Impella® CP with SmartAssist®, and 5.5 with SmartAssist®, Management in Pediatric Patient

ADVANCED CARDIAC THERAPIES IMPROVING OUTCOMES NETWORK

HARMONIZED PROTOCOL

BACKGROUND

Use of mechanical circulatory support in children is restricted to a few devices translated from the adult population. Impella heart pump offers opportunities for mechanical circulatory support in older children. Due to limited pediatric experience with this device, a structured approach to patient selection, assessment and device deployment, followed by careful monitoring and guided therapy de-escalation, is essential.

ACTION REVISED DATE: 4/1/25

Contents

OBJECTIVES

This document will provide an overview of the Impella® CP with SmartAssist®, and Impella® 5.5 with SmartAssist®, devices, patient selection, implantation techniques and management strategies.

PROTOCOL

IMPLANTATION INDICATIONS

As with many temporary and durable mechanical support devices the success of support is dependent on careful patient selection. Current pediatric experience highlights 3 primary disease types that may benefit from Impella support.

1. Support and recovery from acute cardiogenic shock (left sided or biventricular support)[1,2, 18,19]
    a. Acute myocarditis
    b. Acute decompensated heart failure
    c. Acute transplant rejection with graft dysfunction
    d. Malignant arrhythmias

2. Bridge to decision for durable support or transplantation (left sided or biventricular support)[3,4]
    a. Circulatory support and ventricular unloading to enhance the possibility of cardiac recovery
    b. Potential bridge to transplant for patients who are poor candidates for durable VAD due to anatomic or surgical factors
    c. Potential bridge to transplant for adolescents or adults that may have short waitlist time
    d. Left heart unloading to assess PVR response in patients who are poor candidates to transplantation due to elevated PVR of unknown chronicity

3. Left heart unloading on VA-ECMO(ECMO + IMPELLA) [5-8]
    a. Left heart unloading with theoretical goal of maximizing myocardial recovery or in the prescence of acute or ongoing shock
    b. In place of LA vent or balloon atrial septostomy that would subsequently require surgical closure
    c. Facilitate weaning off ECMO in patients with cardiogenic shock

CONTRAINDICATIONS

The following conditions **may not be appropriate for implantation of the Impella system for LV support**.

- Inadequately sized vessels for insertion – will vary based on device type and BSA
- Mural thrombus in left ventricle, [18, 19]
- Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥+2), [18, 19]
- Presence of a mechanical aortic valve [18, 19]
- Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)
- Abnormal arch anatomy precluding catheter advancement, specific to CHD
- Known coagulopathy - should warrant discussion with hematology

PRE-IMPLANTATION EVALUATION AND ASSESSMENT

IMAGING

Echocardiography Assessment and Measurements

Optimal candidacy and device selection will depend on a comprehensive assessment which includes detailed cardiac and vascular imaging.[18, 19]

The following echocardiographic measurements should be performed:

- Assessment of LV or systemic ventricular systolic function [18, 19]
- Measurements of the following cardiac structures are necessary for determining candidacy for Impella insertion:
  - Measure of the systemic ventricular length from the apex to the aortic valve annulus in both an apical 4 chamber view and parasternal long axis view.[18, 19] This is particularly important for smaller patients (<40 kg) as the systemic ventricular length can limit options for device placement.
  - Measure length of the ascending aorta from the aortic valve annulus to the origin of the innominate artery (typically from a high parasternal long axis view). This measurement is not as critical for device selection as the ventricular length.
- Presence of aortic valve insufficiency
  - More than mild insufficiency at baseline could result in worsening AI with Impella placement.
  - Moderate to severe AI is a contraindication to Impella placement.
- Evaluate for any LV or aortic root thrombus. [18, 19]
- For additional diagnostic imaging please refer to publication by Morray et al. 2019[9]

Advanced cardiac imaging

- If any anatomical structures are in question, the assessment should extend to advanced cardiac imaging such as CT chest with contrast. [18, 19]
- Advanced imaging might also be required for planning of surgical implantation to ensure appropriate size of branch vessels as well as determine path of device insertion.[18,19]

Vascular Imaging

- Vascular ultrasound should be used for assessment of potential access sites to exclude presence of any obstruction such as arterial thrombus or arterial collaterals especially in children with chronic illness. For the Impella CP the vessel diameter should be > 5mm.[10, 18]
- Impella 5.5 generally requires larger vessel size (≥ 7 mm)[19] but has been implanted in patients in which the arterial vessels measure smaller than the motor given vessel wall elasticity but should be discussed with surgical team prior to implantation. The Impella 5.5 system consists of a 19Fr microaxial pump and 21Fr cannula mounted on a 9Fr driveline/bearing purge delivery catheter.[11,12,19]
- Caution should be taken in patients with shock on vasopressor support as the access vessel can become much smaller than the native size due to effect of the vasopressors. In these situations nomograms for expected vessel size can be used to determine feasibility of implantation.
- If any suspicion of compromise in distal extremity perfusion (i.e. arterial thrombosis) full assessment for arterial thrombosis in that extremity should be performed prior to device implantation. This might require US doppler at bedside or arterial angiography in interventional suite.

Table 1: Device Critical Dimensions[18, 19]

Dimension	Impella CP	Impella 5.5
Drive Catheter Diameter	9 Fr	9 Fr
Overall Largest Pump Diameter	14 Fr	21 Fr

Cannula Length (cm)	6.7 cm	8.0 cm
Ventricle Length[a] (cm)	8.5 cm	6.0 cm
Aorta Length[b] (cm)	7.0 cm	6.4 cm

a. ventricular length from apex to aortic valve annulus
b. length of ascending aorta from the aortic valve annulus to origin of innominate artery

LABORATORY ASSESSMENT

Table 2: Diagnostics blood tests recommended prior to device deployment

Chemistry and Microbiology				
	☐	Comprehensive Metabolic Panel	☐	Brain Natriuretic Peptide or NT pro-BNP
	☐	Cystatin C	☐	Urinalysis
	☐	CRP	☐	+/- MRSA screen (institutional preference)
Hematology				
	☐	Type and Screen	☐	Plasma-free Hemoglobin
	☐	CBC w/ Differential	☐	LDH
	☐	PT/INR, PTT	☐	Anti-Xa if on heparin
	☐	Fibrinogen, D-dimer	☐	TEG or ROTEM Thromboelastography
	• Consider additional thrombophilia or bleeding work up if concerning family history or clinical course (see Action Pre-Implant Protocol for details)			
Ancillary Studies				
	☐	EKG	☐	Ultrasound Doppler (arterial & venous) to establish vessel size, information on access and line placement
	☐	Echocardiogram	☐	
	• Consider Head CT if patient at high risk (i.e., ECMO) or unable to get reliable neurologic exam • Consider if MRI study (heart or brain) is warranted as cannot be performed after Impella is placed • Consider Chest CT if needed for fit testing/size of heart if anticipate converting to durable VAD later			

MONITORING

- Ensure accurate weight and height is measured and BSA is calculated on the day of procedure.
- The following hemodynamic monitoring should be in place prior to or at the time of Impella implantation:
    - Arterial line
    - Central venous access
    - Swan Ganz catheter in biventricular anatomy and if no contraindications (recommended but may not be utilized in all institutions if experience or training is lacking)
    - Foley catheter
    - Consider tissue oximetry monitoring of the extremity with the implanted device

IMPLANTATION TECHNIQUES

ANTICOAGULATION AT TIME OF IMPLANT

- A bolus dose of heparin should be administered to achieve an ACT >250 seconds prior to introduction of the Impella catheter.[18,19] See below for more information about anticoagulation.

CATHETERIZATION-BASED IMPLANTATION

Femoral Access Approach of the Impella CP with SmartAssist (Impella 5.5 cannot be placed femorally)

- Impella insertion should be performed with fluoroscopic and in most cases, echocardiographic (TTE or TEE) guidance. This is typically done in the catheterization laboratory although implantation in an operating room can be performed with the use of a portable fluoroscopic C-arm. Bedside implantation in an intensive care unit is discouraged. [18, 19]
- The arterial access site may vary depending on the intended duration of support, the size of the patient and size of the pump that will be inserted. [18, 19]
- After ensuring adequate size (>5mm). Access should also be obtained with ultrasound guidance whenever possible. Other imaging techniques, including the use of bony landmarks and angiography may be performed as well. [18, 19]
- Once access is obtained the arteriotomy can be “pre-closed” with 1 or 2 Perclose sutures. This will assist with hemostasis once the device is removed. This has been shown to be helpful in some clinical scenarios but is not in the IFU but described in clinical experience portion of IFU. [18]
- After vascular access is obtained (either percutaneously or via cutdown), appropriately sized peel away sheath is placed in the vessel or chimney graft. This will be peeled away after the Impella CP is in the appropriate position and the repositioning sheath is advanced through the arteriotomy and sutured into position. [18, 19]
- A pigtail catheter is advanced to the systemic ventricle and a guidewire (included with the pump, 0.018 inch Impella wire) is inserted anterior and away from the mitral valve, in the systemic ventricular apex.
- The Impella device is advanced over the guidewire using fluoroscopic guidance and the guidewire removed once the tip of the pigtail is in the systemic ventricular apex. [18, 19]
- The position of the Impella device is verified by echocardiography (see corresponding imaging section). The device may be adjusted if needed using echocardiographic guidance. [18, 19]
- Vessel diameters less than 6 mm may require antegrade perfusion to prevent limb ischemia. [18, 19]
- The Impella repositioning sheath/ may be adjusted (end of sheath is tapered) to optimize distal limb perfusion (based on signal from a distal pulse oximeter and clinical exam).

SURGICAL IMPLANTATION

Right axillary artery approach for Impella CP and 5.5

- Follow institutional practices for pre-op cleansing, anesthesia, time-outs, and ensure appropriate equipment is available.
- Sizes available for this technique: Impella CP and 5.5.
- Pre-op evaluation with CT scan (CTA ideal) to determine the anatomy and largest size Impella device that the vascular access will allow.
- Graft selection: (Hemashield Platinum is the recommended graft). [18, 19]
- Pump standby (CPB), fluoroscopy, and transesophageal echocardiogram are necessary for this

approach.

- Place standard monitoring lines.
- Position patient supine with arms tucked at the side.
- Isolate and expose the axillary artery and obtain control via proximal and distal vessel loops. [18, 19]
- Great care should be taken not to injure or avulse any of the delicate side branches.
- Care is taken to avoid injury to the surrounding axillary vein and brachial plexus located superiorly.
- Isolate and control the right axillary artery using a C-clamp and make an anterior arteriotomy.
- Trim a 10 mm graft[18, 19] to match the arteriotomy and create an end-to-side anastomosis using a running 5-0 Prolene suture to the right axillary artery. Abiomed recommends using at least a 60-degree bevel on the end of the graft to facilitate passage of the rigid motor housing into the artery.
- Great care should be taken to ensure precise suturing and place additional hemostatic sutures as needed as the inferior aspect of the anastomosis is very difficult to see once the graft is tunneled.
- Consider topical hemostatic agents (institutional preference).
- Remove the c-clamp and inspect for hemostasis, while clamping the distal graft.
- Once hemostasis is satisfactory, clamp the proximal graft and tunnel the graft to a remote site (usually anterior to mid-axillary line), bring it out through the skin and temporarily secure it with a clamp.
- Place introducer system in distal graft and de-air.
- Under fluoroscopic guidance (may require cardiac interventionalist or interventional radiology), insert a 0.035 inch diagnostic guidewire with a 4–6 Fr diagnostic catheter into the introducer, Advance the guidewire and catheter into the left ventricle. Remove the diagnostic guidewire and exchange it for a stiff 0.018 inch placement guidewire. With the 0.018 inch placement guidewire properly positioned in the left ventricle, remove the diagnostic catheter. [18, 19]
- Advance the prepped Impella device over the guidewire through the sheath and the graft.
- Confirm Impella device is across the aortic valve and inflow and outflow areas are properly positioned with fluoroscopy and transesophageal echocardiography. [18, 19]
- Confirm that the placement guidewire has been removed and confirm that the controller displays a pulsatile waveform prior to starting the Impella device. The Impella CP will start in AUTO and automatically increase the flow rate over 30 seconds. For the 5.5, slowly increase P-level to desired output/decompression based on position on TEE. [18, 19]
- Reconfirm positioning after final device placement with TEE, as the device has a tendency to advance into the ventricle as flows are increased. Make sure to check positioning again prior to break down of the sterile field at the end of the case.
- Secure the Impella catheter in place to the skin. Catheter fixation accessory may be used to assist in 3-point external fixation of the pump catheter to the patient body. [18, 19]
- Close the right axillary artery cutdown sight in multiple layers and skin.
- Ensure hemostasis of the right axillary artery cutdown site.
- Note the final pump P-level and flow, aortic to mid- inlet measurement by TEE, and pump placement at the cm marker number for changes and repositioning postoperatively.

ECMO + IMPELLA

- Impella can be used in combination with ECMO for left heart decompression.
- Axillary (CP or 5.5) or femoral (CP) approach
- In the circumstance of femoral approach, retrograde insertion of a small caliber sheath in the superficial femoral artery can be performed to augment distal arterial perfusion to the limb and prevent ischemia complications.

POST-OPERATIVE PATIENT AND DEVICE MANAGEMENT

ANTICOAGULATION

Anticoagulation is required to prevent clot formation around the catheter as well as to preserve device motor and pressure monitoring. Optimal anticoagulation is achieved through a combination of purge fluid containing dextrose and heparin or if heparin is contraindicated sodium bicarbinate. and systemic anticoagulation administration. Purge fluid cannot contain NaCl at any point. [18, 19]

Role of Purge Fluid

- Impella pump motors require a constant purge using a dextrose solution in water with heparin (25 or 50 IU/mL) or if heparin is contraindicated, sodium bicarbonate (25 or 50 mEq/L). In addition, Impella pumps are used in conjunction with heparin based systemic anticoagulation therapy. Although direct thrombin inhibitors have been used as an alternative to heparin systemic anticoagulation, this is not aligned with the IFU. During support with Impella pumps, the targeted ACT is 160-180 seconds. [18, 19]
- All Impella pump motors are protected from biomaterial build-up by running fluid through a purge system. The purge fluid is required to maintain function of the device motor and is infused through the internal channel of the catheter, bearings and across the motor. This creates a protective interface or barrier that prevents blood from entering the motor housing. [18, 19]
- Purge system uses a dextrose water solution between D5W and D20W. The solution flows through the internal channel of the Impella catheter in the opposite direction of the blood flow. Through a built-in pressure sensor, the device automatically sets and adjusts the purge flow anywhere between 2 and 30 mL/h to maintain an adequate purge pressure of 300–1100 mmHg.[18, 19] The dextrose concentration of purge fluid determines the viscosity and flow rate. Since the rate of purge fluid is automatically regulated by the controller, the purge infusion rate must be monitored for large changes in dose as this might affect dose of delivered heparin.
- Lower dextrose concentrations, such as 5%, are less viscous and flow more quickly through the purge system, thereby systemically delivering more heparin. Higher (more viscous) concentrations result in a slower purge flow rate and less overall systemic heparin exposure for the patient. Higher dextrose concentrations can also result in more pressure on the pump and should be avoided when possible. The manufacturer recommends a **starting heparin concentration of 25 or 50 IU/mL in a 5% DW as the initial purge solution or if heparin is contraindicated** sodium bicarbonate (25 or 50 mEq/L). [18, 19]
- Since the purge fluid is infused under pressure, care must be taken to document and monitor purge lines and maintain proper fluid and purge cassette change according to institutional guidelines for fluid and line change.
- In 2022 sodium bicarbonate purge solution was approved by FDA as an alternative to heparin, for patients who are intolerant to heparin or in whom heparin is contraindicated (e.g. due to heparin-induced thrombocytopenia or bleeding). The solution is prepared by adding 12.5 mL of sodium bicarbonate 8.4% to a 500 mL solution of D5W.[18, 19]Using sodium bicarbonate purge solution allows for systemic only application of anticoagulation with agents such as Argatroban, Bivalirudin or Heparin.[13-15]
- The Impella catheter has not been tested with any other anticoagulants, such as direct thrombin inhibitors, in the purge solution. Therefore, avoid the use of any alternative anticoagulants in the purge solution to prevent damage to the Impella catheter.[18, 19]

Anticoagulating in Specific Scenarios:

Anticoagulation for isolated Impella CP and 5.5 support

- After implantation of Impella CP, purge fluid is started without any Heparin and should be changed to D5W with 25 or 50 IU/ml heparin **or if heparin is contraindicated** sodium bicarbonate (25 or 50 mEq/L) immediately upon arrival to ICU.
- After implantation of Impella 5.5 the purge fluid should contain Heparin 25 or 50 IU/ml **or if heparin is contraindicated** sodium bicarbonate (25 or 50 mEq/L) upon initiation of support in cardiac cath lab or operating room unless there is concern for significant bleeding.
- In clinical settings where D5W with 25 or 50 IU/ml heparin causes excessive anticoagulation the heparin concentration can be reduced to 12.5 IU/ml or dextrose concentration can be increased to reduce the purge infusion rate. Sodium bicarbonate purge can also be used in this scenario if the reduction of Heparin in purge does not achieve desired anticoagulation goal.
- In situations where D5W with 25 or 50 IU/mL in the purge solution does not allow one to achieve therapeutic goals it is advised to add systemic Heparin drip and titrate that drip to achieve overall therapeutic goals (below).
- Antiplatelet agents are typically not indicated for management of anticoagulation on Impella support.

Anticoagulation on ECMO + Impella

- In the setting of Impella with ECMO support, patients should continue to have purge fluid driven anticoagulation with D5W with 25 or 50 IU /ml heparin and systemic heparin added to achieve desired level of anticoagulation per institutional and patient specific ECMO goals.[16]
- Purge heparin contribution to anticoagulation must be taken into consideration, thus systemic heparin requirements might be lower than prior to Impella insertion.
- Frequent monitoring is recommended especially if the patient is inflamed, infected, coagulopathic or displaying signs of insertion site oozing.
- Sodium bicarbonate purge can also be used in this scenario allowing for use of DTIs for ECMO management.

Initiation and Monitoring of Anticoagulation

- Timing of initiation of heparin purge fluid and systemic heparin (if need additional anticoagulation) may vary based on institutional practice. It is recommended to start anticoagulation as soon as possible.
- Manufacturer recommends maintaining an ACT of 160-180 seconds.[18, 19]
- Institutional practice can include use of PTT or Anti Xa UF Heparin levels for goal anticoagulation (see table below)
- **If the Impella purge system delivers too much heparin**, a purge solution with sodium bicarbonate or a lower heparin concentration (12.5 IU/mL) can be used first followed by increased dextrose concentration to reduce purge infusion rate.

TOTAL HEPARIN DELIVERED TO PATIENT = IMPELLA PURGE HEPARIN + SYSTEMIC IV HEPARIN

Table 3: Anticoagulation lab goals (data taken from Sieg et al. 2015)[17] (Abiomed IFU only recommends monitoring of ACT)[18, 19]

	Anti Xa UF Heparin Level	PTT	ACT
ECMO + Impella	ECMO goals	ECMO goals	ECMO Goals
Impella Support Alone Low risk of thrombosis, short-term use or surgical site bleeding	0.15-0.25	50-60	160-180
Impella Support Alone High risk of thrombosis or long-term use	0.2-0.3	60-70	180-200

LABORATORY MONITORING

Baseline labs post Impella placement: CBC; Chemistry with liver function; Hemolysis labs: plasma Hb, LDH; Coagulation profile: PTT, PT/INR, Fibrinogen, D-dimer, anti-Xa, ACT (POCT), TEG or ROTEM; blood gas with lactate and mixed venous oxygen saturation if available.

Table 4: Recommended laboratory testing following device deployment

Laboratory Markers	24-48h post implantation	Chronic Monitoring
Hematology and Coagulation		
CBC	Q12H	Daily
Plasma free hemoglobin and LDH	Q12H	Daily until stable
DIC Panel	Q24H	Daily until stable
Coagulation panel	Q12H or with every titration	Daily
TEG or ROTEM	Q12H	Daily until stable
Chemistry and Microbiology		
Comprehensive Metabolic Panel	Q24	As indicated
Brain Natriuretic Peptide or NT pro-BNP	Q24	Weekly
Cystatin C	Once	Weekly
Ancillary Studies		
CXR	Daily	Daily
Echocardiogram	Daily	Weekly

These are recommendations only and each center is encouraged to use center-based practice.

Additional Labs:

- Renal panel to assess end organ function
- Hepatic panel to assess end organ function and monitor for hemolysis
- Due to high risk of pancreatitis in patients recovering after cardiogenic shock a pancreatic enzyme panel should be performed and monitored accordingly.

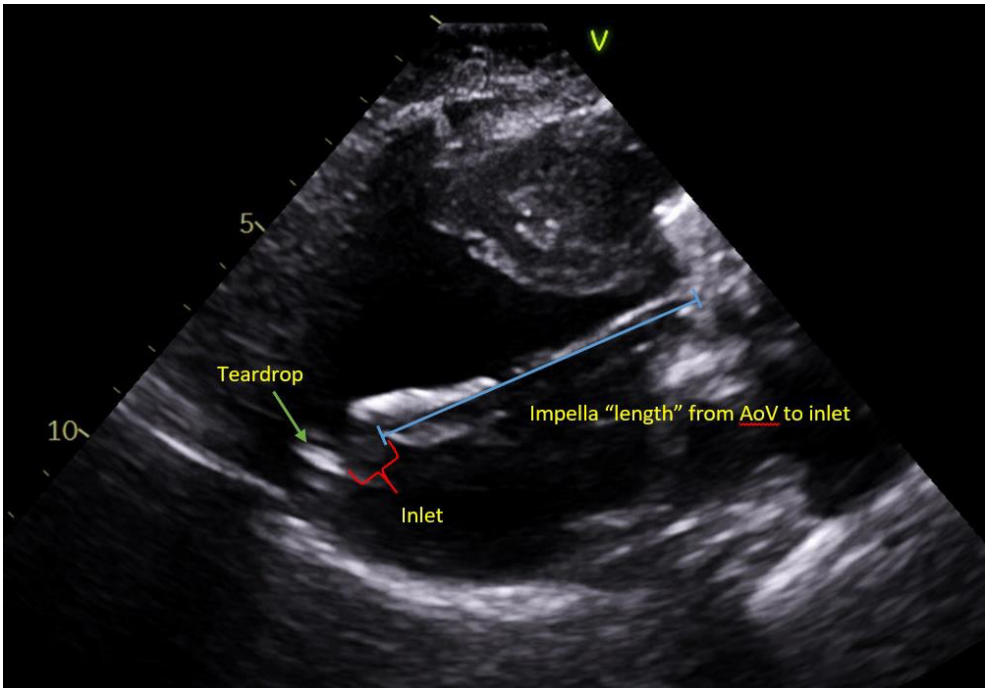
IMAGING TO MONITOR DEVICE POSITION

An echocardiogram provides useful information on Impella positioning for surveillance, if there is an increase in ventricular ectopy, or when evaluating ventricular decompression. [18,19]

Echo Imaging Protocol:

- Positioning of the Impella CP or 5.5 is best seen by echocardiogram in the parasternal long-axis view. To appropriately measure the distance of the Impella in the left ventricle, measure from the aortic valve to the inlet (lucent area prior to teardrop). This will allow for consistent measurements over the patients' course.

Figure 1: Long axis parasternal view delineating intracardiac structures used for measurement of Impella position [18, 19]



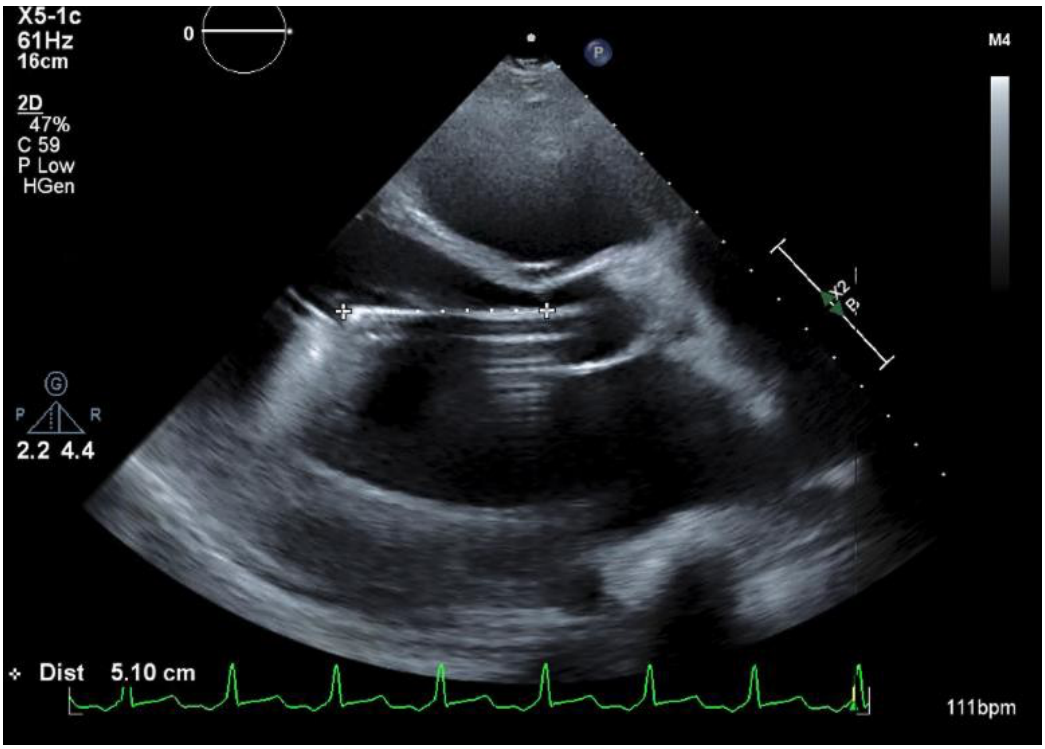
DEVICE POSITION[18, 19]

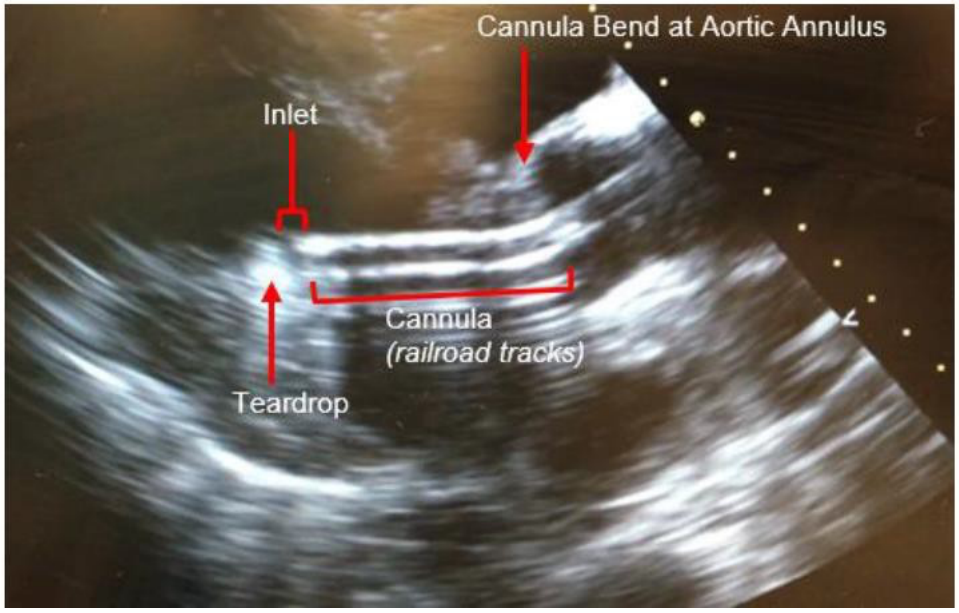
Appropriate device position is crucial for optimal device function. Each device has specific position recommendations which can be found in the imaging section of the IFU.

- Initial device position should be confirmed in the cath lab using fluoroscopy as well as TTE or TEE for correlation.
- It is recommended to re-evaluate the device position upon arrival to ICU and monitor every 48 hours.
- Positioning or suction alarms should prompt a bedside TTE to evaluate device position. The device can be repositioned at the bedside using TTE guidance.
- In smaller patients it may not be possible to place the inlet in the optimal location based on the manufacturer recommendation on distance from AoV to pump inlet. ECHO should be used to ensure the inlet of the device is placed in the mid ventricular cavity, away from cardiac structure, the mitral valve apparatus, and LVOT to avoid suction. The outlet of the device should be a few centimeters above the AoV to ensure uninterrupted flow from the device.

Table 5: Manufacturer recommended device position based on distance of device from the aortic valve to mid-inlet.

Impella Device	CP	5.5
Position below aortic valve per manufacturer IFU	3.5 cm	5.0 cm





DEVICE MONITORING AND MANAGEMENT

DEVICE TERMINOLOGY

- **P-level:** Represents various rotational speed levels at which the device can be programmed to operate. P levels represent range of RPMs that the device will maintain to achieve optimal output (see device manual for specific P-level RPMs and flow rates) [18, 19]

- **Impella Flow (L/min):** Flow is calculated from the current and pressure gradient across the device based on the measured pressure flow curves. Each device is tested in the lab for its performance and accuracy. The flow accuracy is within 10% of max flow error. [18, 19]
- **Motor Current (mA - Green Waveform):** Measures energy required to maintain RPMs, influenced by blood flow, resistance (e.g., thrombus, preload/afterload), and device position. [18, 19]
    - Pulsatility reflects normal systolic/diastolic flow variations.
    - Flat or dampened waveform: Suggests malposition (both inlet and outlet in the same compartment) or severely poor ventricular function.
    - Monitoring: Rising motor current may indicate thrombus formation, device wear, or impending failure, requiring intervention.
- **AO Pacement Signal (mmHg - Red Waveform):** AO Placement signal is measured using an optical sensor at the distal end of the outlet thus measuring aortic pressures. In most clinical cases the waveform should be pulsatile. [18, 19]
    - Impella CP with SmartAssist and Impella 5.5 with SmartAssist contain optical sensors for pressure monitoring directly in the aorta and indirectly in the LV.
    - The AO Placement signal can be used together with motor current waveform to diagnose Impella malposition.
    - The pressure signal can be used together with power waveform to diagnose Impella malposition.
- **LV Placement Signal (mmHg -White Waveform on Impella CP and 5.5):** This signal represents calculated LV pressure. [18, 19]The measurement is deducted from the optical sensor and the derived motor current pressure delta, indirectly measuring LVEDP and LVESP. This feature is available when the P-level is a P-4 or above. The LV placement signal is for informational purposes only and must be validated by an approved clinical diagnostic device.
- **Purge Flow (mL/hr):** The purge flow rate is delivered by purge cassette inside the Automated Impella Control (AIC) and is measured in mL/hr. [18, 19]The purge flow is automatically adjusted by the AIC based on the device needs. **Purge Pressure (mmHg):** The Impella console automatically adjusts the purge flow rate to maintain purge pressures between 300 -1100mmHg.
    - High/low purge pressure alarms should be evaluated by following on-screen instructions.
    - If a ‘purge pressure low’ alarm remains unresolved for more than 20 minutes, the purge cassette will likely need to be changed.

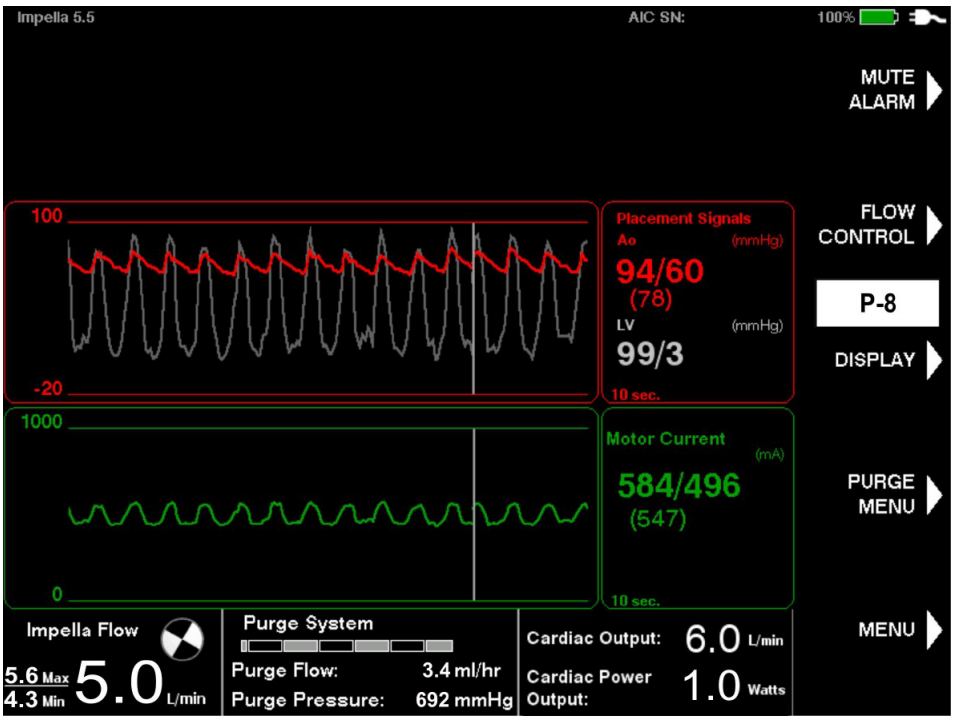


Figure 2: Example of Impella placement screen[18, 19]

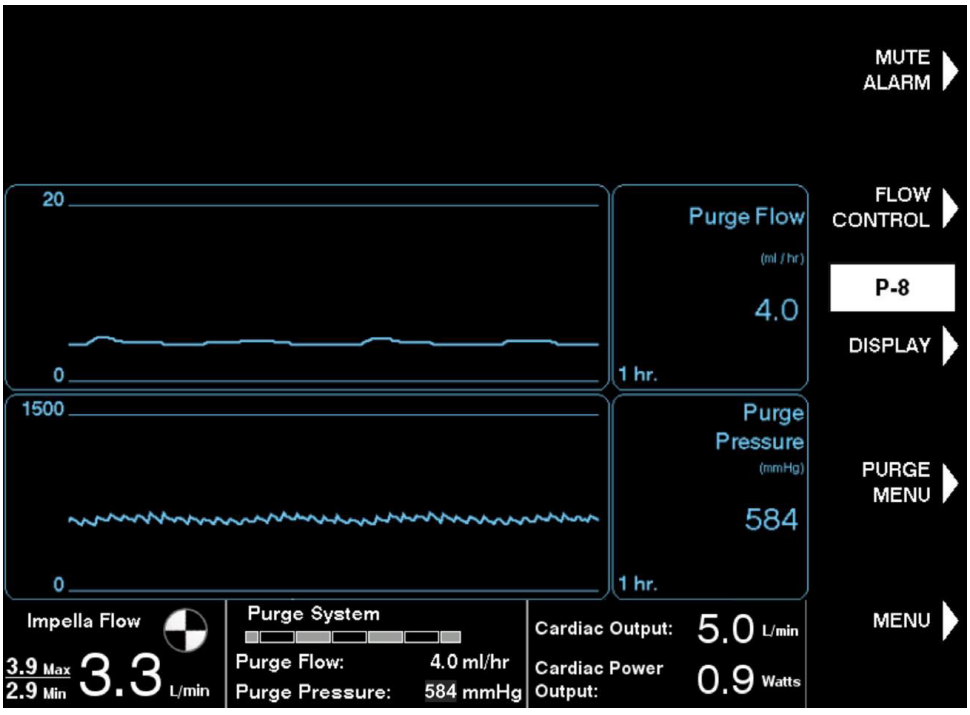


Figure 3: Example of the Impella Purge Screen[18, 19]

MOTOR SPEED[18, 19]

- Motor speed is regulated by P-levels on the controller (P-0 to P-9). Initial P-level after implantation will be in Auto. After 3 hours of operation, the controller automatically switches to P-level mode.
- Optimal lowest P-level should be determined to minimize hemolysis, suction events and other complications, but to maximize cardiac output.

PATIENT MANAGEMENT

DETERMINING OPTIMAL DEVICE SUPPORT:

- Optimal support can change with changes in clinical status (ie. recovery of ventricular function, afterload reduction, intravascular volume status). Advanced hemodynamic monitoring including invasive arterial and venous pressures must be monitored to determine optimal support. PCWP can be directly measured in the cath lab to determine lowest LV filling pressure at the lowest P-level.
- Outside of the cath lab environment, a Swan Ganz (SG) catheter can be used to determine level of LV unloading and optimal speed, as well as the function of the RV. While escalating the P-level, the level of unloading should be measured by monitoring PCWP.
- In addition to the SG catheter, echocardiographic findings can further guide titration of support and monitoring of myocardial response to support.
- Finding the optimal P-level will help minimize hemolysis and optimize device function. The support level should not exceed the required CO for the patient.

ICU ADMISSION [18, 19]

Upon arrival to the ICU, the following should be completed:

- Ensure the AIC is plugged into AC power on arrival to ICU. The controller battery life is only 1 hour.
- The AIC should be positioned at the base of the bed for easy access and screen visibility.
- Device performance and setting should be evaluated and documented.
- ICU nursing should transition to purge fluid per physician order.
- Verify that the Tuohy-Borst connection is tightened to the right and locked in order to prevent catheter displacement or migration (on CP and RPSA/Flex). For the the Impella 5.5, make sure the yellow pin is removed and catheter lock is secured.
- Document insertion length of Impella catheter where the sterile sleeve connects to the sheath.
- Inspect dressing at the insertion site for bleeding and integrity.
- If femoral access, secure the extremity with the knee brace to prevent flexion and injury to the arterial insertion site (see limb care section).

HEMODYNAMIC MONITORING [18, 19]

- Patients in the critical phase of the illness will require more aggressive hemodynamic monitoring than those on long term support.
- Invasive hemodynamic monitoring of arterial blood pressure and central venous pressures is recommended until organ recovery and satisfactory organ function is achieved.
- Hemodynamic parameters and device performance should be documented every hour and as per unit policies.
- Use of a pulmonary artery catheter should be considered; however it must be balanced with experience and training. Parameters (ie. PCWP, PAP, CI) obtained from Swan Ganz catheters can help determine response to device support, need for additional therapies and need for RV support.
- Balance between risk and benefit must be evaluated daily to minimize adverse events associated with invasive monitoring.

The following Impella assessment should be performed at the beginning and end of the shift as well as PRN:

- Device monitoring should include assessment and documentation of the following Q1H:
  - P-level
  - Impella flow (L/min)
  - Motor current (mA -green waveform)
  - AO Placement signal (mmHg -red waveform)
  - Purge pressure (mmHg)
  - Purge flow (ml/h)
  - LV Placement signal
  - Assessment of connections and device alarms
- Verify that the Tuohy-Borst valve (CP) connection is tightened to the right and locked in order to prevent catheter displacement and migration.
- Note and verify the cm marker of the catheter.
- Inspect dressing at the insertion site and confirm securement of Impella catheter.
  - Change dressing as per institutional guidelines.
- Document insertion length of Impella catheter where the sterile sleeve connects to the sheath.
  - Recommended position documentation with any positional changes and patient movement.
- Back-up Impella AIC console should be easily accessible and plugged into AC power.
- Check purge solution
  - Purge solution bag and tubing must be changed per institutional guidleines
  - Ensure one extra Impella tubing cassette is easily accessible
- Reposition patient as per unit protocols.

LIMB CARE, INSERTION SITE AND PERFUSION MONITORING: [18, 19]

The extremity with the Impella insertion site is at a high risk for compromise if there is limited perfusion or nerve compression. Close monitoring and assessment is crucial to minimize these complications.

- If the device is implanted percutaneously in the femoral position, extremity immobilization is recommended.
  - A knee immobilizer can be used to prevent the patient from bending the extremity and causing arterial rupture.
  - Attention must be placed on any pressure points and extremity hyperextension which can result in temporary or permanent foot drop if not recognized early.
  - A physical therapy consult should always be considered for appropriate assessment of knee immobilization.
- **Extremity with Impella must be closely monitored for acute arterial thrombosis or occlusion**. Pulse oximeter provides continuous pulse assessment and local NIRS may be used to monitor deterioration of perfusion. Palpate (or obtain by Doppler) peripheral pulses Q1H. Some institutions use a myometer to monitor loss of neurologic function.
- **Any compromise in perfusion must be immediately addressed**. Potential interventions include arterial jump graft. If unable to improve extremity perfusion, the device must be removed and another MCS strategy considered.
- Observe and document Q1H: Color, capillary refill, warmth, movement, and sensation
- Notify MD if noted signs of diminished peripheral circulation or limb ischemia (i.e. quality of pulses diminished, cool peripheries, change in skin color/mottling or sensory changes including numbness and/or tingling)
- Consider early involvement of physical and occupational therapy to minimize the above complications and address any motor deficiency early
- Observe puncture sites, sheath insertion site or surgical access site for active bleeding, swelling, bruising or hematoma especially when anticoagulation is escalated. Additional bleeding control may be needed by placing mattress sutures at the insertion site.
- With femoral insertion, avoid flexion of leg and keep the head of bed no greater than 30 degrees.

Skin integrity

Due to limitations in patient mobility especially when femoral insertion site is used, close attention must be paid to skin integrity and pressure areas.

- Assess skin integrity Q2H & PRN
- Assess risk of skin breakdown using appropriate pressure ulcer risk assessment tool
- Reposition patient as per hospital protocols

Urine output[18, 19]

Change in urine color can be one of the first indicators of excessive hemolysis indicating device malposition or suction. Foley catheters can be used to diagnose these complications early.

- Observe and document characteristics of urinary output Q1H
- Observe for signs of hemolysis: discoloration of urine, decreasing hemoglobin/hematocrit, increased LDH, plasma free Hgb, AST and bilirubin
- Once stable device position, appropriate hemodynamic status is achieved, and end organ recovery is established, Foley catheter should be removed to minimize risk of infection.

PATIENT TRANSPORT[18, 19]

- Safe transport checklist and expectations should be generated based on intuitional practices with following in mind:
  - Prior to transport, document the insertion length (cm) of the Impella catheter where the sterile sleeve connects to the sheath.
  - A transfer board should be utilized to ensure that the catheter remains in situ and does not kink. The limb with the Impella catheter in situ must remain straight at all times during transport.
  - In preparation for transport the team should check purge fluid, check battery life and that Impella was charging prior to transport, check the catheter connections so as not to dislodge with movement and transfer of patient, monitor urine quality prior and during transport.
  - The Impella controller battery life is 1-hour.

MANAGING COMPLICATIONS AND ADVERSE EVENTS

Potential adverse events include, but are not limited to: aortic valve injury, bleeding, cerebral vascular accident/stroke, hemolysis, limb ischemia, thrombocytopenia, vascular injury and death. [18, 19]

BLEEDING

- Depending on method of Impella insertion, bleeding may occur at the access site and/or surgical sites (subclavian cut down and graft anastomosis). This should always be assessed by the cath or surgical teams and intervened on if needed.
- Compression devices such as safeguard or dressing may be used briefly (<6 hours) and extremity perfusion must be closely monitored during this period and while on support.
- Assess the patient and evaluate the cause of bleeding (over anticoagulation, coagulopathy vs surgical site bleeding).
  - Send labs evaluating for coagulopathy (CBC, PT, PTT, Fibrinogen, Rotem, Anti-Xa) and assess the need for blood transfusions during prolonged periods of bleeding and correct any deficiencies.

Anticoagulation goals may need to be adjusted if there is ongoing bleeding or oozing and the pump itself is otherwise functioning well. Heparin may even need to be held for short periods of time (<6-12 hours) for clinically concerning bleeding. In the event that a patient is intolerant to heparin or in whom heparin is contraindicated (e.g., due to heparin-induced thrombocytopenia or bleeding), sodium bicarbonate (25 or 50 mEq/L) may be added to the purge solution instead of heparin.

- If bleeding continues, consider platelet dysfunction, low fibrinogen, HIT.
- Surgical intervention for bleeding should be considered if bleeding is difficult to control with medical therapies.

HEMOLYSIS[18, 19]

- Some degree of hemolysis may occur at higher P-level settings. It is typical to see some mild hemolysis in the first 24-48 hours of support. This should improve.
- The etiology of hemolysis can be due to the expected mild shearing from the device, from lower than expected flows for the set P-level, suction events, or malpositioning of the Impella device.
- To evaluate the etiology, consider ECHO to assess positioning of cannula, check fluid status, suction events, and P-level setting.
    - P-level setting may need to be adjusted if the setting is too high, as well as fluid administration if patient appears hypovolemic
- If P-level setting and fluid status are unchanged but hemolysis is noted, consider ECHO to assess positioning of cannula. If the Impella has moved further towards the LV apex, the outflow may be close to the aortic valve and cells may be lysed as they exit the outflow of the Impella and hit the aortic valve leaflets. Abiomed recommends repositioning the device, even if the position looks okay.
- Hemolysis is clinically seen as a constellation of findings depending on the degree.
  Mild hemolysis may be seen only with lab findings of elevated LDH or plasma Hb with a stable or slowly decreasing hemoglobin value. Moderate to severe hemolysis manifests with elevated LDH, plasma Hb, elevated bilirubin, AST, and red/tea colored urine with an acute drop in hemoglobin.
- Significant hemolysis can induce AKI, continue to monitor renal function.

DEVICE CLOT

- In the setting of subtherapeutic anticoagulation or periods of profound inflammation, the device is at risk of developing fibrin deposition or thrombus formation, resulting in device failure.
- There may be a rise in purge pressure and drop in purge flow, rise in motor current either acutely or gradually, or drop in device flow overall.
- Consider TPA administration to the device in consultation with Abiomed, or your institution's protocol. Tissue plasminogen activator (tPA) alteplase has been reported to be used for suspected Impella thrombosis (increasing purge pressure, elevated LDH levels).
    - Sterile water is used as the diluent used in the tPA purge solution instead of D5W or normal saline. The solution is prepared by diluting tPA (2 mg) in 50 or 25 ml sterile water for injection in an intravenous piggyback (IVPB) to produce a 0.04 or 0.08 mg/ml solution. The tPA solution replaces the Impella purge anticoagulation solution and runs at the device determined rate while systemic anticoagulation is used to maintain a therapeutic ACT or aPTT. The lower tPA (0.04 mg/hr) purge solution can run over up to 12 hours, or longer if there is improvement but not normalization of the purge pressure. If there is no improvement in purge pressure at 12 hours, the higher tPA (0.08 mg/ml) purge solution can be used for up to 12 hours. Once tPA finishes infusing, the purge solution is switched back to the prior solution. [17]
- If the device stops, support the patient clinically as indicated, and consult interventional cardiology and CT surgery as soon as possible.

DEVICE FAILURE[18, 19]

- This is not a common occurrence with the Impella device, however, when used beyond the indicated device duration of support (≤ 4 days for Impella CP with SmartAssist or ≤ 14 days for Impella 5.5 with SmartAssist), there may be a risk of device failure/stoppage.
- Close monitoring of motor current trends will help to assess the function of the motor.
- Each Impella device has a different motor current upper limit for a P-level setting. If the motor current is approaching the upper limit, notify the ICU and procedural teams. Consult with your Abiomed representative, discuss recommendations for thresholds and potential device exchange.

INFECTION

- As with any foreign indwelling device, there is a risk of infection. Prophylactic antibiotics are not generally recommended for the duration of the device. However, for surgical prophylaxis, cefazolin or other antibiotic covering skin flora may be administered for 24 hours postoperatively.
- Monitor site and continue site care, as described above, continuously evaluating for infection.
- If an infection occurs related to the device, antibiotic regimen to be individualized based on your institution.

SUCTION

- Several factors may cause a suction alarm, including inadequate left ventricular filling or preload, incorrect Impella position against the papillary muscle or the mitral valve, or right ventricular failure. [18, 19]
- Suction may occur if the blood volume available for the Impella catheter is inadequate or restricted. [18, 19]
- Suction limits the amount of support that the Impella can provide to the patient and results in a decrease in expected Impella flow, arterial pressure and cardiac output. It can damage blood cells, leading to hemolysis.
- If a suction alarm occurs, reduce the Impella P-level by 1 or 2 levels, or more, if suction continues. Assess the patient's volume status, assess hemodynamics and RV function, evaluate catheter position using the placement signal, motor current, and imaging. Reposition Impella if necessary. When the suction alarm is resolved, resume pre-alarm flow rate.

OTHER CLINICAL CHALLENGES

Ectopy and arrhythmias

- Periods of ectopy or arrhythmia might be experienced with the Impella device in place. As long as there is preload to the left ventricle, the patient should be adequately supported with the Impella providing continuous flow and perfusion pressure. [18, 19]
- Recurrent refractory ventricular arrhythmias warrant assessment of device parameters and alarms for suction events as well as device position, LV filling and RV function by echo.
- During periods of arrhythmia, the patient may lose synchronous intrinsic contractility and therefore pulsatility, but will have a non-pulsatile blood pressure instead with a mean arterial pressure (MAP). If the MAP range is appropriate during the periods of arrhythmia, the patient is well supported.
- If the patient doesn't have adequate MAPs during periods of arrhythmia, assess RV function, volume status, antiarrhythmic agent and consider adjusting P-level if appropriate to better support the patient clinically while the arrhythmia is being medically managed.

EMERGENCY PROCEDURES

CARDIOPULMONARY ARREST[18, 19]

If your patient arrests and loses blood pressure and perfusion pressure, and CPR is required:

- Decrease P-level of Impella and continue chest compression as usual
- Notify interventional cardiologist and/or surgeon ASAP

During CPR reduce P-level to minimize potential damage due to dislodgement of the device during resuscitation. Once hemodynamics have been restored, an echo should be done to re-confirm placement. Increase P-level by two levels at a time until desired P-level is achieved.

Active CPR maneuvers may change the position of the Impella Device, introducing the risk of cardiac or vascular injury (including ventricular perforation).

DEFIBRILLATION/CARDIOVERSION[18, 19]

If defibrillation and/or cardioversion is required:

- P-level does not need to be adjusted
- Defibrillate/cardiovert as usual
- Image after to confirm accurate device position

DEVICE ALARMS AND MAINTENANCE

The Impella controller will sound an alarm tone, and display both an alarm message and a resolution message on the display screen. Alarm severity is color coded. Please refer to device manual for alarm indications: [18, 19]

Advisory (White)
Serious (Yellow)
Critical (Red)

A few of the alarms are listed below:

Impella Stopped

- Clinically support the patient. If CPR is needed, decrease Impella P-level and perform CPR.
- To troubleshoot the device, check the electric outlet and ensure that the Impella is plugged in. If device is powered off, attempt to restart.
- Replace Impella Controller if there are concerns for Controller Failure.
- Obtain STAT echo and Xray.
- If it restarts, decrease P-level by 1-2 lower than what was set, not going below P-2, and monitor for improvement of flow and function along with patient hemodynamics. If flow resumes at a lower P-level, evaluate the patient's intravascular volume status as well as positioning.
- If flow does not resume at lower P-level or P-2, assess the patient and make sure the patient is stable, call Abiomed, Interventional cardiology and CT surgery STAT for potentially removing and/or replacing malfunctioning Impella. If concerns for clot in device, discuss TPA administration.

Suction

- Clinically support the patient
- Obtain STAT echo and Xray. Decrease P-level by 1-2 lower than what was set, not going below P-2, and monitor for improvement of flow and function along with patient hemodynamics. If flow resumes at a lower P-level, evaluate the patient's intravascular volume status as well as positioning. [18, 19]

Purge Pressure High/Blocked [18, 19]

- Purge pressure is >1100 mmHG with the purge flow <1-2mL/hr
- Check all purge system tubing for kinks or blockages
- Decrease concentration of dextrose in the purge solution
- Replace purge cassette
- High pressure/Blockage may be due to clot. Contact Abiomed representative. Consider TPA administration.

Purge Pressure Low [18, 19]

- Purge pressure is <300 mmHG with the purge flow 30mL/hr
- Check all purge system tubing connections for leaks/damage
- Replace purge cassette
- Increase concentration of dextrose in the purge solution (D5% - D20% acceptable)

Refer to the **QR codes** for additional device alarms in the manufacturer IFU.

Impella CP IFU

Impella 5.5 IFU

MAINTENANCE

Impella Connect System Setup

OVERVIEW: The Impella Connect system consists of two parts: • A web-based user portal that allows authorized users to remotely view the screen of the Automated Impella Controller™ (AIC). The Impella Connect hardware connects to the VGA output of the AIC and transmits the display of the AIC screen to a cloud based server. The transmitted image can be viewed by authorized remote users, which may include hospital clinicians, Abiomed local support staff and Abiomed Customer Support Center (CSC) team members. The Impella Connect only enables passive viewing the AIC video screen. Changes to the controller settings can only be made using the physical controls on the AIC. Impella Connect may be configured and connected to the hospital's secured Wi-Fi network or be plugged in directly via Ethernet cable to the secured hospital network in order to transmit the video image to a web-based portal.
INTENDED USE: Impella Connect is intended to be used to enable remote viewing of the AIC's user interface by clinicians and by trained Abiomed personnel who assist clinicians with troubleshooting AIC alarms or other issues. Impella Connect transfers the video stream from the AIC (via the VGA output) to a cloud-based remote viewing portal. Communication between the AIC and Impella Connect is one-way (AIC to Impella Connect), and the streamed video is limited to Impella device operating parameters and alarm messages with no patient identifiable information. Impella Connect is powered directly by the AIC.
Please contact impellaconnect@its.jnj.com to begin the process of Impella Connect Setup

Transfer from AIC to AIC:

- Please see Instruction for Use or Impella App for detailed instructions

Changing Impella Purge Solution:

- Please refer to Impella App or Impella Instruction for Use

Changing the Impella Purge Cassette and Fluid Bag:

- Please refer to Impella App or Impella Instruction for Use

De-airing the Purge System:

- Please refer to Impella App or Impella Instructions for Use

DEVICE WEANING AND REMOVAL

- Length of use of the devices: please refer to FDA PMA indications on page 1.
- The length of Impella support is dependent on underlying myocardial disease and indications for its use. In setting of acute cardiogenic shock, the length of therapy tends to be short (<5days). In the setting of bridge to decision the length of therapy might be longer depending on the designated destination or recovery.
- In the setting of good hemodynamics and evidence of improved ventricular function, the Impella can be weaned gradually.
- If a patient shows clinical improvement and the care team feels Impella support may no longer be needed, a gradual decrease in P-level settings may be performed first with close monitoring of hemodynamic parameters.
- Impella 5.5 and CP with SmartAssist allows for monitoring of LVEDP trends as long as the P-level is 4 or greater.

Rapid weaning:

If the Impella has been used for temporary circulatory support (<5 days or clinically showing early signs of hemodynamic improvement with ability to wean P-level), the device can be weaned rapidly over the course of 24-48 hours while closely watching hemodynamics and patient tolerance to weaning. While weaning, assess hemodynamics and echocardiograms to assess native heart recovery with decreasing pump flows. If the patient has been weaned successfully to P-2, do not wean further until ready to remove the device. If the patient's hemodynamics remain stable, decrease the P-level to P-2, pull the catheter into the aorta, and stop the motor by decreasing the P-level to P-0.

Weaning on ECMO:

For patients supported with Impella on ECMO the sequence of transition includes weaning Impella to lowest level possible before deciding to wean off ECMO (not lower than P-2). Typically, Impella support is maintained until the patient is liberated from ECMO and then weaned off.

Slow weaning:

- If the patient has been supported by the Impella over a long period of time (>5 days or clinically needing full Impella support and showing slow signs of clinical improvement on Impella support), the Impella should be weaned gradually. Wean the P-level on the Impella 1 or 2 times a day, while closely watching hemodynamics and clinical tolerance. While weaning, assess hemodynamics and echocardiograms to assess native heart recovery with decreasing pump flows. Wean Impella P-level until you've reached P-2 and wean no further unless ready to remove the catheter.
  - On the Impella 5.5, the LVEDP and native cardiac output can be monitored while weaning.
- Monitoring the hemodynamics (blood pressure, perfusion, CVP) are very important at this time.
- Echo guidance during Impella support wean may also be beneficial to evaluate ventricular size and function.
- In the event the patient doesn't tolerate Impella support wean, the team must consider continuation of current therapy versus transition to a durable VAD.

While weaning and once at P-2, if the patient's hemodynamics remain stable and the team is ready to remove the device, decrease to P-1for the 5.5 and to P-2 for the CP, pull the catheter into the aorta and stop the motor (P-0). If the patient's hemodynamics remain stable, follow instructions in the next section for removing the Impella Catheter.

Specific instruction for removal of the device:

- Femoral access:
  - When the device is in the descending aorta turn the device to P-0 and unplug the power cable from the AIC.
  - The catheter shaft is pulled until the motor housing reaches the repositioning sheath at which point the repositioning sheath and the catheter are removed. Apply pressure to the puncture site.
  - If pre-closure sutures have been previously placed, tie down the sutures and observe hemostasis.
  - This can be done in the cath lab or at the bedside for uncomplicated femoral arterial access.

- Axillary access:
  - If the Impella was placed via a graft, device removal should be performed in the cath lab or operating room. The surgeons will assist with removal and control bleeding at the graft before tying off the graft and closing the incision.
  - If the Impella was placed percutaneously, it is advised to remove it in the cath lab. Access can be obtained in the femoral artery and a wire advanced into the axillary artery. This will allow for balloon tamponade of the subclavian to create a dry field for obtaining hemostasis.
  - The Impella pump is removed as described in the femoral access section. Hemostasis can be achieved by pressing the vessel against the second rib. If pre-closure sutures have been previously placed those can be tied down. Again, having another point of access and a compliant balloon in the subclavian artery can allow for tamponade to temporarily control bleeding if necessary.

AUTHORS

Sebastian Tume, MD, Svetlana Shugh, MD, Asma Razavi MD, Muhammad Ghbeis, MD, Andrea Maurich, RN, Brian Morray MD, Eleanor Greiner MD, Mary Raffel, MSN, Tanya Perry,DO, Jonathan Edelson, MD, Kathleen Simpson MD, Ryan Davies MD, Immanuel Turner MD, Alejandro Torres MD, Iki Adachi MD, Athar Qureshi MD, Angela Lorts, MD.

CONTRIBUTING CENTERS

Texas Children's Hospital TX, The Hospital for Sick Children CA, Boston Children's Hospital MA, Joe DiMaggio Children's Hospital FL, Seattle Children's Hospital WA, St. Louis Children's Hospital MO, NYP Morgan Stanley Children's Hospital NY, UT Southwestern Children's Hospital TX, Cincinnati Children's Hospital Medical Center, Cohen Children's Medical Center, Children's Hospital of Philadelphia.

Disclaimer: *The ACTION network is focused on quality improvement efforts such as harmonizing best practice protocols, disseminating them among institutions, and helping centers to improve care practices at the local level. This protocol was developed as a consensus tool for pediatric VAD programs. The information in the protocols are based on center practices, individual opinions, experiences, and, where available, published literature. Centers may choose to adapt this protocol to include in their center-specific protocols with reference to ACTION with the understanding that these are meant as guidelines and not standard of care. (Revised: 4/1/2025)*

Please refer to the Instructions for Use (IFU) for both CP with SmartAssist and 5.5 with SmartAssist for specific manufacturer recommendations regarding their use.

**Unless expressly noted with an IFU reference, this guideline embodies the best practices as determined by the ACTION Learning Network and NOT Johnson & Johnson MedTech.*

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