting up another circuit if de-airing or a second blood pump is required.

5

Priming a Second Blood Pump

1. To avoid developing a potential air or vapor lock, drain all fluid from the reservoir inflow tubing before priming the second blood pump by one of these methods:
 - a. disconnect the inflow tubing from the reservoir and empty the solution into a basin.
 - b. lower the reservoir while a person in the sterile field holds up the inflow tubing, forcing the fluid back into the reservoir.
2. Add 500 cc's of additional priming solution to reservoir.
3. Repeat STEP TWO through STEP FOUR.

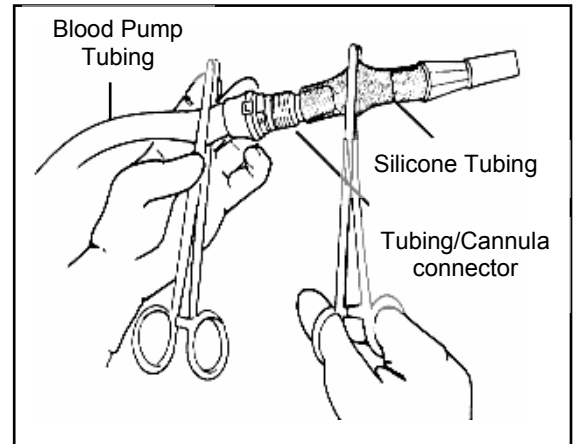


Figure 2

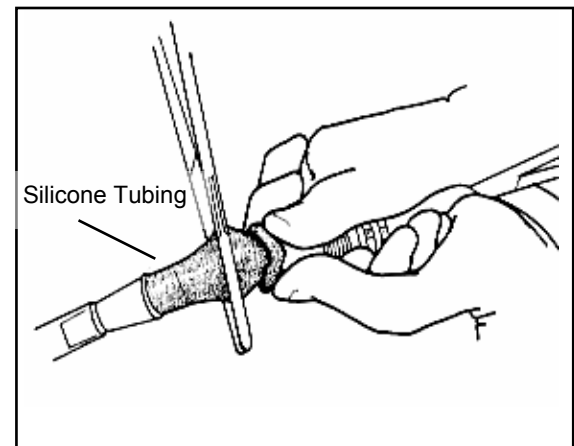


Figure 3

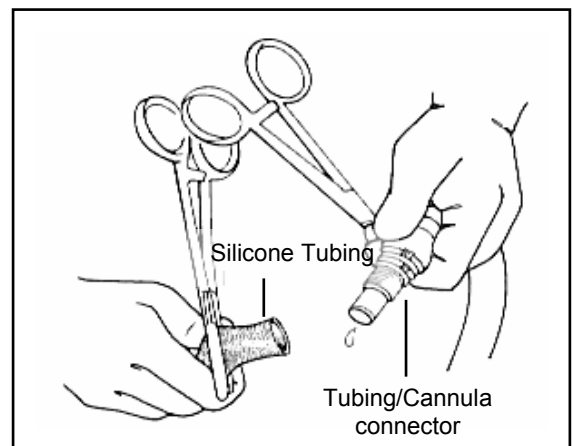


Figure 4

***Refer to Surgeon's Guide to Cannulation & Start-Up Guide**

1

Remove Contents of Blood Pump Set

Set Includes:

- 1 – Blood Pump
- 1 – Atrial & Arterial Cannula
- 2 – Accessory Pack
- 1 – Tubing Cover Set

Note: Both the arterial & atrial cannulae are individually packaged and are located beneath the blood pump. Each package includes a cannula, tunneling bullet, cannula restraint and tie wraps.

