

CLINICAL
REFERENCE
MANUAL

Circulatory Support Systems

ABIOMED®

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Contents

Chapter 1 Indications and Contraindications.....	1
Indications for Use	1
Contraindications for Use	2
Chapter 2 Introduction to the Systems	3
Overview.....	3
Consoles.....	4
AB5000™ Console.....	5
BVS® 5000i (and 5000) Console	6
BVS® 5000r Console	7
Cannulae	8
Description.....	8
Atrial Types.....	8
Arterial Types.....	9
Blood Pump	10
Chapter 3 How the Blood Pump Works	11
Operation	11
Blood Pump Cycles	12
Diastole.....	12
Systole.....	12
Example	12
Effects of Change in Preload	12
Effects of Change in Afterload	13
Optimizing Filling and Flow.....	13
Volume	13
Blood Pump Height	13
Precautions with Height Adjustment.....	14
Causes of Inadequate Filling of Atrial Bladder	14
Physiological	14

Mechanical.....	15
Causes of Inadequate Emptying of Atrial Bladder	16
Physiological.....	16
Mechanical.....	16
Bi-Ventricular Flow	16
Flow Imbalance.....	16
Options for Balancing Flows.....	17
Chapter 4 Priming the Blood Pump	18
Preparation.....	18
Console Start-Up.....	20
Priming	20
Priming a Second Blood Pump.....	23
Chapter 5 Implantation	25
Atrial (Venous) Cannulation Sites.....	25
Right.....	25
Left	25
Ventricular Cannulation	26
Atrial Cannulation Techniques.....	27
Arterial Cannulation Sites	28
Right.....	28
Left	28
Arterial Cannulation (Grafting) Techniques	28
General Guidelines.....	28
Placing the Arterial Cannula (Graft).....	29
Connecting the Blood Pump to the Cannulae.....	29
Initiating Support	30
Assessing Support.....	31
Bi-Ventricular Support.....	32
Chapter 6 Patient Management.....	33
Achieving Hemostasis.....	33

Excessive / Uncontrolled Bleeding	34
Hemodynamic Management	35
Pharmacologic Therapy	36
Inotropes	37
Sedation	37
Pain Management	37
Antibiotics	37
Anticoagulation Management	38
ACT Monitoring	38
PTT Monitoring	39
Anti-Thrombin III	39
Decreasing the Risk of Thrombus Formation	39
Renal Management	40
Pulmonary Management	41
Arrhythmia Management	41
Ventricular Fibrillation and Ventricular Tachycardia	41
Atrial Fibrillation	42
Bradycardia or Asystole	42
Intra-Aortic Balloon Pump (IABP)	43
Nutrition	43
Cannulation Site Care	43
Patient Activity	44
Patient Transport Within the Hospital	44
Chapter 7 Weaning from Support	45
Procedure	46
Assessing Recovery	46
Chapter 8 Explantation	47
Preparation	47
Procedure	47
Chapter 9 Transporting the Patient	49

ABIOMED® HUB Program	49
Guidelines.....	50
Special Considerations For Helicopter and Fixed-Wing Transports.....	52
Appendix A.....	53
Appendix B.....	55

List of Figures

Figure 1: AB5000™ Console	5
Figure 2: AB5000™ Control Panel at a Glance	5
Figure 3: BVS® 5000i (and 5000) Console	6
Figure 4: BVS® 5000i (and 5000) Control Panel at a Glance	6
Figure 5: BVS® 5000t Console.....	7
Figure 6: BVS® 5000t Control Panel at a Glance.....	7
Figure 7: Cannulae.....	8
Figure 8: Blood Pump	10
Figure 9: Priming Circuit	19
Figure 10: Clamping the Tubing.....	22
Figure 11: Removing the Silicone Connector	22
Figure 12: Disconnecting the Priming Circuit.....	23
Figure 13: CSS Support During Ventricular Fibrillation.....	42
Figure 14: Synchronous Native Ejections	45
Figure 15: Native Ejections During Weaning	46

List of Tables

Table 1: Console Features and Specifications.....	4
Table 2: Target Hemodynamics.....	35
Table 3: Vasoactive Medications.....	36

About This Manual

This *Clinical Reference Manual* is a training aid intended to accompany ABIOMED® Circulatory Support System (CSS) educational offerings. It is also a guide for the healthcare professional to use when employing CSS therapy.

Patient management directives in this *Clinical Reference Manual* are suggested guidelines. Each medical professional must determine the suitability of these guidelines based on the needs of the individual patient.

IMPORTANT GUIDELINE: Prior to use, refer to the appropriate ABIOMED® Operator's Manuals or Instructions for Use.

Chapter 1

Indications and Contraindications

Indications for Use

ABIOMED[®] Circulatory Support System (CSS) therapy is intended to treat patients suffering from reversible ventricular dysfunction. Typical patients have undergone successful cardiac surgery and subsequently developed low cardiac output, or have suffered from acute cardiac disorders leading to hemodynamic instability. (For additional information, see *Appendix B, Acute Cardiogenic Shock Intraoperative Strategies*.)

The intent of CSS therapy is to provide circulatory support, restore normal hemodynamics, reduce ventricular work, and allow the heart time to recover adequate function.

CSS therapy is intended to be short-term.

Approved patient groups include those that are likely to recover cardiac function after the myocardium is permitted to rest. Examples include, but are not limited to:

- Patients who fail to wean from cardiopulmonary bypass (CPB) following heart surgery
- Failed transplant patients who require ventricular assist following heart transplantation
- Patients who require right ventricular assist device (RVAD) support while on implantable left ventricular assist device (LVAD) support
- Patients suffering from acute cardiac disorders such as viral myocarditis

Chapter 1 Indications and Contraindications

Contraindications for Use

A patient who meets all of the following criteria is a candidate for CSS therapy:

- Patient has a body surface area $> 1.3 \text{ m}^2$ and is ≤ 75 years of age.
- Patient is in relatively good health other than the cardiovascular problem for which surgery was undertaken.
- All appropriate measures have been attempted to correct low arterial pH, arterial blood gas abnormalities, electrolytes, hypovolemia, hypervolemia, inadequate cardiac rate, arrhythmias, and residual hypothermia.
- Cardiac resuscitation using pharmacologic agents has been attempted. Although the use of the Intra-Aortic Balloon Pump (IABP) is recommended prior to CSS therapy, its use may not always be appropriate (e.g., fibrillating heart, peripheral atherosclerosis).
- Patient is unable to be weaned from CPB or is unable to maintain acceptable hemodynamics in the immediate postoperative period (< 6 hours after the first attempt to wean from CPB) *or* Patient is unable to maintain acceptable hemodynamics following a significant cardiac event despite the measures cited above.

Contraindications for Use

- Major cardiac or extracardiac catastrophes occurring during the operation or in the postoperative period that preclude survival, such as uncontrolled hemorrhage, massive air embolization, interstitial pulmonary hemorrhage with inability to maintain adequate ventilation, CPB or perfusion difficulties, or massive transfusion reaction, hemolysis during CPB, or inadequate CSS cannulation
- Central nervous system damage resulting in fixed or dilated pupils

Chapter 2

Introduction to the Systems

Overview

CSS therapy is approved for the treatment of any cardiac condition that indicates a need for resting the native heart. These Systems automatically respond to changes in preload and afterload.

Each System consists of three major components:

- **Console** – four models are available.
- **Cannulae** – all Systems use identical Cannulae.
- **Blood Pump(s)** – all Systems use identical Blood Pumps.

