

The Royal Children's Hospital

Melbourne, Australia

Victorian Paediatric Cardiac Surgical Unit

*Ventricular Assist Device
Protocol*

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1. Indications and Contraindications

There are basically three types of patients who might require VAD.

Postoperative circulatory support constitutes the most common indication for VAD. The majority of patients will have undergone reparative or palliative open heart procedures or transplantation and are unable to be separated from cardiopulmonary bypass due to severe ventricular dysfunction. A smaller number of patients require support for low cardiac output in ICU following successful weaning from bypass.

Patients with ventricular dysfunction not associated with cardiac surgery requiring circulatory support include those with potentially reversible acute myocarditis, sepsis syndrome, cardiac trauma and acute rejection following heart transplantation.

Patients with irreversible cardiac dysfunction may receive VAD support without a realistic expectation of myocardial recovery, as a bridge to transplantation.

In all children, with the exception of bridge to transplant patients, the ventricular dysfunction should be potentially reversible. In the case of postoperative patients the repair or palliative procedure should have been adequate.

Multiorgan failure, severe coagulopathy, intracranial bleeding, neurological problems and infection are all relative but not absolute contraindications for VAD support. Prolonged cardiac arrest need not be a contraindication if CPR has been adequate.

Bridging to transplant, although technically possible, is not undertaken due to the length of time typically required for procuring organs.

2. Testing for Suitability

For patients who cannot be weaned from cardiopulmonary bypass the first decision to make is whether to use any extracorporeal support. This question relates to the technical adequacy of the procedure and whether anything further can be done surgically. Transoesophageal echo, direct chamber pressure measurements and mixed venous oxygen saturation levels can provide important information. Assuming the procedure has been adequate an assessment of potential for recovery of ventricular function can be made based upon pre-operative condition and underlying anatomy.

The next decision involves the type of support: VAD or ECMO? Patients with severe pulmonary insufficiency or RV and LV failure, and/or severe pulmonary hypertension generally will not be good candidates for univentricular support, and may need to be supported on ECMO. Patients with isolated ventricular dysfunction can usually be supported by VAD.

The assessment is carried out while the patient is still on CPB. Ventricular and pulmonary functions are evaluated. A left atrial cannula is inserted (via a Y connector) into the venous line of the CPB circuit. The right atrial cannula is clamped and blood from the left atrium drains by gravity into the venous reservoir of the oxygenator. In patients with univentricular anatomy no cannula changes are necessary. Ventilation parameters are increased to pre-bypass levels, the oxygenator FiO₂ is reduced to 21% and the sweep gas is turned off.

While on VAD using the CBP circuit right ventricular and pulmonary artery pressures and function can be observed. At full flow, good contraction of the right ventricle and right atrial pressure of less than 12 mmHg (without pulmonary hypertension or right heart distention) indicate that right heart function may be adequate to allow the use of VAD. Serial blood gases are analysed to evaluate lung function. If oxygenation, CO₂ clearance and lung compliance remain in an acceptable range over 15-20 minutes the patient is deemed suitable for VAD. If either right ventricular or pulmonary function is inadequate ECMO may be required.

3. Circuit Set-up and Priming

The circuit consists of a centrifugal pump head, flow probe, PVC tubing, connectors, taps, aortic and venous cannulae, and pump inlet and outlet pressure monitoring lines (see diagram). All or some of these components may be heparin bonded.

The pump head is mounted remotely on either the HLM or a drip stand, at patient height, as close to the patient as practicable. The flow probe should be kept near to the remote head and ready to connect to the adapter.

The pre-packaged circuit is opened onto the surgical field and primed with from the CPB circuit via a Luer lock connector and tap on the aortic cannula. The CPB flow is temporarily increased to facilitate filling the VAD circuit. Once filled, the circuit is tapped to de-air it and excess blood is returned to the bypass circuit via a sucker. The two open ends of the VAD circuit are then clamped closed approximately 2 cm from each end and the priming line is removed.