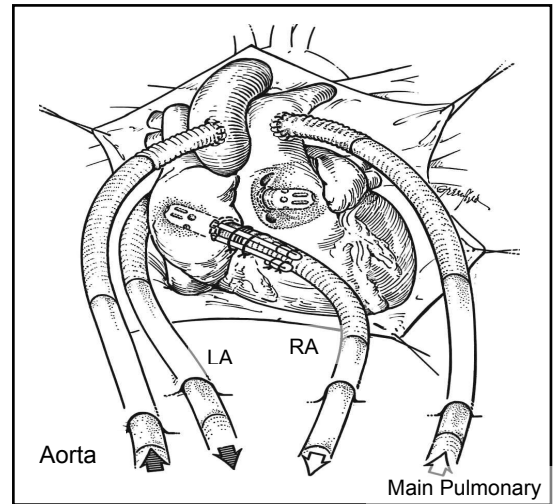


Figure 2

3

Externalize Cannula

1. Attach tunneling bullet to cannula and thread distal tip of bullet with heavy suture or umbilical tape.
2. To externalize, tunnel the cannula through the skin just below the ribs.
3. Care should be taken to assure, with chest closure, cannulae do not cross over each other or occlude graft sites. **(Fig.2)**
4. Remove bullet tip and slide cannula restraint onto cannula (slotted end facing out). **(Fig.3)**

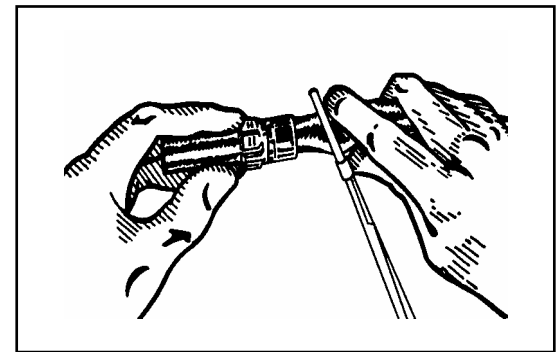


Figure 3

5

Atrial Cannulation Placement and Suturing Technique

Note: If biventricular support is required or anticipated, determine left atrial cannulation site first!

Possible Sites for Cannulation

Left Atrium

- Inter-atrial groove
- Dome (between aorta & SVC)
- Atrial Appendage

Right Atrium

- Mid-Free Wall (preferred)
- Atrial Appendage

1. Place pledgeted double purse string sutures around the desired cannulation site. **(Fig.4)**
2. Pericardial patches or large *Teflon*™ pledgets and 2-0 or 3-0 polypropylene sutures are recommended.

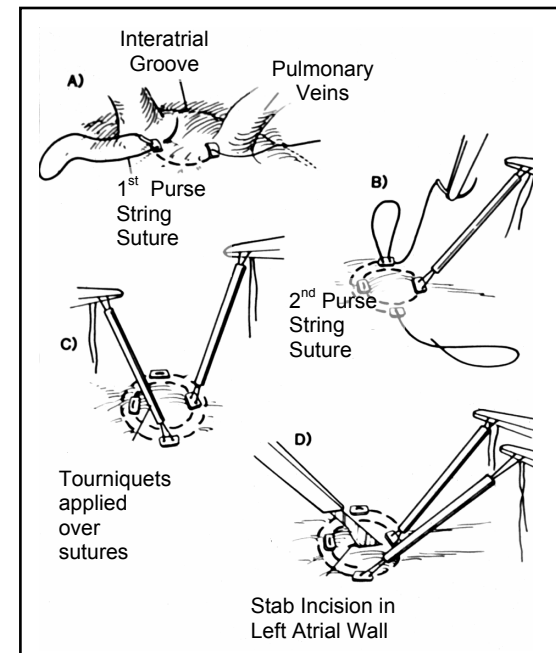


Figure 4

(over)