IMPORTANT GUIDELINE: *Prior to use, refer to the appropriate ABIOMED® Operator's Manuals or Instructions for Use.*

Consoles

Table 1: Console Features and Specifications

Features and Specifications	AB5000™	BVS® 5000 & 5000i	BVS® 5000t
Width	23" (58.4 cm)	24" (61 cm)	16.3" (41.4 cm)
Depth	12" (30.5 cm)	22" (56 cm)	11.2" (28.5 cm)
Height	29" (73.7 cm)	33.25" (84.5 cm)	36.4" (92.5 cm)
Weight	96 lb. (43.5 kg)	187 lb. (85 kg)	125 lb. (56.8 kg)
Battery Run Time	1 hour	1 hour	1 hour
Emergency Backup Pump	Hand Pump	Foot Pump	Foot Pump
Pump Flow (*excludes BVS® 5000)	Up to 6 L/min	Up to 6 L/min*	Up to 6 L/min
Approved FDA indications include all patients with potentially reversible heart failure.	X	X	X
Uni- or Bi-ventricular support.	X	X	X
Compatible with BVS® Blood Pump and wide range of arterial and atrial cannulae.	X	X	X
Automatically adjusts beat rates and flows in response to patient's preload and afterload.	X	X	
Does not require operator to adjust or monitor beat rate, pressure, triggering, or timing.	X	X	
Blood Pump flow, beat rate, and alarm messages are shown on the screen.	X	X	
Easy on/off and weaning controls.	X	X	
Multiple backup and alarm systems for increased confidence of the clinical team.	X	X	X
Designed to simplify patient transfers.	X		X
Console and Blood Pump can operate in horizontal or vertical positions.	X		X
Designed for use in wide range of air transport and ground transport vehicles.	X		X
Alarm volume control.	X		X
Ease of mobility with detachable 4-wheeled cart. (Cart adds 50 lbs. and increases size to 28" x 18" x 38")	X		
Storage for IV pole mount, bed plate, and Instructions for Use.	X		
Simplified Startup Procedure.	X		
Help screens.	X		
Easily upgraded for future generations of pumps.	X		

AB5000™ Console



Figure 1: AB5000™ Console



Figure 2: AB5000™ Control Panel at a Glance

BVS[®] 5000i (and 5000) Console



Figure 3: BVS[®] 5000i (and 5000) Console

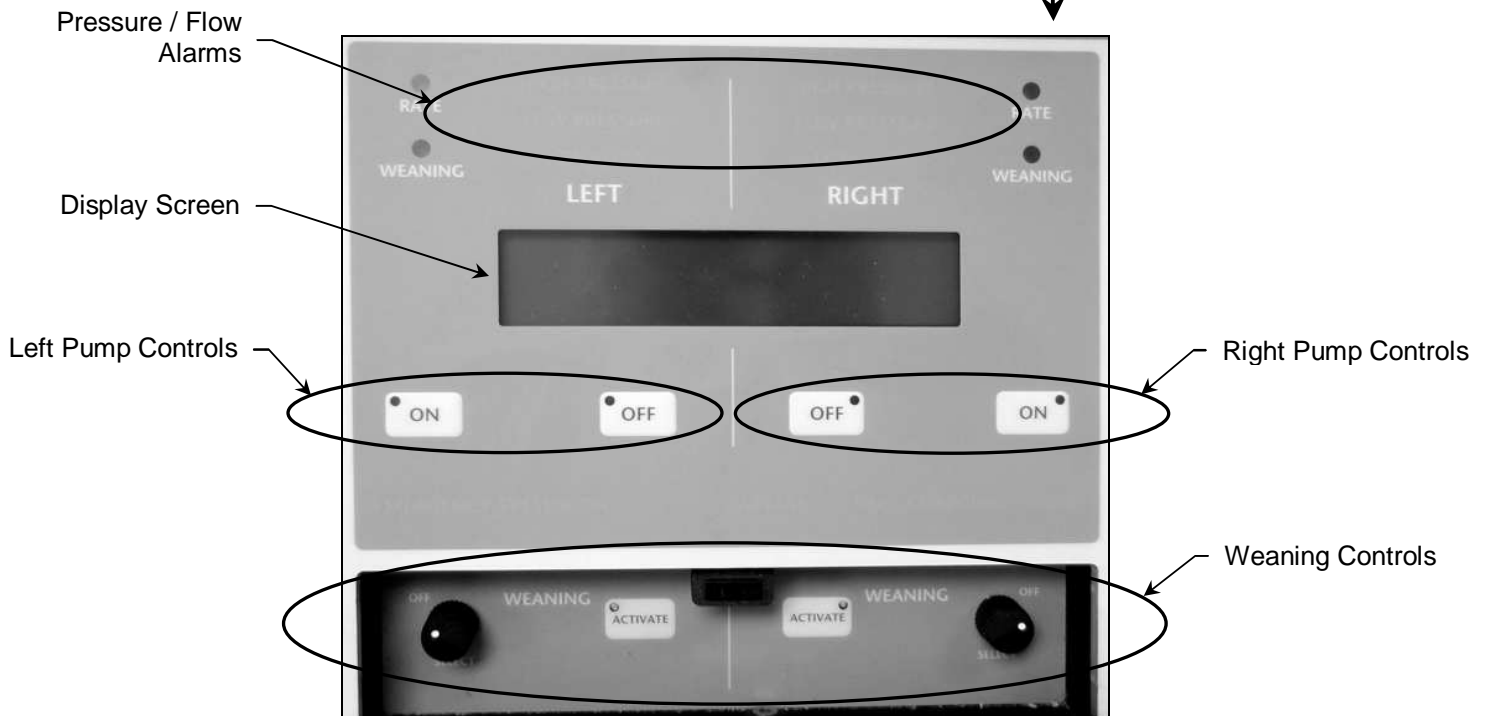


Figure 4: BVS[®] 5000i (and 5000) Control Panel at a Glance

BVS[®] 5000t Console

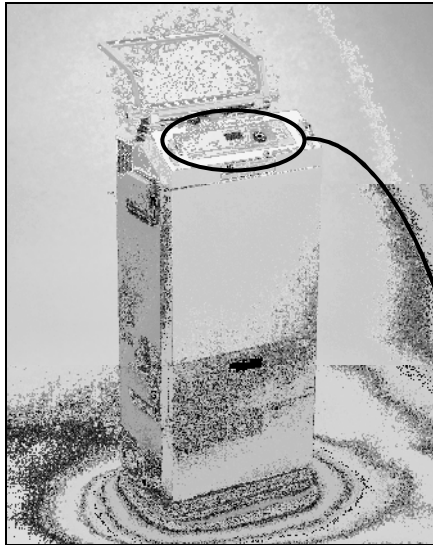


Figure 5: BVS[®] 5000t Console

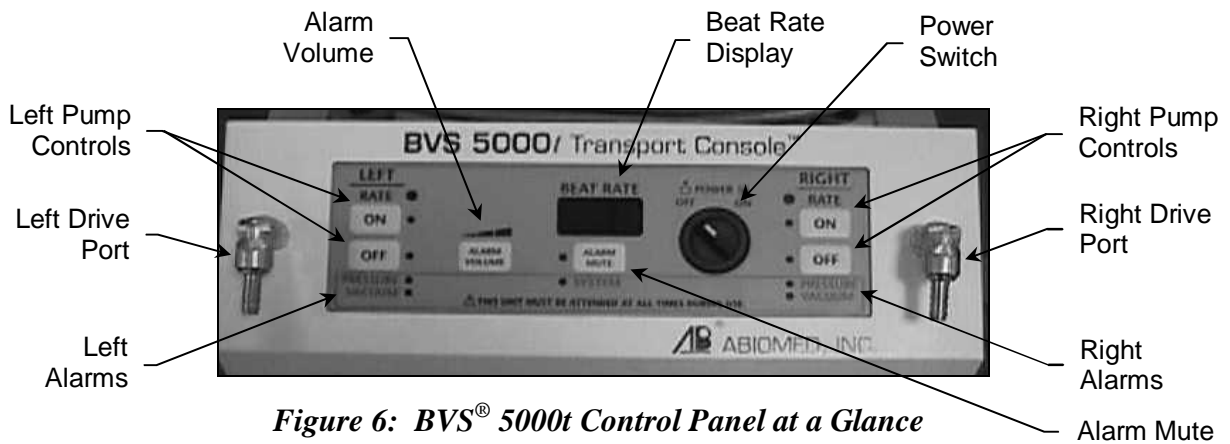


Figure 6: BVS[®] 5000t Control Panel at a Glance

Cannulae

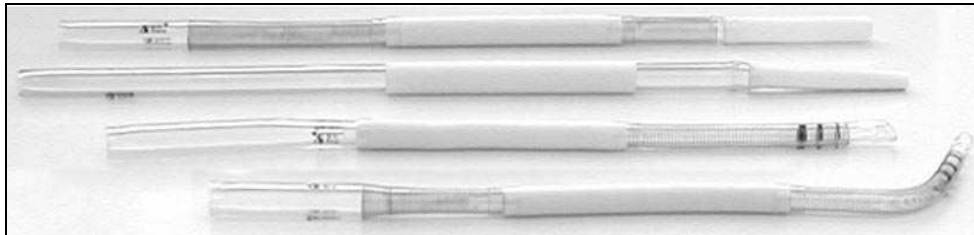


Figure 7: Cannulae

NOTE: Prior to use, refer to the appropriate ABIOMED[®] Cannulae Instructions for Use.

Description

ABIOMED[®] Cannulae are surgically implanted. Each cannula has a Dacron[®] velour sleeve to promote hemostasis and reduce the risk of infection at skin exit sites.