In ICU the circuit is primed using a 50 ml syringe using either Plasmalyte or blood. It is then de-aired and clamped at both ends.

We currently use Jostra Rotaflow pump heads with Biomedicus consoles and flow probes or Jostra centrifugal pump consoles. We prefer to use the Jostra pump console.

4. Initiation of VAD

Bypass is stopped and the aortic and venous cannulae are double clamped. The cannulae are then prised or cut from the CPB circuit between the double clamps. Luer lock connectors with taps are included in the circuit pack already joined to the tubing. The pump inlet and outlet ends of the circuit are then connected to the appropriate cannulae. The circuit is de-aired, via the taps on the Luer connectors, using a syringe.

Both sides of the circuit must be free of air before VAD flow is started. The flow transducer must have been zeroed and connected to the flow probe in the correct orientation before flow is commenced with the Biomedicus console. The flow transducer on the Jostra console and remote drive must have the special gel applied to ensure proper operation prior to the initiation of support.

VAD support is commenced at minimal flow and quickly increased to a predetermined flow rate. Usually 80% of the calculated CPB flow rate to ensure some flow across the AV valve.

A pressure monitoring line is attached to the tap on the Luer connector of the pump inlet tubing and the other end is handed out to the perfusionist who connects it to a monitoring line with an isolator fitted. This line and transducer isolator must be filled with heparinised normal saline (1 unit per ml), via a 50 ml syringe on the tap on the isolator, and completely de-aired. It is then connected to the pressure transducer situated in the Biomedicus pump console. When using the Jostra console an extra pressure transducer must be set up with the patient pressure transducers to monitor pump inlet pressure. In this case a monitor isolator is not required.

The pump inlet pressure monitoring line should be turned off to the patient. To zero the transducer, open the transducer side of the tap to air and flush the line from the syringe on the transducer isolator. Then zero the transducer using the control inside the Biomedicus console. When the pressure display on the console reads zero, recap the tap. Ensure that the pressure monitoring line is connected through to the transducer, not the flush syringe. Turn the tap on the Luer connector so that the pump inlet pressure is being monitored. Using the Jostra console the pump inlet pressure transducer is set up according to out standard protocol.

Measuring the pump inlet pressure enables patient volume status and venous cannula placement to be monitored. VAD pump outlet pressure is set up and monitored in the same way except that a standard disposable pressure transducer is used, connected to the theatre or ICU monitoring system. Measuring pump outlet pressure allows changes in arterial resistance and aortic cannula placement to be monitored.

Once the patient is stable on VAD support, the heparin is reversed with protamine. An activated clotting time (ACT) of 130 - 140 seconds is aimed for and surgical haemostasis is attempted. When surgical haemostasis has been attained the skin is closed with the cannulae exiting at either pole of the incision.

Start a VAD record.

5. Transport.

Despite differences in bed sizes, Ohios to cots to beds, the same basic technique is used to move the patient from the operating table to the bed. Wherever possible the VAD base plate and pole should be used to secure the remote pump head to the bed. The procedure requires a minimum of 5 people. One person is required to hold the remote pump head and flow probe. One person is required to ensure that the cannulae are secure during the move. Another should watch the flow and pressure readings on the Biomedicus console. The normal pressure transducers need to be set free from the operating table as do the drains, urine bag, heating mattress lines and anything else connected to the table. The patient is then lifted by an appropriate number of people. The operating table is slid away forward and the bed is moved into position under the patient who is then lowered onto it. The VAD base plate pole is secured in the base plate and the remote head is clamped to the pole in a position that ensures that the circuit will not kink. The flow probe holder is also clamped to the base plate pole in a position such that the tubing will not kink. Changing the bed may result in some change in VAD flow and pump inlet pressure. Small changes in patient position on the bed may be necessary to permit optimum flow and pump inlet pressure.

Once the syringe pumps, drains etc. have been attached to the bed, the patient is ready for transportation to ICU. It is easiest for the VAD trolley to follow behind the bed. Someone should be positioned between the VAD trolley and the bed to ensure that the remote head drive cable does not get caught up anywhere and that the pump inlet pressure monitoring line does not disconnect or put undue stress on the venous cannula.