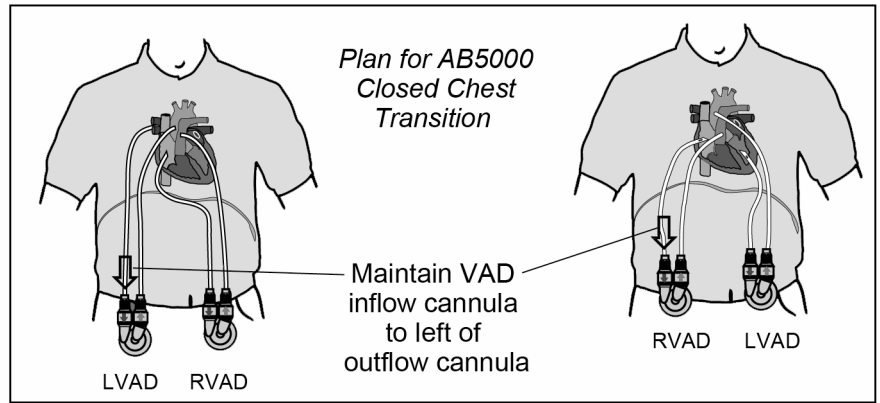


Figure 1

2

Select Cannula Exit Location

1. Externalize cannula before cannula implantation. (**Fig.1**)
2. Plan cannula exit sites during BVS implant to assist possible change to AB5000™ Ventricle.
3. Cannulae should exit patient parallel to each other, just below ribs, and spaced approximately 4.5 cm apart to match AB5000 Ventricle.

4

Select Cannulation Locations

1. The most common locations are listed in table below.
2. Inflow refers to blood from the patient into the VAD and outflow refers to blood from the VAD back to the patient.
3. When using the Hemashield® graft, bevel Hemashield® outflow graft at 30 degrees; 3-0 or 4-0 polypropylene sutures are recommended.

Support Side	Location	Advantage	Cannula Size
Left-Inflow	Left Atrium – Interatrial Groove	Most common for left atrial placement	42F – 32F
Left-Inflow	Right Superior Pulmonary Vein	Ease of insertion and removal	32F
Left-Inflow	Left Ventricular Apex	Maintains blood flow across prosthetic valves and LV Chamber Off-loads left ventricle	42F – 32F
Left-Outflow	Anterolateral aspect of the Ascending Aorta	N/A	10mm
Right-Inflow	Right Atrium Mid Free Wall	Most common for right-side support	42F – 32F
Right-Outflow	Pulmonary Artery	N/A	10mm

6

Securing Atrial Cannula

1. Reduce cardiopulmonary bypass flow to fill atrium.
2. Make stab incision inside purse string, dilate the opening and insert the cannula to at least the 2 cm depth marker. **(Fig.4)**
3. Tighten purse strings and secure the tourniquets. **(Fig.5)**
4. Perform Valsalva maneuver to fill atrial cannula.

7

Arterial Cannulation

Sites for Cannulation

Left Ventricular Assist	Right Ventricular Assist
Ascending Aorta	Main Pulmonary Artery

1. Trim graft to fit. DO NOT PRECLOT, graft is blood and air tight.
2. Perform end-to-side anastomosis using a running suture (3-0 or 4-0 polypropylene). **(Fig.6)**
3. Consider using surgical glue at arterial site to reduce bleeding.
4. Release clamp and allow cannula to fill with blood.
5. Massage or lightly tap graft to remove air.
6. Backflush cannula and clamp.

8

Connection of Blood Pump

1. Cannulae should be clamped and cannula restraints should be in place.
2. Remove silicone adapters. Connect sterile end of blood pump tubing with the cannula (arrows on the tubing identify the atrial and arterial connections).
3. Irrigate the junction with fluid and press the tubing connector into the cannula as illustrated. **(Fig.7)**
4. Inspection junction for air and purge as required.
5. Repeat procedure with the other cannula.
6. Release clamps prior to initiation of support.
7. DO NOT secure the cannula restraints or the tie wraps until after support has been initiated and there is no air in the system.