Atrial Types

32 Fr. and 42 Fr. Malleable Cannula

- Open beveled tip optimizes atrial drainage
- Wire-reinforced backbone to permit various cannula angles and to make insertion easier

Arterial Types

10mm Cannula (with 10mm Hemashield®)

No preclotting necessary

42 Fr. Cannula (with 12 mm coated Dacron® graft)

- No preclotting necessary
- Wire-reinforced

Blood Pump

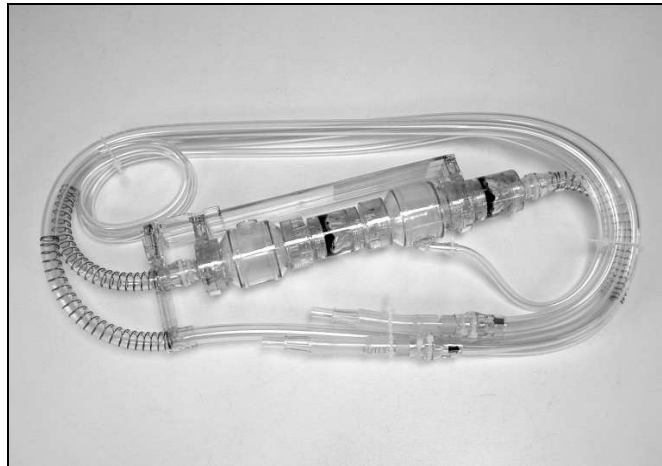


Figure 8: Blood Pump

NOTE: Prior to use, refer to the appropriate ABIOMED® Blood Pump Instructions for Use.

The ABIOMED® Blood Pump (or “Pump”) is a pneumatically driven device that provides pulsatile hemodynamic support. Following are some key features of the Pump:

- Dual-chamber design
- Sterile and single-use
- Includes attached driveline, blood tubing, and cannula restraints
- Atrial chamber fills passively

Chapter 3

How the Blood Pump Works

Operation

Assisted by gravity, blood flows from the native heart into the atrial bladder. The atrial bladder fills and empties throughout the Pump cycle and serves as a reservoir to supply blood to the ventricular bladder. Each bladder holds about 100 cc of blood.

When the pressure in the atrial bladder exceeds the pressure in the ventricular bladder, a valve opens and allows blood to flow into the ventricular bladder.

As the ventricular bladder fills, the air that surrounds the bladder is displaced through the driveline to the Console. A sensor in the Console detects when this airflow stops, indicating that the bladder is full.

When the bladder is full, the Console returns a bolus of air through the driveline. This compresses the ventricular bladder and delivers about 80 cc of blood to the patient.

Blood Pump Cycles

Diastole

- Duration is the period of time necessary to fill the ventricular chamber.
- Pump adjusts to changes in volume or preload.
- Diastole shortens with increasing preload.

Systole

- Duration is the period of time necessary to eject about 80 cc.
- Pump adjusts to changes in afterload.
- Systole lengthens with increasing afterload.

Example

Hypovolemia

Time to fill ventricular bladder increases, diastole lengthens, Pump rate decreases, Pump flow decreases.

Effects of Change in Preload

↑ Preload results in: ↑ Beat Rate and ↑ Cardiac Output

↓ Preload results in: ↓ Beat Rate and ↓ Cardiac Output

Effects of Change in Afterload

Systemic Vascular Resistance (SVR)

↑ SVR results in: ↓↓ Beat Rate and ↓↓ Cardiac Output

Pulmonary Vascular Resistance (PVR)

↑ PVR results in: ↓↓ Beat Rate and ↓↓ Cardiac Output

Optimizing Filling and Flow

Volume

- Is preload-sensitive.
- Cannot generate more flow than volume available.
- Works in a fill-to-empty mode.

Blood Pump Height

- Is a passive, gravity-assisted filling system.
- Height is determined in part by cannula size:
 - 32 Fr. atrial cannula: average height is 4 to 14 inches (10 to 36 cm) below the atrium.
 - 42 Fr. atrial cannula: average height is 0 to 10 inches (0 to 25 cm) below the atrium.

Precautions with Height Adjustment

- Raising the Pump too high may decrease preload, resulting in a decrease in flow.
- Lowering the Pump too far will increase afterload, resulting in a decrease in flow.

Causes of Inadequate Filling of Atrial Bladder

Physiological

Inadequate Volume

Tamponade

Postoperative bleeding is the most common complication in CSS patients. When an accumulation of thrombus or pooled blood compresses the heart, Pump filling is affected and flow decreases. This can occur in the immediate postoperative period or at any time during the CSS therapy. Maintaining patency of the chest tubes can prevent or delay tamponade.

Symptoms of tamponade in CSS patients are similar to those of other post-cardiotomy patients. (In late tamponade, these symptoms may not be readily apparent.):

- Cessation of previously rapid bleeding
- Bilateral elevation of filling pressures
- Poor filling of Pumps with decreasing flow
- Hypotension
- Minimal response to volume
- General signs and symptoms of low output

IMPORTANT GUIDELINE: *Diagnosis and intervention should be swift. Until the patient can be re-explored, system and organ perfusion **must** be supported with drugs and volume.*

Failure of the Unassisted Ventricle

If only one side of the heart is supported, the unsupported side may be more vulnerable to failure. Heavy bleeding and the resulting requirement for blood product administration can exacerbate right heart failure in the LVAD patient. This leads to hepatic congestion, hepatomegaly, and increased coagulopathy.

Failure of the unassisted ventricle can be precipitous and should be treated aggressively. Inotropes and vasoactive drugs will be needed to assist the failing ventricle and support end organ perfusion. Increasing preload usually leads to worsening of the hemodynamic picture. If the patient does not improve sufficiently with non-surgical interventions, plans should be made to return to surgery for BiVAD support.

Symptoms of failure of the unassisted ventricle are:

- Increasing filling pressures on the unassisted side
- Normal-to-low filling pressures on the assisted side
- Poor filling and decreased Pump flow
- Signs and symptoms of low output

Mechanical

Pump Position Too High Relative to the Patient

Kink in Inflow Cannulae or Tubing

Cannulae Placement

- Poor drainage
- Vena cava compression

Causes of Inadequate Emptying of Atrial Bladder

Physiological

Increased Afterload

- Elevated SVR with left-side support
- Elevated PVR with right-side support

Volume Overload

Mechanical

Pump Position Too Low Relative to the Patient

Kink in Outflow Tubing or Graft

Bi-Ventricular Flow

During bi-ventricular support, Pumps operate independent of each other. Because each Pump responds to its own preload and afterload, right and left flows may not be equal. This difference is usually within 0.5 liter per minute (L/min) and is not a cause for concern. If the flow differential is > 0.5 L/min, determine the cause of the imbalance before intervening.

Flow Imbalance

- If right-side flow exceeds left-side flow, and the pulmonary and hemodynamic status is *stable*, balancing flows is not necessary. (Flow imbalance may be caused by native heart ejections that are contributing to the total cardiac output. Observe the arterial waveform for native ejection spikes that correlate with the patient's R-wave on the EKG.)
- If right-side flow exceeds left-side flow, and the pulmonary and hemodynamic status is *unstable*, this may be due to pulmonary hypertension or elevated SVR.

- Systemic vascular resistance (SVR) will increase with hypertension, decreasing left-side flow.
- High pulmonary vascular resistance (PVR) impedes blood flow across the lungs, decreasing right-side flow.
- Right-side flow exceeding left-side flow could contribute to pulmonary edema.
- Decreasing right-side flow to less than left-side flow has been employed to help resolve pulmonary edema.

Options for Balancing Flows

- Medically optimize preload by giving volume.
- Medically optimize afterload by giving vasoactive drugs.
- Mechanically optimize preload and afterload by adjusting Pump height.
- Use the weaning control to maintain balanced flows (± 0.5 L/min).
- Allow the Console at least 2 minutes between changes in Pump height or weaning reductions to adjust flow.

Chapter 4

Priming the Blood Pump

Preparation

- 1 A cardiomy reservoir that will accept 3/8-inch tubing is placed in the holder on the IV pole.
- 2 Next, the Pump is passed out of the sterile field and placed on the pole mount.
- 3 The nurse in the sterile field extends both ends of the Pump tubing (each of which are marked with a colored arrow) using 6-foot lengths of sterile tubing. These extensions are then passed to the perfusionist.
- 4 The perfusionist connects the extensions as follows:
 - **Blue** arrow to the **bottom** of the reservoir.
 - **Red** arrow to the **top** of the reservoir.

