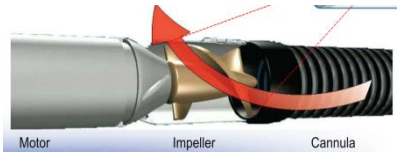
ABIOMED IMPELLA

KEY MAINTENANCE POINTS

For Review Only – Not For Initial Education

Abiomed Slides Used For Document Creation

VUH CVICU: Revised 7/13

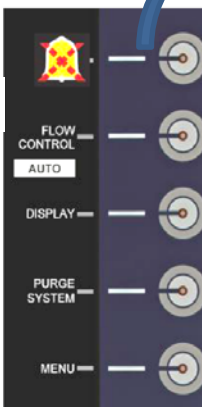


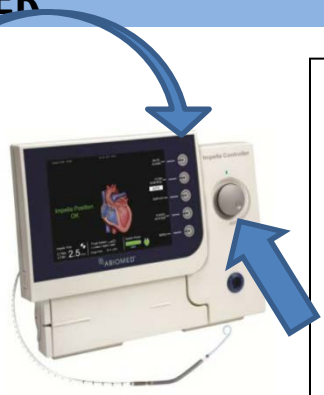
- Continuous Flow Device: Flow is limited by catheter size / Rotation speed is proportional to flow
- Sits across the aortic valve – blood from the LV is pulled to the aortic root via a micro-axial pump.
- If fully charged, the controller battery can run the device for 60 minutes.
- To turn on, press and hold power switch for 3 seconds.
- To turn controller off, reduce flow to 0L/min, disconnect the white connector cable from the controller, press and hold the power switch for 3 seconds, select OK to confirm shutdown. *(See page 5 for weaning and explant steps – including when to perform flow reductions.)*
- Chest compressions may displace the catheter, but are not contraindicated. (Check with MD.)
- For Impellas with femoral access, do not elevate the HOB higher than 30 degrees.
- Prevention of flexion with a knee immobilizer may help to maintain correct position. (This is especially important with the 3.5L/CP device!)
- If a patient is transferred in on the "old" MPC controller, an AIC controller, a white connector cable, a purge cassette, and purge fluids will be needed. The controller, cable, and cassette are obtained from Cath Lab. Purge fluid comes from Pharmacy. (VHVI only has AIC controllers, so this switch will only be necessary for some transfers from outside hospitals.)

CONTROLLER

Soft Buttons

- **MUTE ALARM** silences or clears an alarm; bell icon with red X displayed when alarm is muted for two minutes or until a new alarm is detected
- **FLOW CONTROL** sets flow rate, p level, auto, or boost
- **DISPLAY** opens a menu from which you can select different display screens and change time and display scale
- **PURGE SYSTEM** opens the Purge System menu for selecting various purge procedures
- **MENU**
  - Settings/Service
  - Alarm History
  - Started Timed Data Recording
  - Start Repositioning Guide
  - Case Start





Navigation: The soft buttons take you to screens. This is the only touch-screen part of the controller.

The gray navigation knob is used to move through and select items on the screens. Turn to navigate/ push to select.

Common Screen Elements

- Current flow rate
- Max / Min display
- Catheter operation icon
- Purge system marquee
- Y connector icon
- Purge flow
- Battery status
  - **Full-partial green:** ≥50% charged
  - **Partial yellow:** 16% to <50% charged
  - **Partial red:** <15% charged
  - **Moving gray:** charging
- AC plug indicator
  - **Green:** running on AC power
  - **Gray with red X:** on Battery

This information is on the bottom of every screen.

Display Screens (Purge and Infusion History)

Purge Screen

Infusion History Screen

Purge Screen displays the purge <u>pressure.</u>

NOTE: Purge <u>infusion rate</u> is displayed at the bottom of all screens.

Infusion History Screen shows how much heparin was infused via the purge fluid.

VERY IMPORTANT NOTE!! If systemic heparin is ordered, it must be adjusted to supplement – not be in addition to – the purge fluid heparin.

Display Screens (Placement and Home)

Placement Screen

Home Screen

Keep on Placement Screen!!