6. ICU Set Up

On arrival in ICU move the console into a position close to the bed, plug it into mains power and lock the wheels. Regular pressure, ECG and saturation monitoring should be set up as soon as possible. Secure the circuit to the bed using rubber bands and safety pins making sure that the tubing will not kink. Inform the nursing staff of the required flow rate for the VAD and the expected pump inlet pressure at that flow rate. Handover should also include current ACT, cannula sizes, minimum and maximum acceptable flow rate and pump inlet pressure, and a brief description on how the VAD has run until transport to ICU. The pump inlet pressure transducer should be re-zeroed and connected to the patient monitoring system to take advantage of the alarm parameters and screen position if the Biomedicus console is used. The aortic line pressure should be connected via an isolator to the transducer in the Biomedicus console and zeroed. If the Jostra console is used both pump inlet and outlet pressures must be connected to the ICU patient monitoring system and zeroed again. ACT should be measured.

The patient is kept sedated and paralysed with full mechanical ventilation. Anticoagulation is managed with a heparin infusion titrated to an ACT of 140 - 160 seconds. Inotropic support is reduced to the minimum level required to support the non-VAD side of the heart. Normothermia is maintained. If normal pulse oximetry will not work due to diminished pulse pressure using a CPB venous saturation meter on the pump inlet tubing will give an accurate reading of saturation of blood coming from the lungs.

7. VAD Circuit Maintenance

Hourly records of arterial pressure, pump inlet pressure, pump outlet pressure, left atrial pressure, right atrial pressure, pump flow, pump RPMs, ACT and heparin infusion rate are recorded in the VAD record.

All patients receive vasodilators, antibiotics, parenteral nutrition, and periodic fresh Frozen plasma (FFP) and platelet infusions as required to maintain haemostasis. The heparin infusion rate is increased by 10% while platelets are infused. Renal support, if necessary, is provided by peritoneal dialysis.

Daily plasma haemoglobin measurements are taken, and if the level rises to above 0.60 mg/l, consideration is given to changing the pump head.

The circuit is inspected for clots at each change of nursing shift by both nurses. The pump head is auscultated to determine the relative noisiness. Observations are noted in the VAD record.

8. Weaning

Patients are maintained on VAD for a minimum of 24 hours, unless complications arise, before any assessment of ability to wean from support is made. After 24 hours the VAD flow rate is reduced to allow some ventricular ejection at a left atrial pressure of 8 - 10 mmHg. Using echocardiographic guidance, increased fractional shortening and a positive Starling response on a reduced degree of VAD support are considered to be indications of myocardial recovery.

If the haemodynamics remain stable over a period of a few hours the flow rate is reduced again, otherwise it is returned to its previous rate. This procedure is continued until the patient is haemodynamically stable on a minimal safe flow rate (approximately 200 ml/min).

It is possible to cease support and leave the cannulae in situ with the circuit tubing clamped for short periods of time. For periods of more than 4 or 5 minutes a heparinised saline solution (5 units/ml) can be flushed continuously at a rate of 5 ml/hour through the cannulae via the taps on the Luer connectors.

9. Decannulation

Decannulation can occur in ICU or theatre. Decannulation is preceded by decreasing the VAD flow rate to virtually no flow. At this point in time the surgeons clamp the cannulae and remove them in the same manner as for removal of cannulae after CPB. The pump can be turned off. If the pump is already off and the cannulae are being hep/saline flushed, only the pumps driving the flush syringes need to be turned off. Once the sternal wound is dressed and the pins securing the circuit to the bed have been removed the VAD circuit can be handed back.

Following decannulation the VAD trolley, remote pump head, Bioprobe flow probe, Biomedicus or Jostra console, VAD base plate and any other perfusion equipment used must be cleaned and returned to the pump room ready for use. A copy of the VAD record must be made and filed.