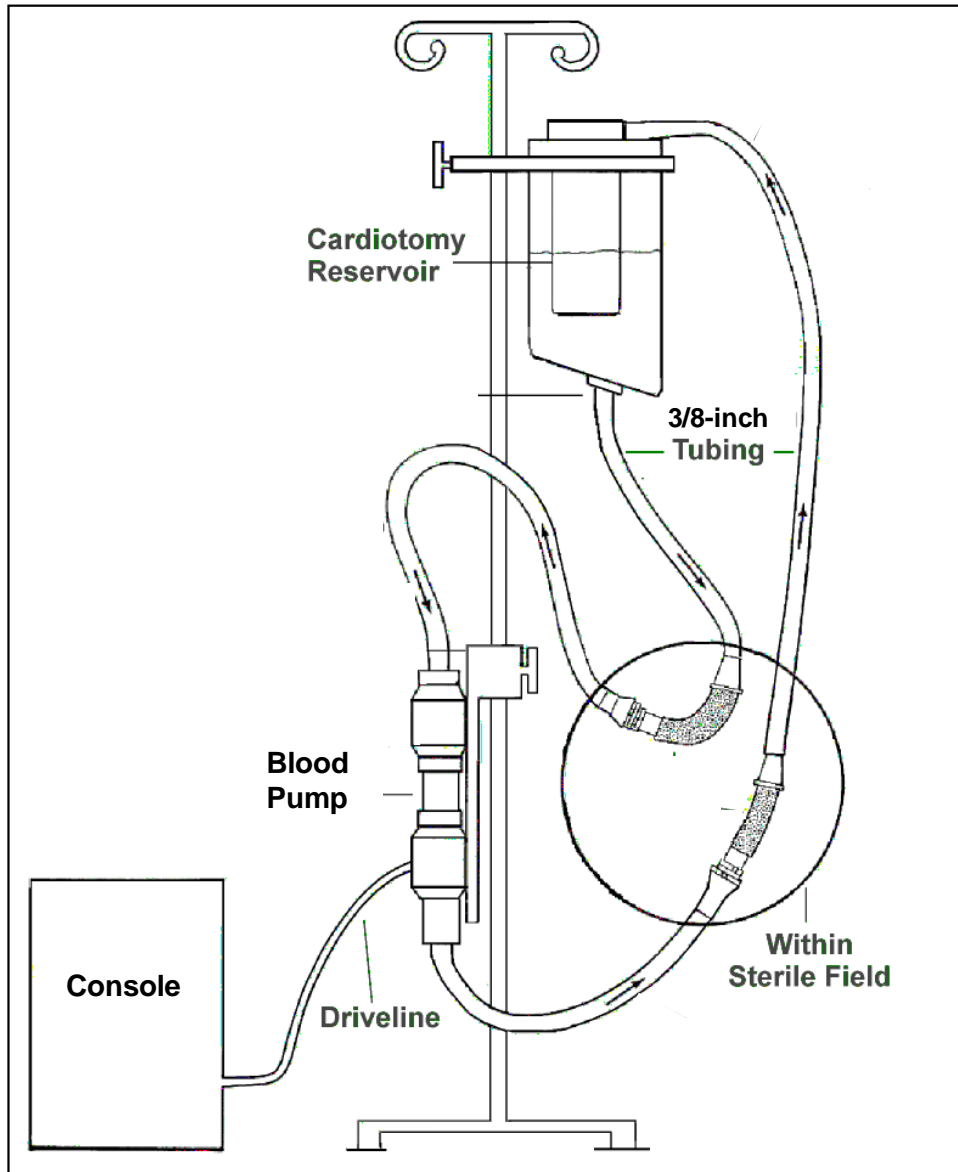


Figure 9: Priming Circuit

Console Start-Up

- 1 The Console is turned on and allowed to run through its self-test, which takes about 20 seconds. The Console's controls, except for the alarm mute button, should not be used during this time (to prevent the need to reset the Console).
- 2 When the messages "LEFT SYSTEM READY FOR USE" and "RIGHT SYSTEM READY FOR USE" appear on the display, the system is in Standby.

Priming

◆ **NOTE**

*The use of **warm** priming solution may help prevent the formation of air bubbles.*

- 1 First, the cardiotomy reservoir outflow tubing is clamped close to the connection at the bottom of the cardiotomy reservoir. The reservoir is then filled with 2 liters of **warm** priming solution and adjusted to a height of about 3 feet (1 m) above the Pump.
- 2 The Pump is removed from the IV pole, inverted (so that the driveline is on top), and raised above the level of the reservoir.
- 3 The tubing clamp is released and the Pump is **slowly** lowered. Air is displaced as the fluid level rises.
- 4 After the priming solution has passed through the entire Pump, the Pump is returned to its normal position on the IV pole.
- 5 The driveline is connected to the correct port on the back of the Console, and the Pump is started by pressing ON.

- 6** During circulation of the priming solution, flows may not be > 3.0 L/min, due to the extra tubing and the small diameter of the reservoir ports. If HIGH PRESSURE LOW FLOW alarms occur during priming, the Pump should be raised (or the reservoir lowered) to clear the alarm condition.
- 7** The Pump is rotated back and forth to help remove any trapped air bubbles (gentle tapping may help release bubbles). After this movement, the valve sinus areas and the inflow and outflow lines are carefully inspected for air bubbles.
- 8** After *all* bubbles have been removed, the priming solution is allowed to circulate for about 5 minutes.
- 9** Pumping should be stopped when ready for patient connection.

A person in the sterile field performs the next 3 steps:

- 10** The Pump tubing and silicone connector are clamped (see Figure 10.)

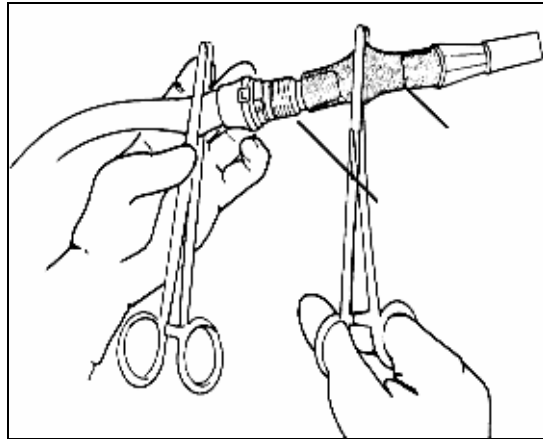


Figure 10: Clamping the Tubing

- 11** The silicone connector is removed from the Pump tubing (see Figure 11).

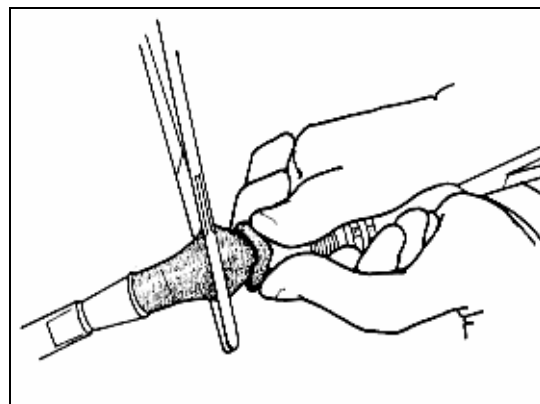


Figure 11: Removing the Silicone Connector

- 12 The Pump tubing is ready to be connected to the primed atrial cannula or arterial graft.

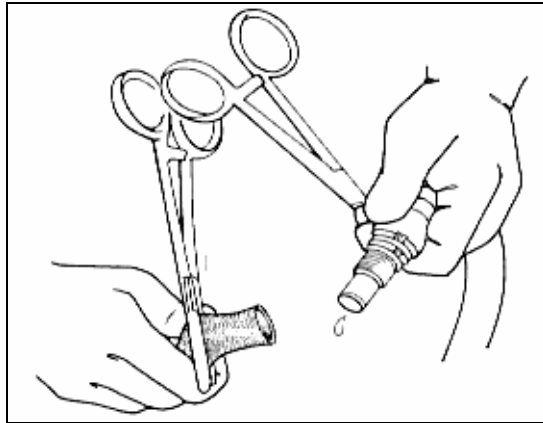


Figure 12: Disconnecting the Priming Circuit

- 13 The priming circuit should be kept intact and in the sterile field (in case it is needed again) until the case is completed. (If uni-ventricular support is being initiated, skip the next section and proceed to Chapter 5.)

Priming a Second Blood Pump

- 1 To avoid developing an air lock when priming a second Pump, ***one of the following methods*** should be used to drain fluid from the reservoir tubing:
 - Disconnect the extension tubing from the top of the reservoir and empty the priming solution into a basin.

OR

 - Lower the reservoir while a person in the sterile field holds up the extension tubing, forcing the priming solution back into the reservoir.
- 2 Warm priming solution (.5 liter) is added to the reservoir.