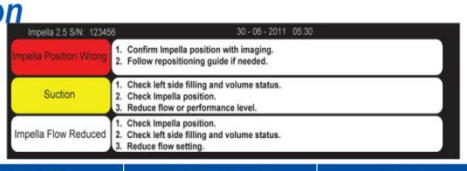
Pulsatile motor current is the **MOST** significant placement indicator. Absence of or change in motor current pulsatility flags placement concerns.

(The Impella is a continuous flow device; power requirements to produce consistent flow are different when the aortic valve is open versus closed. A pulsatile motor current shows that this variation is present.)

The Home Screen creates a pictogram based on information from the placement screen. Tracking/trending motor current and placement waveform change is more reliable than relying on the picture.

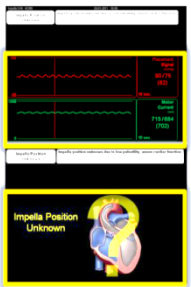
SELECT ALARMS

Suction



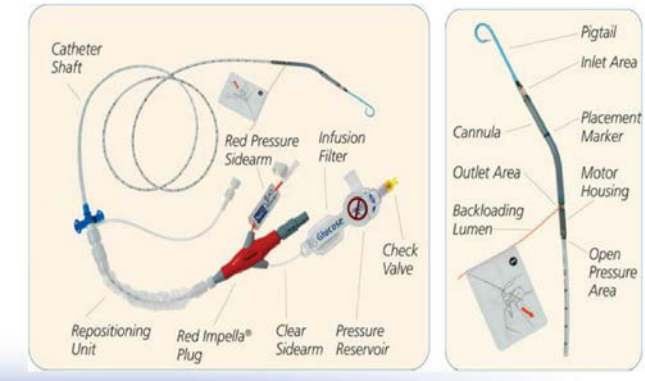
What is it?	What to look for	What to do
Causes of suction: •Incorrect position in LV •Inadequate LV filling **Effects of suction:** •Lower than expected Impella flow •Patient may not fully benefit from Impella support	• "Impella Flow Reduced" advisory alarm • "Suction" alarm • Lower than expected flows • Reduced mean motor current (5-minute display) • Lower patient blood pressure	1. Evaluate catheter position using placement signal, motor current and imaging; reposition if necessary 2. Assess volume status 3. Confirm RV function 4. Return flow rate to pre-alarm setting when suction resolved

Low Native Heart Pulsatility

What is it?	Where to look	What to look for	What to do
• Low native heart function • May not generate sufficient pressure difference across aortic valve		• Placement signal flattened • Motor current signal dampened or flat • Yellow question mark on heart icon • Position message: "Impella Position Unknown"	Monitor Impella Catheter position using: •Patient hemodynamics •Periodic echo assessment

CATHETERS

Impella 2.5 Catheter



The 2.5 L and 3.5L (CP) catheters have an **open pressure port** with an actual pressure waveform.

An aortic waveform should be displayed; if a ventricular waveform is present, inlet and outlet ports are both in the ventricle.

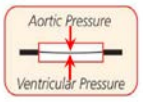
Can use auto function with 2.5 and 3.5 L catheters – in auto, the motor speed will self-adjust to achieve maximum flow without causing suction. *(Can use P levels, but there is no auto adjustment with P levels.)*

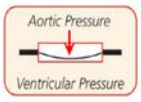
IMPELLA 5.0L CATHETER

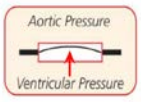
Differential Pressure Sensor—Overview

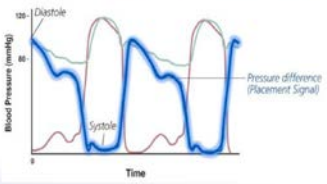
- Flexible membrane integrated into the cannula
- Generates the placement signal used to monitor position and calculate flow

Differential Pressure Sensor Electrical Signal









The 5.0L catheter does not have an open port for transmission of chamber/vessel pressure waveforms.