10. BiVAD and UniVAD

VAD for biventricular support is also possible. The right atrium and main pulmonary artery can be cannulated in the same way as the left atrium and ascending aorta for LVAD. Two pumps generating similar flows are used. A competent pulmonary valve is necessary for BiVAD support.

It is also possible to provide support for a univentricular heart with systemic shunt dependent pulmonary blood flow by cannulating the right (or common) atrium and the ascending aorta.

Blood flow required may be higher than for regular VAD support.

11. Mechanical Complication Management

1. Accidental Decannulation

Arterial Decannulation.

- Indications:
1. Decreased blood pressure.
 2. Increase in blood in chest drains.
 3. Clinical signs of tamponade.

Venous Decannulation.

- Indications:
1. Some air in circuit tubing.
 2. No pump flow.
 3. More negative pump inlet pressure.

Management.

1. Clamp arterial and venous circuit tubing and turn pump off.
2. Put the patient head down if air is suspected to be in the aortic cannula.
3. Call the surgeons, ICU consultants etc..
4. Administer volume if necessary.
5. Increase inotropic support and perform cardiac massage if required.
6. Prepare for chest opening.

2. Air in Venous Line or Pump Head

Management.

1. Clamp the cannulae.
2. Turn the pump off.
3. Maintain cardiac output.
4. Attach a 50 ml Luer lock syringe to the tap on the connector on the cannula end of the pump inlet pressure line.
5. Disconnect the pump head from the remote drive unit.
6. Holding the pump head lower than the cannula, shake and tap the circuit to move the air up towards the 50 ml syringe.
7. Aspirate with the syringe until all the air is removed.
8. Remove the syringe ensuring the tap is turned the correct way.
9. Re-attach the pump head to the remote drive.
10. Reinstigate VAD. Remove the venous clamp, increase the pump speed to 700 rpm, remove the arterial clamp and increase the pump flow to the required level.

3. Air in Arterial Line and Patient.

1. Clamp the arterial and venous lines, not the cannulae. Turn the pump off.
2. Find out where the air came from and stop it.
3. Put the patient head down so the air will move to the lower half of the body.
4. Call the ICU consultant, registrar etc.
5. Maintain cardiac output.
6. Have plenty of filling available and someone to administer it.
7. Attach a 50 ml Luer lock syringe to the 3 way tap on the connector between the circuit and the arterial cannula and open the tap.
8. If air is seen in the cannula, aspirate blood from the arterial cannula to remove any air sitting in the cannula. Clamp the cannula once the air is removed.
9. Remove the clamp from the arterial circuit line and tap the tubing to move the air towards the syringe. Aspirate the air from the circuit. Fill the patient as required.
10. If no more air is seen reinstitute VAD.

4. Pump Head Failure.

- A). Crack inside plastic head.
Cause: a) contact with alcohol.
(rough surface will cause hemolysis).

- B)..Blood leak from Pump.
Cause: a) as above
b) pump split.

Procedures:

- a) Clamp arterial, venous and shunts lines.
- b) Ventilate patient and maintain cardiac output.
- c) Replace any volume lost.

PUMP HEAD CHANGE:

Equipment required:

- a) Pump head.
- b) Fluid administration set.
- c) Betadine solution, sterile scissors, gloves, gown, and towels.
- d) Tubing clamps.
- e) 50 ml syringe filled with 5 % Glucose or normal saline.

Procedure

- a) Put on hat, safety glasses and mask.
- b) Scrub hands and don sterile gown and gloves.
- c) Ask assistant to open box with sterile pump head and administration set, keeping contents sterile.
- d) Hand off the spiked end of the giving set and close the clamp.
For patients below 25 kg spike a unit of blood.
For patients greater than 25 kg Plasmalyte 148 may be used as the priming solution.
- d) Holding the pump head with one sterile finger over the outlet port, put the other end of the administration set into inlet port. Fill with fluid.
- e) Shake or tap to displace any bubbles upwards. Check under the magnet for any bubbles.
- f) If bubble free you are now ready to change the head.