Chapter 5 Implantation
Priming a Second Blood Pump

- 3** The nurse in the sterile field connects each end of the Pump tubing to the appropriate ends of the extension tubing that has remained in the sterile field. (**Blue** arrow on Pump tubing goes to the extension tubing connected to the **bottom** of the reservoir. **Red** arrow on Pump tubing goes to the extension tubing connected to the **top**.)
- 4** The priming procedure (except for steps 1 and 6) is performed for the second Pump.

Chapter 5

Implantation

IMPORTANT GUIDELINE: The ***TIMING*** of the implant is critically important to the ***SUCCESS*** of the implant. See Appendix B, *Acute Cardiogenic Shock Intraoperative Strategies*.

Atrial (Venous) Cannulation Sites

Right

Mid-Free Wall

Most commonly used site

Appendage

Usually used for venous CPB cannulation, making accessibility difficult for CSS cannulation

Left

Inter-Atrial Groove

- Requires more manipulation of the heart than other sites
- Following implant, this site should be closely observed for impaired filling of the Pump secondary to:
 - Compression of the vena cava
 - Cannula pushing on the septum, causing it to bow into the right atrium and obstruct flow

Superior Pulmonary Vein

Consider use of 32 Fr. cannula

Appendage

- Usually small and inaccessible in most non-cardiomyopathy patients
- May be difficult to obtain good drainage
- Tissue may be more fragile than other sites, making implant more difficult

Dome

- Consider for small hearts and small patients
- Located posteriorly, between the superior vena cava and the aorta
- Requires less manipulation of the heart during explantation than other sites

Ventricular Cannulation

LV Apex

- Affords more complete decompression of the LV, eliminating stasis
- Recommended approach for patients with prosthetic mitral valve, because it maintains flow across the mitral valve to inhibit stasis and thrombus
- Involves the use of concentric, pledgeted purse string sutures placed on the anterior aspect of the LV apex
- Bevel to be positioned away from the septal wall.
- TEE to be considered to verify cannula position below cordae and valve apparatus

Atrial Cannulation Techniques

◆ **NOTE**

The location of the exit site is determined by the orientation of the atrial cannula.

- 1** The tunneling bullet is inserted into the distal end of the cannula for externalization. The surgeon then tunnels the cannula from the pericardial space out through the skin below the ribs.
- 2** After the cannula is externalized, the tunneling bullet is removed. The cannula restraint is attached with the notched end away from the heart.
- 3** It is recommended that 2-0 or 3-0 polypropylene sutures be used to perform double concentric purse strings with pledgets. Bovine pericardium, pericardial patches, or pledgets may be used to seal the purse string sites.
- 4** The CPB flow should be reduced to allow the atrium to fill.
- 5** A stab incision is made inside the purse string. If necessary, the site is dilated.
- 6** The surgeon inserts the atrial cannula into the incision to at least the 2-cm depth marker.
- 7** The purse strings are tightened and the tourniquet is secured. The purse strings can be wrapped around the tourniquet and secured to keep them from loosening or knotting. Metal clips can also be used.
- 8** The tourniquets are secured onto themselves and then onto the cannula with heavy suture to stabilize the cannula and help prevent loosening of the purse strings.
- 9** The Valsalva maneuver is performed to fill the atrial cannula.

Arterial Cannulation Sites

Right

Main Pulmonary Artery

Left

Ascending Aorta

Arterial Cannulation (Grafting) Techniques

General Guidelines

- Consider the use of 4-0 or 5-0 polypropylene sutures.
- Consider heel and toe pledgets or a pericardial collar at the anastomosis site. Surgical glue may also be used.
- Consider the placement of the proximal anastomoses of the bypass grafts to allow room for placement of the Pump arterial graft. The anterolateral wall of the aorta is the common anastomosis site for left arterial grafting. However, the posterior wall of the aorta has been used when bypass grafts crowd the anterolateral.

IMPORTANT GUIDELINE: *Care must be taken to place the right arterial graft high enough on the main distal pulmonary trunk. Placing the right arterial graft too close to the pulmonic valve could deform the valve, causing valvular insufficiency and retrograde flow.*

Placing the Arterial Cannula (Graft)

- 1 The excess graft is trimmed and then beveled at a 30° angle to prevent tension on the end-to-side anastomosis site.
- 2 The graft does not require pre-clotting. The graft is tapped or massaged to release trapped air.
- 3 The surgeon externalizes the cannula using the tunneling bullet. (Some surgeons prefer to externalize the arterial graft after it has been anastomosed to the great vessel; this allows the heel of the suture site to be checked for oozing while the graft is backflushed.)

Connecting the Blood Pump to the Cannulae

- 1 The surgeon clamps the distal end of the graft or cannula, taking care not to clamp on wire-reinforced areas.
- 2 The sterile, clamped ends of the Pump tubing must be aligned with both the atrial cannula and the arterial graft.

IMPORTANT GUIDELINE: *The atrial cannula and the arterial graft **must** be connected to the correct Pump tubing ends. Also, to prevent air from entering the system, a continuous saline irrigation should be used when making these connections.*

- The atrial cannula marked with a **black** arrow is connected (about 1 cm beyond the 2 barbs) to the Pump tubing marked with a **blue** arrow.
- The arterial graft marked with a **red** arrow is connected (about 1 cm beyond the 2 barbs) to the Pump tubing marked with a **red** arrow.

Initiating Support

Support is initiated using the foot pump (the hand pump or the single shot feature, in the case of the AB5000™ Console). Using the foot pump permits a slow, controlled initiation of flow through the system and reduces the risk of air embolus. CVP should be at least 6-10 mmHg prior to initiation of support.

◆ **NOTE**

Potential causes of air intrusion are:

- *Purse strings not tight enough.*
- *Atrium not filled prior to initiation of support.*
- *Atrial cannula not positioned deeply enough.*
- *Atrial wall torn.*

- 1 The Console's transfer lever is moved to the horizontal position, and the foot pump is removed from the Console. (The transfer lever must be moved before the foot pump can be removed.) This step does not apply to the AB5000™ Console.
- 2 The nurse places the patient in the Trendelenberg position.
- 3 Atrial cannulation sites are submerged to aid in detection of air bubbles.
- 4 The Pump is raised to the level of the patient's atrium.
- 5 CPB is decreased to allow the heart to fill.
- 6 Clamps should be readied at the base of the atrial cannula and at the Pump inflow tubing.
- 7 The foot pump is slowly pressed while the system is carefully checked for *air intrusion*.

IMPORTANT GUIDELINE: *If air enters the Pump, reconnection to the priming circuit will be necessary to circulate the air out of the system. After the air is removed, the Pump tubing and cannula can be reconnected under continuous saline irrigation. Then start-up can be re-initiated using the foot pump.*

- 8 If air is noted in the Pump inflow tubing during start-up, the following steps should be performed:
 - a. The use of the foot pump should be discontinued.
 - b. The Pump/cannula connection is clamped. Then the air bubble(s) are worked towards and out of the junction.

- c. While using continuous saline irrigation to prevent air from entering the system, the surgeon reconnects the Pump tubing and cannula.
 - d. The foot pump is slowly pressed while the system is carefully checked for *air intrusion*.
- 9 The foot pump is returned to the Console, and the transfer lever is moved to the vertical position (does not apply to the AB5000™ Console).
 - 10 Support is initiated by pressing ON.

Assessing Support

◆ **NOTE**

Incremental changes in the beat rate are normal, especially during the first 2 minutes after initiating support.

- 1 After the pumping has reached a steady state, the perfusionist observes the filling and emptying of the Pump to determine preload and afterload status.
- 2 Volume replacement is considered.
- 3 The Pump height is adjusted downward. The system should be allowed to stabilize for 2 minutes after each adjustment.

After support has been assessed, the following steps are performed:

- 1 The cannula is advanced as far as it will go onto the Pump tubing.

IMPORTANT GUIDELINE: *The traction grooves on the Pump tubing are to help provide a grip during the connection process. They are **not** the endpoint for cannula restraint placement.*

- 2 The cannula restraint is wetted with saline and pushed onto the Pump tubing/cannula connection. A tie wrap is then placed in the groove of the cannula restraint and securely tightened.

Bi-Ventricular Support

- 1 After the patient has been on uni-ventricular support, bi-ventricular support is considered.
- 2 If necessary, the patient may be placed back on full CPB. If the patient *is* placed on CPB, CSS therapy *must* be discontinued.
- 3 The foot pump (or hand pump) should be used intermittently to move blood through the cannulated side of the heart and Pump to prevent stasis of the blood.
- 4 To use the foot pump during CPB, the bypass flow must be reduced and the atrium allowed to fill. Blood can then be moved through the Pump by pressing the foot pump (or pumping the hand pump) 2 or 3 times every 2 to 5 minutes. Full CPB can then be resumed.
- 5 The second Pump is primed.
- 6 Cannulation is performed and connections are made as previously described.
- 7 After the Pump is connected and free of air, the foot pump (or hand pump) is returned to its compartment and CSS therapy is started, beginning with the left side.
- 8 If the right and left sides of the heart are cannulated at the same time, support is first initiated on the left side, then on the right side.