- It has a flexible membrane that senses aortic and ventricular pressure difference (i.e., differential pressure).
- The 5.0 "placement signal" is "upside down" from the usual systolic/diastolic ventricular highs and lows.
- The gradient between the highest and lowest pressures are monitored to assess change. (Highest = diastole / Lowest = systole)

Differential pressure is measured through a flexible, but closed diaphragm – not open ports.

- The pressure pigtail that the pressurized NSS solution is connected to on the 2.5/3.5 (CP) catheters is <u>not</u> present on the 5.0 catheter.
- Pressure differential numbers are displayed on the screen.

Normal Pressure Differential: <u>30 - 60 mmHg</u>
0 - 10 mmHg

Auto flow control cannot be used with the 5.0 catheter. Flow is controlled with P levels.

More about FLOW CONTROL...

Mode	Controller Function
AUTO	• Motor speed set to achieve maximum possible flow without causing suction
ON	• Flow rate set to 1 L/min initially and can be changed manually (eg, weaning)
BOOST	• Flow maximized for 5 minutes and then returns to AUTO setting
P-LEVEL	• Flow determined by one of ten performance levels (P0-P9); enable through MENU

FLOW CONTROL

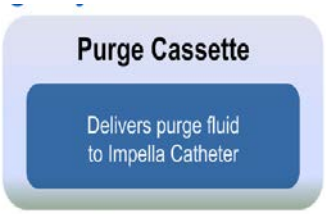
2.5 and CP (3.5) Catheters

- "Auto" - used during support. In auto, motor speed self-adjusts to achieve maximum flow without creating suction.
- "On" - used during weaning
- P-levels - can be used instead of auto – if MD preferred. (If P-level driven, assess for suction events.)

5.0 Catheter

- "P-Level" is used for setting rotational speed.
- "P-Level" is adjusted for weaning.
- Assess for suction events. (No pump self-adjustments)

PURGE SYSTEM



Automatic Purge Pressure Management

- Pressure sensor reads purge pressure from the purge pressure transmitter
- Controller automatically adjusts purge flow
- Warnings or alarms are displayed if purge pressure is too high or too low

The purge system prevents blood from entering the Impella catheter motor.

CVICU Usual Solutions: D_{20} with 50 units heparin/ml or D_5W with no heparin.

- The D_{20} solution is listed in WIZ under Heparin for Impella.
- The solution viscosity assists with maintenance of purge pressure and motor protection. If heparin is not used, higher purge volumes are optimal. More D_5 than D_{20} will be infused to maintain optimum purge pressure.
- No NSS purge solution - could corrode motor.

Purge Pressure should be between 300 and 1100 mmHg.

To change purge solution:

- Procure new purge solution bag from Pharmacy
- Press PURGE SYSTEM
- Select "Change Purge Fluid"
- Follow directions – including entering fluid and heparin concentration.

Purge Cassette is changed every 96 hours.

- Press Purge System and follow directions.
- Cassettes are obtained from Cath Lab.

PURGE ALARMS

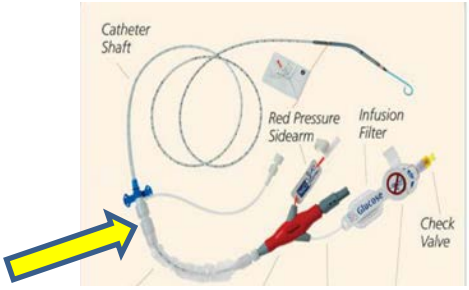
Purge Pressure < 300 mmHg and ***Purge Flow > 30 cc/hr***

	Where to look	What to look for	What to do
1		Are there any leaks in the purge cassette or luer connections to the catheter?	Tighten any loose connections
2		Is the dextrose (purge fluid) concentration too low?	Increase the dextrose (purge fluid) concentration
3		Is the leak coming from the purge cassette?	Replace the purge cassette

Purge Pressure > 1100 mmHg and ***Purge Flow < 2 cc/hr***

	Where to look	What to look for	What to do
1		Are there any kinks in the purge tubing, the clear sidearm, or anywhere along the catheter?	Straighten the tubing, clear sidearm, or catheter
2		Is the purge fluid concentration too high?	Reduce the purge fluid (dextrose) concentration

CHECKING TOUHY BORST CONNECTOR

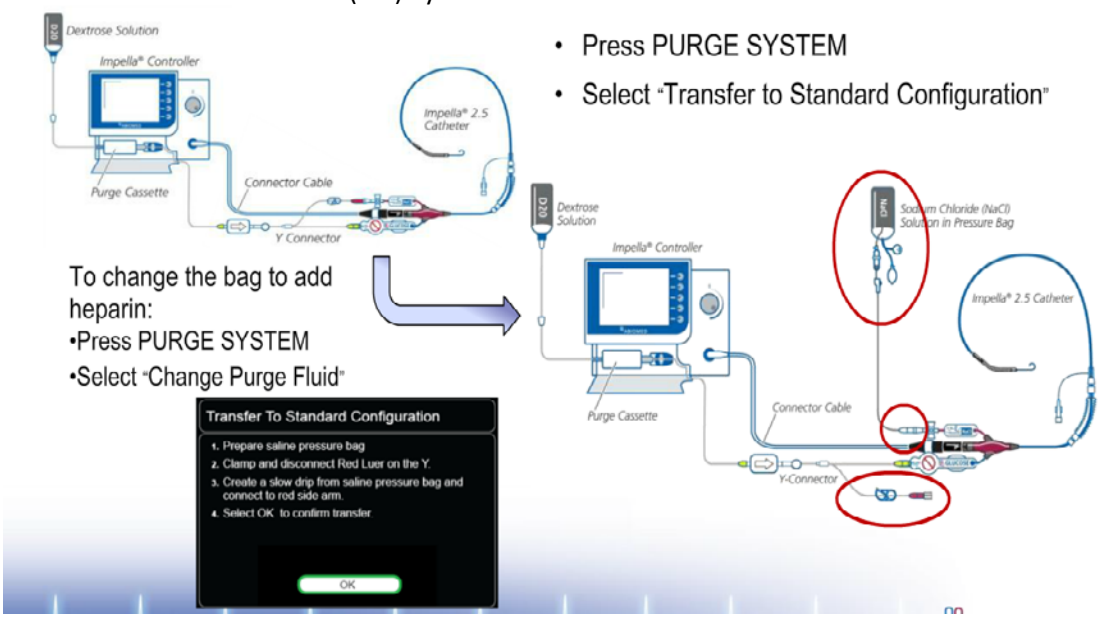


A Touhy-Borst (screw-down) adaptor is located between the introducer and catheter sleeve. This adaptor needs to be screwed down tightly to prevent accidental catheter movement.

Catheter immobilization via the Touhy Borst adaptor is checked with handovers and after catheter repositioning. These checks are documented on the flowsheet.

Transfer to Standard Configuration

Transfer Impella 2.5 System to standard configuration as soon as practical.
or CP (3.5) System



If a 2.5 or CP (3.5L) catheter comes from the Cath Lab with both purge tubing pigtails still connected to the dextrose solution Y connector, a "transfer to standard configuration" is required.

1. Prime the solution administration set (from the Impella basket) with NSS. Put NSS in pressure bag.
2. Choose "Transfer to Standard Configuration" from the purge system screen.
3. Clamp the prime tubing pigtail with the **red luer end** (the pigtail without the glucose-only label), disconnect, and reattach to primed NSS tubing.
4. Establish a slow drip rate from the pressurized NSS.

WEANING AND EXPLANT OF 2.5 IMPELLA

Weaning and Explant

1. Decrease flow rate by 0.5 L/min as cardiac function allows
2. Maintain support at 1 L/min until hemodynamics stable
3. Decrease flow rate to 0.5 L/min and pull catheter into aorta
4. Reduce flow to 0 L/min
5. When ACT < 150 seconds, explant Impella
6. Apply manual compression per hospital protocol

Do NOT decrease flow rate below 0.5 L/min (or P2) until just before removing the catheter from the ventricle

Note: Flow rate is not turned to 0L/min until the catheter tip is in the aorta. (Turn to 0 immediately before catheter removal.)