Discuss with your partners your plan of action for changing the head, assigning roles to each of them.

- a) Place a towel on the floor underneath the ECLS equipment to catch any spills.
- b) Betadine swab the tubing of the venous inlet line and between the pump head and oxygenator.
- c) Clamp any shunt lines, turn off any infusions into the haemofilter shunt line and if using a haemofilter turn off the replacement and filtrate pumps.
- d) Ventilate the patient and maintain the cardiac output.
- e) Get one non sterile assistant to wean down the flow, clamp the arterial line, turn the pump OFF and then clamp the venous line. Remove the old pump head from the magnetic link.
- f) Quickly place two clamps on the venous inlet tubing to the pump, close to the pump head, and two clamps on the tubing between the pump head and oxygenator, pinching the tubing to avoid splashing.
- g) First cut the tubing between the two clamps on the outlet port of the old pump and join the new pump outlet port to it. Shake any bubbles up to the inlet port.
- h) Next cut the inlet tubing between the two clamps of the old pump head. With the 50 ml syringe fill the head with the extra volume to remove any air and connect the inlet tubing air free to the inlet port of the new pump.
- i) Wipe the pump head to remove any blood and recheck for that all the air has been removed before reinstating ECLS.
- j) Remove the venous clamp first and slowly turn the pump ON watching for any air in the circuit. Increase the pump speed to 700-800 RPM and take off the arterial clamp. Set the flows to the required rate and turn on all infusions and open the shunt lines again

C). Noisy Pump Head.

Thudding Cause: Clot/s in head. Plasma Hb > 0.6 g/L.
Procedure: Change pump head.

D). Pump Head Noisy & Shaking. Cause: Clot in head.

Procedure: Replace pump head before it splits.

5. Power failure

The Biomedicus console has an internal battery that will run for 3/4 hour at 300 RPMs. The Jostra console has an internal battery that will run for about 25 minutes. If mains power still OFF after 1/4 hour collect another pump from theatre in readiness for transfer of pump head.

6. Console Power Failure

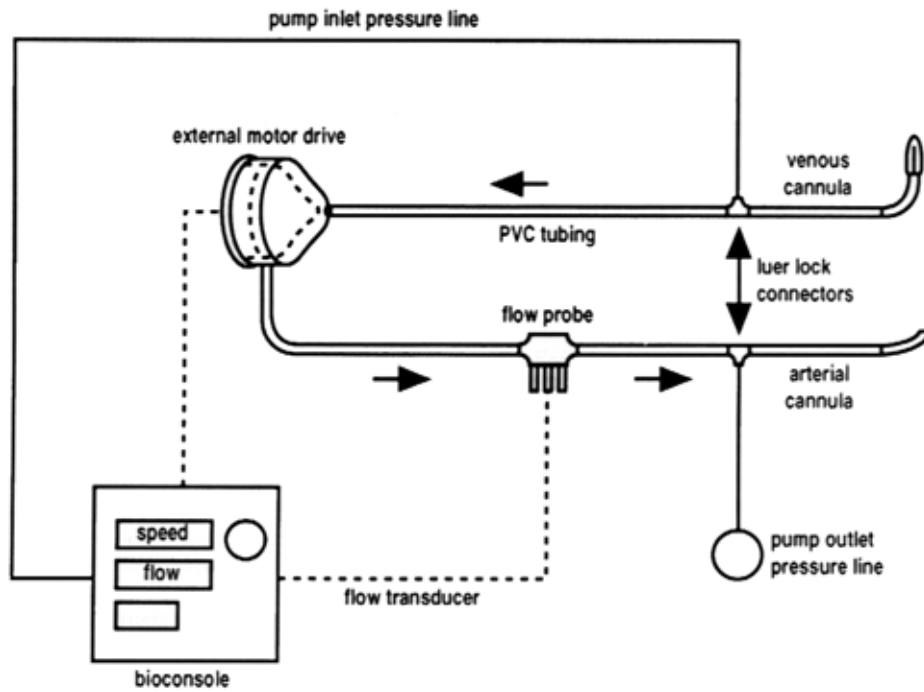
1. Clamp arterial line.
2. Turn pump off.
3. Clamp venous line.
4. Maintain BP with inotropes, volume or cardiac massage as necessary.
5. Check all electrical connections.
6. Try changing electrical mains lead.
7. Collect another pump from theatre and ensure it will function on battery.
8. Position the replacement console next to the failed one and change the cables for the external drive, flow probe, mains power and the inlet pressure line.
9. Check the zero on the flow probe. Run back onto support and zero the inlet pressure transducer.