IMPORTANT GUIDELINE: *If the unassisted side of the heart cannot effectively pump because of the increased flow from the assisted side, consider BiVAD support.*

Chapter 6

Patient Management

Achieving Hemostasis

The most important consideration in the postoperative management of CSS patients is achieving hemostasis. Because postoperative bleeding can be caused by many factors, it is important to be systematic when determining the source of the blood loss.

IMPORTANT GUIDELINE: *The approach to achieving hemostasis begins in the OR by attaining flow > 3 L/min.*

Recommended guidelines are as follows:

- 1 Heparin is reversed in the OR to achieve a preoperative baseline ACT.
- 2 Reversing post-bypass coagulopathy by rewarming the patient to a normothermic state, while generously administering blood products and clotting factors, has been successful in limiting post-implant bleeding. These blood products include, but are not limited to: packed red blood cells, platelets, FFP, and cryoprecipitate.
- 3 Chest tube drainage is closely monitored.

Chapter 6 Postoperative Management

Excessive / Uncontrolled Bleeding

- 4 Normothermia ($> 36\text{ }^{\circ}\text{C}$) is achieved and maintained by using the following methods:
 - Using tubing insulators (included with the Pump). These may be removed if the patient's temperature becomes elevated.
 - Using warming blanket.

IMPORTANT GUIDELINE: *Direct heat must **not** be applied to Blood Pumps, cannula, or tubing. The application of heat may promote thrombus formation.*

- Administer warmed blood products.
- 5 Blood components are replaced as needed. Recommended target values are:
 - Hemoglobin $>10\text{ gm/dL}$
 - Hematocrit $>30\%$
 - Platelets $>100,000/\text{mm}^3$
 - 6 Leukocyte filtration is considered in order to prevent potential elevation of panel reactive antibody. Leukocyte filtration may also reduce CPB-induced inflammatory response.

Excessive / Uncontrolled Bleeding

- R/O surgical bleeding vs. coagulopathy.
- Consider the use of:
 - Cryoprecipitate
 - Amicar
 - DDAVP
 - Aprotinin
- Consider RVAD implantation.

The need for extensive blood product transfusion can cause a weakened RV to fail. This leads to liver congestion, reduction of clotting factor synthesis, and increased venous bleeding.

Hemodynamic Management

Volume administration, vasoactive pharmacologic support, and efficient removal of fluid overload are important factors in successful patient management. Optimization of hemodynamic parameters is key in achieving maximum Pump flows and systemic perfusion.

To properly assess right- and left-sided pressure values, a Swan-Ganz catheter is recommended for at least 48 to 72 hours.

Table 2: Target Hemodynamics

Target Hemodynamics	
MAP	70-80 mmHg
CVP	12-16 mmHg
LA / PCWP	12-14 mmHg
SVR	$\cong 1000 \text{ dynes} \times \text{sec} / \text{cm}^5$
PVR	$< 250 \text{ dynes} \times \text{sec} / \text{cm}^5$
CI	$> 2.0 \text{ L/min/m}^2$

IMPORTANT GUIDELINE: *Volume replacement with blood, blood products, and albumin (rather than crystalloid) is recommended to promote increased colloidal osmotic pressure. This helps limit interstitial edema. Due to the potential for inducing or worsening a pro-inflammatory and coagulopathic state, auto-transfusion should be avoided.*

IMPORTANT GUIDELINE: *In the presence of an RVAD, thermodilution cardiac outputs would be inaccurate due to the altered path of injectate through the right blood pump. The following formulas are used to calculate SVR and PVR:*

$$\text{SVR (in dynes x sec / cm}^5\text{)} = ((\text{MAP-CVP}) \div \text{LVAD flow}) \times 80$$

$$\text{PVR (in dynes x sec / cm}^5\text{)} = ((\text{MPAP-PCWP}) \div \text{RVAD flow}) \times 80$$

Pharmacologic Therapy

Vasoactive medications may be required to achieve and maintain the target hemodynamics. However, inotropic support should not be needed in the BiVAD-supported patient.

Table 3: Vasoactive Medications

Vasoconstrictors (to maintain vascular tone and normal peripheral resistance)	Vasodilators (to reduce afterload)
Vasopressin (physiologic dose: 0.04 – 0.1 units/min or 2.4 – 6 units/hr) (Physiologic replacement doses of the hormone L-arginine vasopressin have been shown to restore vascular tone, increase mean arterial pressure, and rapidly reduce catecholamine requirements.)	For SVR: Nitroprusside For PVR: Milrinone, Prostaglandin E1, Nitric Oxide
Norepinephrine	---
Epinephrine	---
Neosynephrine	---

Inotropes

If only the left side of the heart is supported, there may be a need to pharmacologically assist the unsupported ventricle, thus helping to provide the preload for the assisted side of the heart.

Sedation

Patients do not need to be chemically paralyzed, unless the patient's condition dictates otherwise. Sedation levels appropriate to ventilator management and anxiety relief are advised. During CSS therapy, initial and periodic neurologic assessments must be performed.

Pain Management

In addition to sedation, pain management should be addressed.

Antibiotics

A broad-spectrum antibiotic is recommended while on CSS therapy. Organism-specific coverage should be prescribed as needed.

Anticoagulation Management

The approach to anticoagulation begins in the OR and is based on achieving surgical hemostasis and a stable coagulation profile.

Recommended guidelines for initiating anticoagulation therapy are as follows:

- Mediastinal drainage 50 to 75 cc/hr for 3 consecutive hours
- Normothermia achieved ($> 36^{\circ}\text{C}$)
- Hemoglobin > 10 gm/dL
- Hematocrit $> 30\%$
- Platelets $> 100,000/\text{mm}^3$

It is recommended that anticoagulation be attained by using heparin, with an initial infusion of 10 to 15 units/kg/hr. To maintain anticoagulation parameters within the targeted range, adjustments to the heparin drip are necessary. Heparin bolus is not recommended.

IMPORTANT GUIDELINE: *Once started, heparin should not be discontinued until explantation. Maintenance of a consistently therapeutic level of anticoagulation is key in decreasing the risk of thrombus formation.*

ACT Monitoring

ACTs should be monitored hourly until the therapeutic level of 180 to 200 seconds is achieved (values close to 200 are recommended). When a therapeutic level has been reached and maintained, testing frequency can be extended to every 2 hours.

ACT levels should be increased to 250 to 300 seconds for unresolved atrial or ventricular fibrillatory rhythms, as well as for low flow states (< 3 L/min).

PTT Monitoring

If PTT values are used to manage anticoagulation, values should be assessed every hour until the target range of 2 to 2.5 times the lab control's normal value is achieved. When a therapeutic level has been reached and maintained, testing frequency can be extended to every 2 hours.

PTTs should be increased to 2.5 to 3 times the lab control's normal value for unresolved atrial or ventricular fibrillatory rhythms, weaning, and low flow states (< 3 L/min).

Some surgical teams use thrombelastograph to guide anticoagulation and factor replacement decisions.

Anti-Thrombin III

Anti-Thrombin III (AT III) deficiencies are common in patients receiving a constant heparin infusion. This condition can manifest as an inability to sustain a therapeutic level of anticoagulation without significant increases in the drug. Most clinicians treat this condition with the administration of one or two units of FFP because AT III is found in plasma at about 1 unit/ml.

Decreasing the Risk of Thrombus Formation

IMPORTANT GUIDELINE: *Once started, heparin should not be discontinued until explantation. Maintenance of a consistently therapeutic level of anticoagulation is key in decreasing the risk of thrombus formation.*

Maintaining flow > 4 L/min will minimize stasis in the Pump and ensure proper washing of the inflow and outflow valves.

If flows are < 3.0 L/min, ACTs should be increased to 250 to 300 seconds (or PTTs to 2.5 to 3 times the lab control's normal value). Flows < 2.0 L/min should be avoided.

Care must be taken when cannulating in a patient with a prosthetic heart valve. Cannulae implanted in the atria will divert blood from the atria to the Pump and potentially isolate the ventricle. The flow of blood across the valve may be insufficient and cause the valve to remain closed. This diminished flow may lead to valvular thrombus formation.