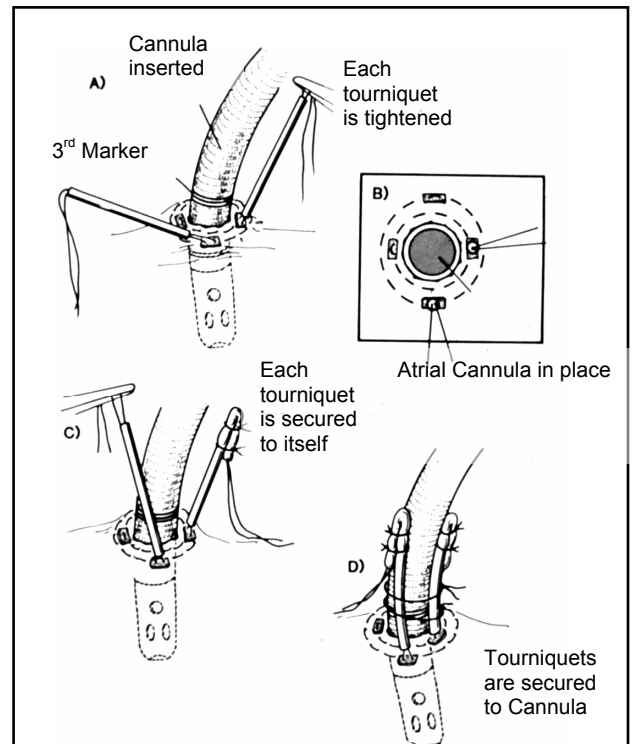


Figure 5

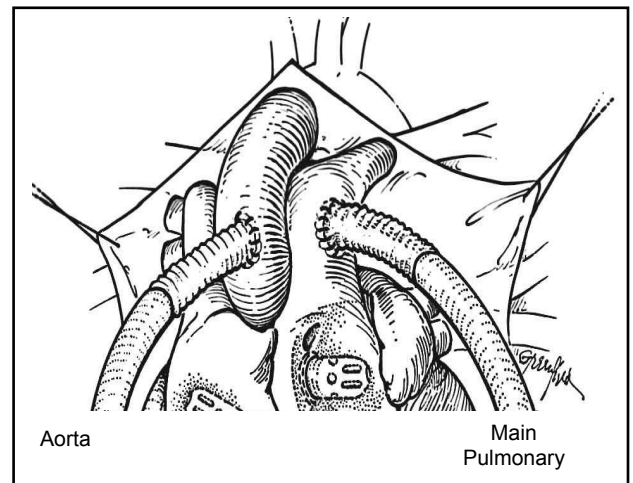


Figure 6

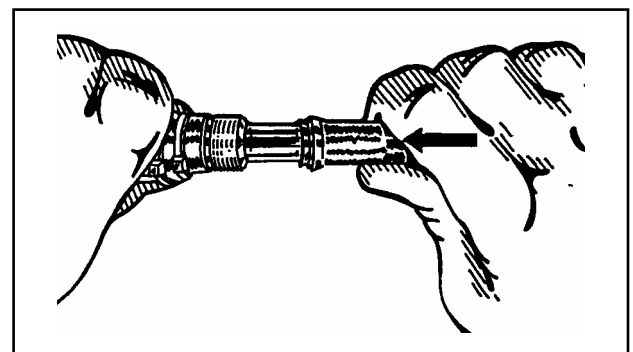


Figure 7

9

Cannulation Considerations

1. Assess cannula placement.
 - Before closing the chest, record hemodynamics and VAD operating parameters.
 - Approximate chest and note any changes in hemodynamics and VAD operating parameters; if changes are noted, assess cannula positioning.
 - TEE should be used to evaluate cannula inflow with target velocity of < 400 cm/sec.
2. Ensure that restraints are properly secured.

ABIOMED® BVS® 5000
Surgeon's Start-Up Guide

1

Place the patient in Trendelenberg position.

2

Submerge cannulation sites with blood or saline to reduce the Possibility of air entry at the cannulation sites.

3

Place the blood pump at the level of the atrium.

4

Reduce CPB flow to obtain filling pressure of >10mmHg. Filling the Atrium will reduce the possibility of air entrapment.

5

Place open tubing clamp at atrial cannula / blood pump connection and immediately clamp the tubing if air is observed in the system.

6

The foot pump is used to initiate flow in a slow controlled manner, and reduces the likelihood of air embolus.

7

If air enters the blood pump, it may be necessary to disconnect the blood pump tubing from the patient and reconnect it to the priming circuit to remove the air. Reconnect to patient when the system is free of air.

ABIOMED® BVS® 5000

Perfusionist's Start-Up Guide

1

Turn the Blood Pump OFF by depressing the soft key twice within 13 seconds.

2

Open the rear cover and move the transfer lever up to the horizontal position. Pull out the foot pump and place on the floor.

3

Once the patient's cannulae are connected to the blood pump tubing, flow should be initiated using the foot pump. Use of the foot pump permits a slow, controlled start-up and reduces the likelihood of air embolus.

4

Depress the foot pump slowly and allow it to return to its original position. Continue to pump slowly, simultaneously checking for air in the system.

5

If air enters the blood pump, it may be necessary to disconnect the blood pump from the patient and reconnect it to the priming circuit to remove the air. Reconnect to patient when the system is free of air.

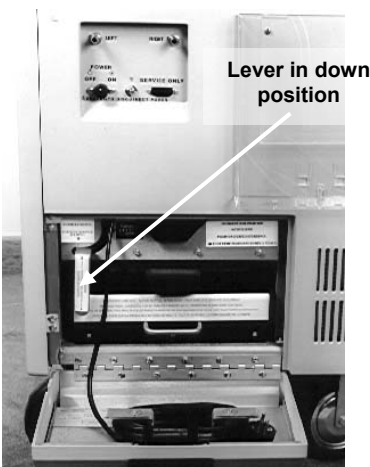
6

When the system is free of air, place the foot pump back into the console slot.* Pull the transfer lever down to a vertical position to engage console pump.

7

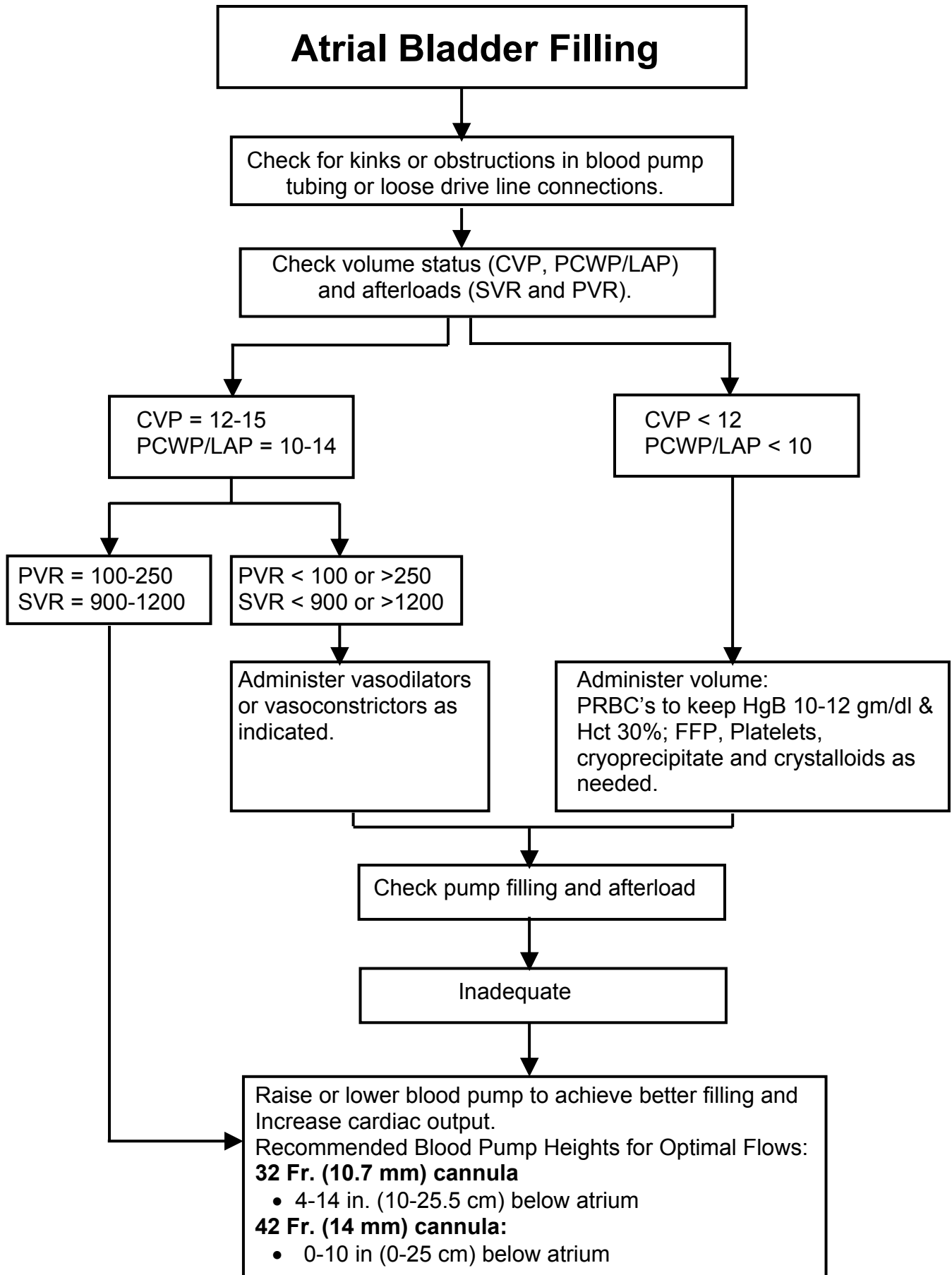
Depress the ON key on the front of the console to begin automatic pumping.

IMPORTANT: The transfer lever must be down or the console will not operate. If the lever is not down, the message: **WARNING: FOOT PUMP HANDLE IS DISLODGED** will appear on the console display.



* The foot pump should remain out until the surgeon is certain a second system is not required. The transfer lever can be moved down even with the foot pump out.

ABIOMED® BVS® 5000
Troubleshooting inadequate Atrial Bladder Filling



ABIOMED® BVS® 5000

Guide to Clinical Management

Anticoagulation

- Initiate heparin therapy as soon as bleeding is controlled (chest tube output < 100cc/hr with normal coagulation factors), **but always within 24 hours.** Draw baseline ACT at bedside and give heparin bolus to achieve ACT 180-200 seconds. Follow with heparin infusion to maintain ACT at 180-200 seconds.
- If flows are less than 3 liters per minute or the patient is in AFIB or VFIB, increase ACT to 300 seconds.
- If resistance to heparin is noted (increased need for heparin to maintain ACT level), ATIII deficiency is possible. Consider administration of FFP.
- **Do not** turn heparin off for line placement, removal of IABP or when returning to OR for procedures or explantation of device.

Helpful Clinical Hints

- Thermodilution Cardiac Output and Continuous Cardiac Output will be inaccurate on Bi-VAD or RVAD support.
- Height of blood pumps may need to be adjusted independently for patients on biventricular support to maintain balanced flows and avoid pulmonary edema. It is not unusual for right flow to exceed left flow in the early support period. If right flow exceeds left, watch for signs of pulmonary edema or right heart failure, but there is no need to intervene if patient is asymptomatic.
- Maintain blood pumps 0-10 inches (0-25 cm) below the level of patient's atrium when using the 42 Fr. (14 mm) cannula and 4-14 inches (10-35.5 cm) when using the 32 Fr. (10.7 mm) cannula.
- Maintain filling pressures on the high side of normal (CVP 12-15mmHg; PCWP/LAP 10-14mmHg).*
- Maintain SVR between 900-1200 dynes per second and PVR between 100-250 dynes per second.*
- For patients on univentricular support, watch for signs of failure of the unassisted ventricle.
- Do not apply direct heat or cold to blood pumps. Use tubing covers as needed.
- **No Chest Compressions or Pre-cordial thumps.** Consider placing sign at head of bed.
- To assist PA catheter insertion in a patient on RVAD or BiVAD (support), decrease flow through the right blood pump by turning on the weaning mode. Decrease flow to approximately 2 liters to fill the patient's ventricle and allow the catheter to pass into the pulmonary artery. Once catheter is in place, return to full support by turning off the weaning mode.
- When assisting with TEE, reduce flow to approximately 2 liters to fill the ventricle in order to assess ventricular wall motion. Reduce flow by utilizing the weaning mode as outlined above. Upon completion of TEE, return to full support by turning off the weaning mode.

* **All hemodynamic parameters are recommended guidelines only, please refer to normal values set by your institution.**

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