7. External Drive Failure

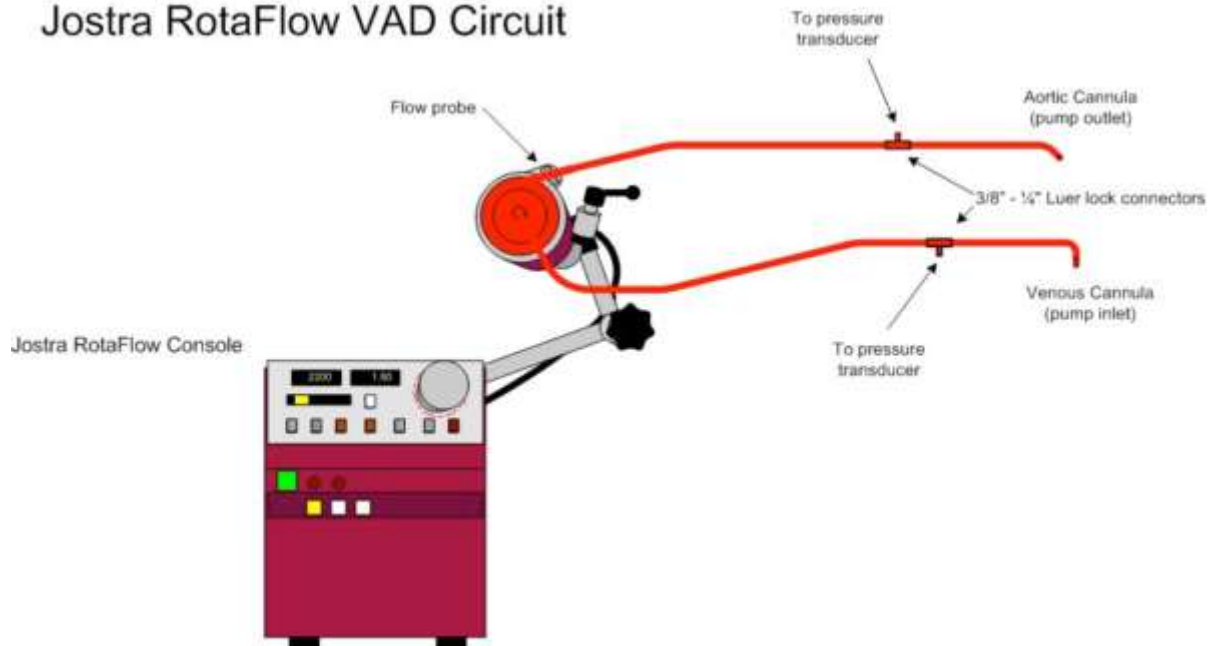
1. Proceed as for changing pump console.
3. Turn pump off.
4. Open top drawer of console and switch motor to internal drive.
5. Move the console to where the pump head can be placed on the internal drive plate.
6. Place pump head on rear drive unit of console.
7. Place patient back onto support