For patients with prosthetic mitral valves, cannulation of the LV apex allows for flow across the valve while providing maximal ventricular decompression.

With a prosthetic aortic valve, there is no alternate cannulation choice. The use of inotropic support, which enhances LV ejection, has been used by some clinicians to achieve flow across the aortic valve. Others have used the CSS weaning mode; this allows partial flow into the LV and across the aortic valve. Prophylactically increasing the anticoagulation level should also be considered.

Renal Management

Diuretics administered in a continuous infusion (rather than bolus) are recommended to offer protection from sudden decreases in Pump preload and flow.

Some clinicians recommend titration of the infusion to yield a urine output of 100 to 200 cc greater than input each hour. Short-term hemodialysis is not usually a viable option due to rapid shifts in intravascular volume.

The use of CVVHD is recommended in patients with compromised renal function. Many of the pro-inflammatory biological mediators are also filtered out during this process, potentially reducing the inflammatory cascade.

Pulmonary Management

In the immediate postoperative period, CSS patients will require mechanical ventilation. Patients can be weaned from the ventilator and extubated while on CSS therapy.

Monitoring the patient's pulmonary status helps prevent hypoxia, which can lead to pulmonary vasoconstriction that will impede Pump ejection and flows.

Aggressive pulmonary toilet and turning the patient side-to-side should be considered. Many institutions provide pulmonary therapy beds for their CSS patients.

Arrhythmia Management

Because the CSS System works asynchronously to the native heart, the BiVAD-supported patient will remain hemodynamically stable during episodes of malignant arrhythmia. However, prompt intervention may be necessary to preserve myocardium.

IMPORTANT GUIDELINE: *If only one side of the heart is supported, the arrhythmia **must** be treated.*

Ventricular Fibrillation and Ventricular Tachycardia

- Chest compressions or precordial thump should **not** be performed.
- The heart should be defibrillated. It is not necessary to turn off CSS therapy prior to defibrillation. Pharmacologic support is recommended.
- If sustained, the following recommendations apply:
 - ACTs should be increased to 250 to 300 seconds.
 - PTTs should be increased to 2.5 to 3 times the lab control's normal level.



Figure 13: CSS Support During Ventricular Fibrillation

Atrial Fibrillation

- Electrical cardioversion is recommended. (It is not necessary to turn off CSS therapy prior to cardioversion.) Pharmacologic support is also recommended.
- If chronic, the following recommendations apply:
 - ACTs should be increased to 250 to 300 seconds.
 - PTTs should be increased to 2.5 to 3 times the lab control's normal level.

Bradycardia or Asystole

- Chest compressions or precordial thump should *not* be performed.
- Consider the use of a temporary pacemaker to support electrical conduction.
- Pharmacologic support is recommended.

Intra-Aortic Balloon Pump (IABP)

With a functioning LVAD in place, the need for an IABP is eliminated. Discontinuing IABP therapy while still in surgery allows more effective hemodynamic management and a less cumbersome patient transport to the ICU. Otherwise, the IABP should be discontinued in the initial postoperative period after hemostasis is achieved and prior to the start of anticoagulation therapy.

Because the CSS System works asynchronously to the native heart, timing the IABP to the EKG trigger may compromise VAD flow if balloon inflation occurs during VAD ejection. It is recommended that the IABP be timed using the arterial pressure trigger that synchronizes the IABP to the VAD cycle.

An IABP may be used in conjunction with an RVAD. In this instance, the IABP can be timed to the EKG because the left side of the heart will be synchronous with normal conduction activity.

Nutrition

Nutritional support should be started as soon as possible. Patients requiring ventricular assist may have an increased need for protein. Tube feeding or TPN can be initiated while the patient is still intubated.

Cannulation Site Care

Cannulation sites should be cleansed daily and as needed using standard sterile dressing change technique. To prevent damage to the Dacron[®] velour sleeve, petroleum-based products should not be used.

Patient Activity

After hemodynamics have stabilized and the chest is closed, progressive activity is encouraged as tolerated. The head of the bed may be raised, using caution to prevent kinking of the Pump tubing.

Patients should be turned frequently to prevent pulmonary complications and skin breakdown. Patients can be assisted to sit at the side of the bed or in a cardiac chair.

IMPORTANT GUIDELINE: *Pump height may need to be readjusted after the patient is moved or re-positioned.*

Turning the patient may alter atrial bladder filling because of caval compression. It is advised to assess bladder filling before and after turning the patient. The patient should be re-positioned as necessary.

Physical therapy should be initiated as soon as possible. Isometric exercises should be included if the patient's condition permits.

Patient Transport Within the Hospital

Whenever the patient is being transported, care must be taken to prevent damage to the Pumps and drivelines. Drivelines should be kept from contacting the ground, and the driveline/drive port connection should be protected from tension during transport.

The Pumps may be briefly lifted over the bed or placed beside the patient while transferring the patient to a gurney or bed for transport. This may temporarily decrease flow because the gravity component to Pump filling will be negated. It is important to reposition the Pump at the proper level after the patient is moved.

Chapter 7

Weaning from Support

The arterial waveform is checked for native ejections to evaluate LV recovery. The pulmonary artery waveform is checked for native ejections to evaluate RV recovery. In most cases, some evidence of myocardial recovery is seen between 48 and 96 hours after CSS therapy is initiated.

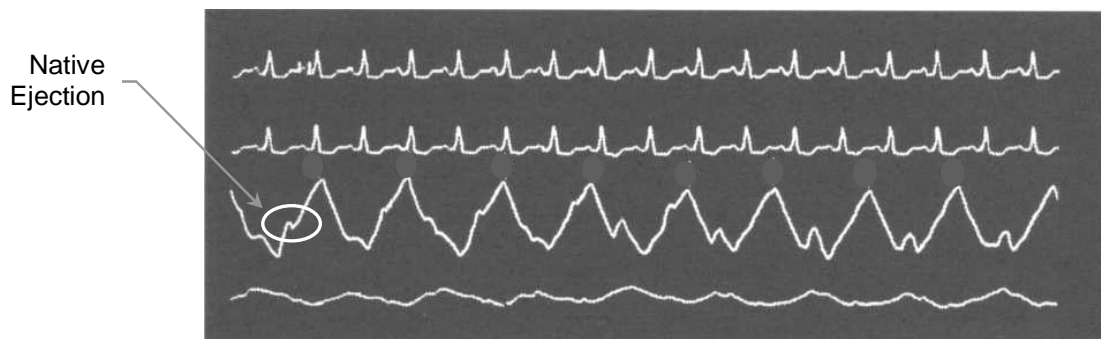


Figure 14: Synchronous Native Ejections

Weaning should be attempted only after native heart recovery has been confirmed by TEE. The first postoperative TEE is often performed on the second or third day of CSS therapy. TEE should demonstrate improved wall motion and increased ejection fraction in a volume-loaded heart. Reasonable hemodynamic stability should be sustained during the process as further evidence of ventricular recovery.

Following a successful weaning process, minimal inotropic support may be required prior to explantation. In some cases, an IABP has been used after explantation to provide ventricular support.

Procedure

- 1 The TEE probe is advanced into position. Baseline hemodynamics are observed.
- 2 Flow is reduced by 0.5 L/min every 5 minutes using the weaning controls.

IMPORTANT GUIDELINE: *Slower movement of blood through the Pump may increase the risk of thrombus formation.*

- 3 Flow should not be reduced below 3.0 L/min without increasing ACT to 250 to 300 seconds (or PTT to 2.5 to 3 times the lab control's normal value). It is not recommended to reduce flow below 2.0 L/min.
- 4 The ventricular response to the increased workload is evaluated.
- 5 If normal hemodynamics are maintained for 5 to 10 minutes, explantation should be considered. If hemodynamics are not satisfactory, the patient should be returned to full CSS therapy.

Assessing Recovery

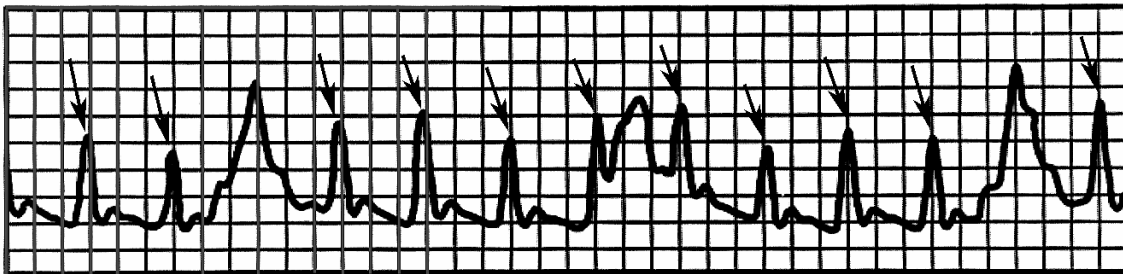


Figure 15: Native Ejections During Weaning

As flow is decreased, native ejections should become more prominent on the arterial waveform.

Chapter 8

Explantation

Preparation

Recommended guidelines for the period *prior* to explantation are as follows:

- The patient should be fully anticoagulated until explantation.
- Low-dose inotropic support should be considered.
- A portion of the Pump volume is returned to the patient before explantation. This is done by clamping the atrial cannula and allowing the Console to pump 2 times.

Procedure

◆ **NOTE**

Explantation can be performed with or without CPB.

- 1 If only one side has recovered, the recovered side is explanted, and support is maintained for the non-recovered side. (If both sides have recovered, the right side is explanted first.)
- 2 After the atrial cannula is removed, about 100 cc of back-bleeding is allowed to expel any pannus formation at the cannula tip and/or in the atrium.
- 3 An arterial side-biting clamp is used. The arterial graft is cut and removed; it is then oversewn or stapled.
- 4 When explanting the LV Apical cannula, consider having CPB on standby.

Chapter 8 Explantation
Procedure

- 5** The arterial graft is entirely removed if the patient is infected or receiving a transplant.
- 6** All cannulae and grafts are removed from the thoracic cavity.
- 7** A small ellipse of tissue is excised around each skin exit site. Sites are then closed primarily.

Chapter 9

Transporting the Patient

ABIOMED[®] HUB Program

Patients are placed on CSS therapy in anticipation of myocardial recovery. Transplant centers (or “HUBs”) have teams and resources dedicated to the management of these patients.

Establishment of a relationship with one or more HUBs is important. Criteria for accepting patients into their program should be determined between the non-transplant hospital (or “SPOKE”) and the HUB. This should be helpful in planning the management of future patients in your practice.

Most transplant centers prefer to have CSS patients transferred to them within the first 72 hours following implantation. Discussions between the SPOKE and the HUB should begin while the patient is still in the OR, or immediately afterwards.

Guidelines

Optimizing the patient's hemodynamic status and correctly positioning the Pump(s) are key factors in managing the patient during transport. Steps should be taken to eliminate or minimize any aspect of the transport that might adversely affect Pump filling or CSS performance.

Recommended guidelines are as follows:

- The ABIOMED Clinical Hotline should be notified.
- The transport should be coordinated with the receiving hospital. Some questions that should be discussed with the HUB are:
 - Will the HUB be using their own CSS Console?
 - Will the HUB need an extra Pump or other supplies?
 - Will the HUB be prepared for transporting a CSS patient from an airport in an ambulance?
- Consider taking additional personnel to move and monitor the Pump(s), driveline(s), and Console. One member of the transport team could be assigned primary responsibility for the safety of the Pump(s) and driveline(s).
- Pump tubing and driveline kinking should always be avoided.
- Transport of CSS patients between hospitals requires a helicopter *or* a fixed-wing aircraft and an ambulance. Transport vehicles should be pre-qualified (using *Appendix A, Transport Qualification Test Procedure*) for transportation of CSS patients. During transport, the CSS must be plugged into the vehicle's power source (inverter).

- The Console battery should be fully charged prior to transport. The Console is plugged into a power source whenever possible.
- Stretcher height, patient position during transport, and Pump positioning issues should be evaluated as they relate to gravity filling of the Pump.
- For safety, one (each) additional 6-foot length of ¼-inch tubing (with ¼-inch connectors) may be necessary to *temporarily* extend the drivelines during loading and unloading. The driveline extensions should *not* remain in place during transport. The installation and removal of these extensions should be done as quickly as possible to minimize change in patient support.
- A lengthy transport may require a portable ACT machine for maintaining therapeutic anticoagulation levels.
- The Console should be positioned to allow easy access to the control panel and foot pump (or hand pump) compartment.

IMPORTANT GUIDELINE: *The Console should be plugged into transport vehicle's power source **only after** the vehicle's engine has been started. Also, the Console should be unplugged from the transport vehicle's power source **prior** to engine shutdown.*

- The patient should be moved from ICU and loaded into the transport vehicle only after all preparations have been made.
- Extra blood volume may be required during transport (especially air transport) to maintain adequate preload.

Special Considerations For Helicopter and Fixed-Wing Transports

Space and weight are crucial when planning helicopter or fixed-wing transports. Repositioning seats in the aircraft may be necessary for accommodation and securing of equipment.

CSS patients should be positioned with their feet toward the front of the aircraft so that preload can be better maintained during take off and ascent.

Requirements governing air transport vary from company to company. Contact ABIOMED for specific regulations and standards concerning air transport.

Appendix A

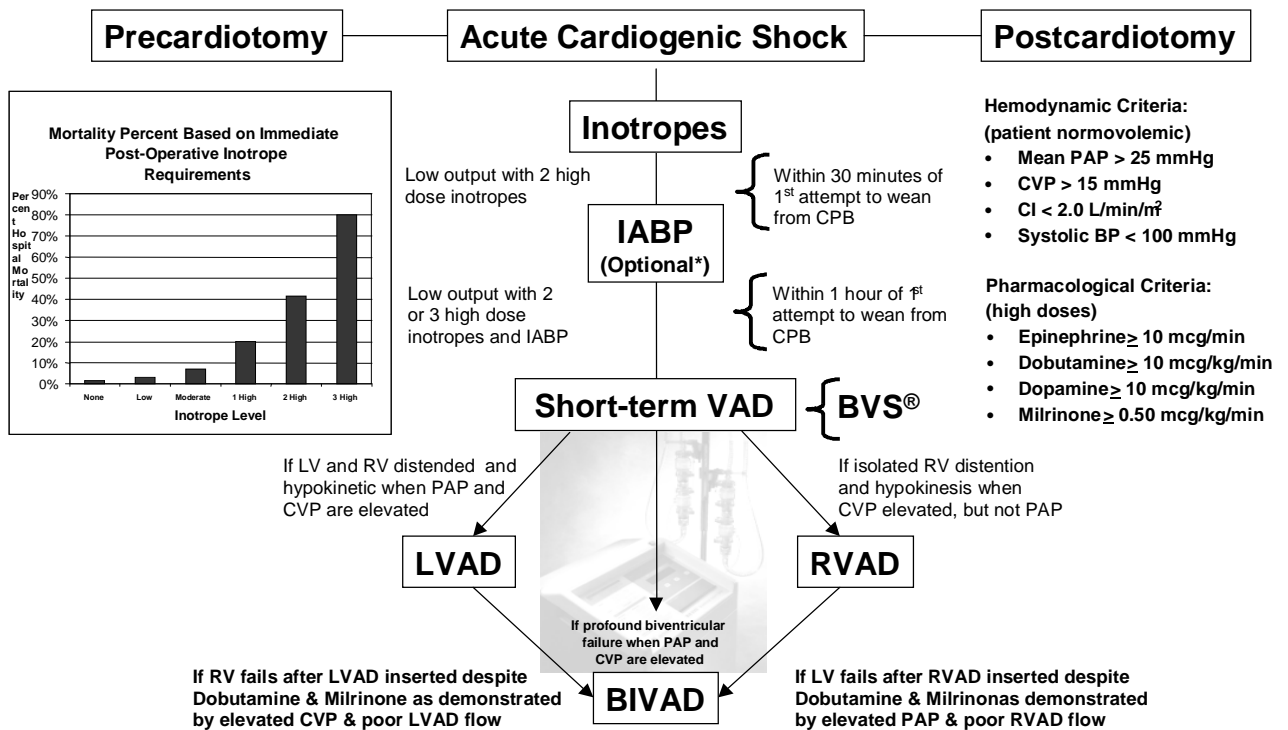
Transport Qualification Test Procedure

- 1 With the Console unplugged, turn the power on and allow the self-test to complete. The BATTERY ON indicator turns on.
- 2 Initiate open-port pumping on the left and right sides by pressing the left and right ON switches. Check the output airflow during pumping. (Pressure alarms are activated—this is normal. Pressing the alarm mute button silences the alarms.)
- 3 Make sure the transport vehicle is running and the shoreline heater is off.
- 4 Plug the Console into the transport vehicle's power outlet. The BATTERY CHARGING indicator turns on. There should be *no noticeable change* in the Console's output airflow as described in step 2.

The vehicle is qualified for transport use if it meets the criteria in steps 1 through 4.

Appendix B

Acute Cardiogenic Shock Intraoperative Strategies



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 *IABP is OPTIONAL if, in the judgment of the clinician, the shock is so profound as to warrant direct VAD insertion.

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