12. Diagrams and Forms

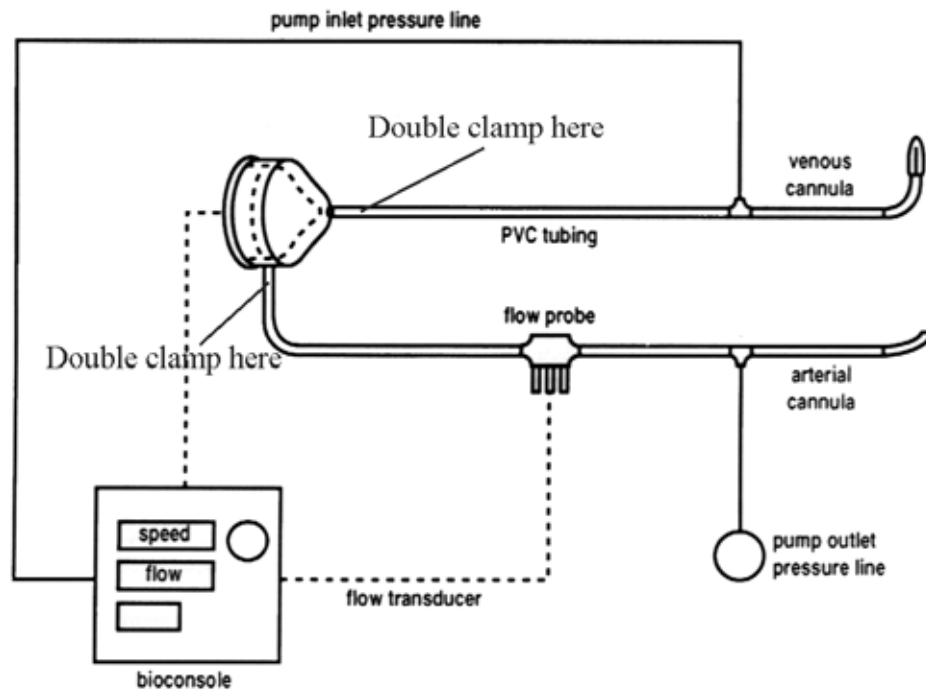
1. Biomedicus VAD Circuit



Jostra RotaFlow VAD Circuit



2. Clamp positions for pump head changes



3. VAD Record Sheet

Affix Patient Label

DATE: / / .

TIME:	Pump Speed (R.P.M.)	Pump Flow (ml/min)	Pump Inlet Pressure (mmHg)	Pump Outlet Pressure (mmHg)	Patient Aretial Pressure (mmHg)	ACT (sec)	Heparin Infusion Rate	Comments
0100								
0200								
0300								
0400								
0500								
0600								
0700								
0800								
0900								
1000								
1100								
1200								
1300								
1400								
1500								
1600								
1700								
1800								
1900								
2000								
2100								
2200								
2300								
2400								

YOU MUST: DATE EACH PAGE & **COMPLETE** PARAMETER SHEET OVER.

CANNULATION (MUST BE COMPLETED BY PERFUSIONIST)

	PATIENT INFLOW	PATIENT OUTFLOW
CANNULA POSITION		
CANNULA TYPE		

VAD PARAMETER ORDER SHEET

(MUST BE COMPLETED BY MEDICAL PRACTITIONER)

DATE: / / .

TIME				
PUMP FLOW (ml/min)				
PUMP INLET PRESSURE (mmHg)				
PUMP OUTLET PRESSURE (mmHg)				
ACT (sec)				
HEPARIN INFUSION (ml/min)				
I.A. PRESSURE (mmHg)				
R.A. PRESSURE (mmHg)				
L.A. PRESSURE (mmHg)				
P.A. PRESSURE (mmHg)				
SIGNATURE				

PATIENT INFORMATION - PREVIOUS 12 HOURS

(MUST BE COMPLETED BY R.N. AT 1200 & 2400 HRS)

	1200 hrs.	2400 hrs.
RBC's TRANSFUSED	ml	ml
FFP TRANSFUSED	ml	ml
PLATELETS TRANSFUSED	ml	ml
PLATELET COUNT		
INR/APPT		
PLASMA Hb	G/L	G/L
LACTATE	mmol/l	mmol/l
URINE OUTPUT	ml	ml

COMMENTS: