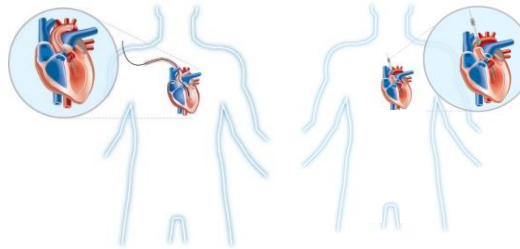
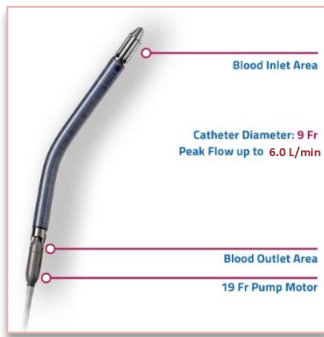


The Impella 5.5 with SmartAssist is a minimally invasive surgical heart pump that provides full cardiac support with maximum unloading, allowing the heart to rest and recover. It unloads the left ventricle, reduces ventricular work, and provides the circulatory support necessary to allow recovery and early assessment of residual myocardial function.

IMPELLA 5.5 WITH SMARTASSIST - TECHNOLOGY OVERVIEW

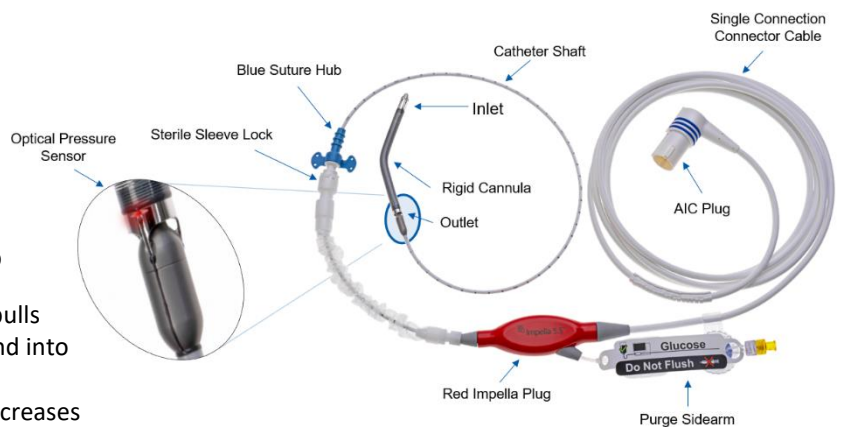


The Impella 5.5 with SmartAssist pump is surgically implanted via the axillary artery or anterior aorta and guided into the left ventricle.

Key Components

- Inlet Area – where blood is drawn into the cannula
- Outlet Area – where blood exits the cannula into the aorta
- Optical Sensor – assists in positioning, managing, and weaning the Impella heart pump

When the Impella[®] device is properly positioned, it pulls blood from the ventricle, through the aortic valve, and into the root of the ascending aorta. This flow reduces ventricular end-diastolic volume and pressure and increases the mean aortic pressure and flow.

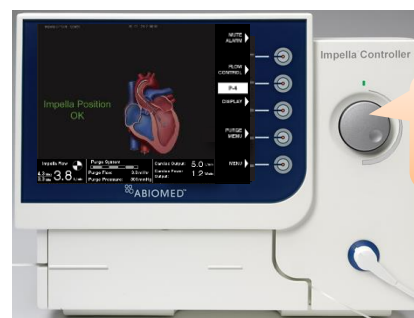


Automated Impella Controller™ (AIC)

The Automated Impella Controller provides:

- an interface for monitoring and controlling the Impella heart pumps
- purge fluid to the Impella devices
- backup power (when fully charged, can operate on its battery for at least 60 mins.)

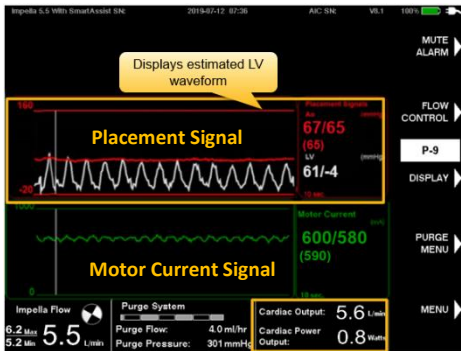
The AIC display provides insight to catheter function at a glance.



Push selector knob to open/close menus; Rotate to navigate through menus

AIC Home Screen

AIC Placement Screen Waveforms



AIC Placement Screen

The AIC Placement Screen displays real-time operating data. The screen displays the Placement Signal waveform and estimated LV waveform (shows when running at P-4 or higher); below is the Motor Current waveform which determines whether the Impella catheter is properly positioned.

When correctly positioned across the aortic valve, the **Placement Signal is aortic**, the **Motor Current is pulsatile**.

AIC calculates Cardiac Output and Cardiac Power Output (following entry) to aid in measuring end organ perfusion.

Bottom of each SmartAssist AIC screen shows Impella flow, current purge flow and purge pressure, and Cardiac Output and Cardiac Power Output



AIC OVERVIEW

IMPELLA 5.5 WITH SMARTASSIST – PATIENT MANAGEMENT



ICU Checklist

Follow these ICU proactive actions and processes to ensure successful Impella patient management.

ICU Patient Check-In: Assessment

- Record the centimeter marking on the Impella catheter closest to the sheath
- Check the Tuohy-Borst valve to be sure it is locked tightly on the repositioning sheath
- Check that the Impella Sidearm Retainer is secured on the purge sidearm
- Ensure that the external fixations are secured near Tuohy-Borst and red plug
- Record the urinary output, both color and amount
- Assess the patient’s overall volume status (target CVP ≥ 10 mmHg if frequent suction alarms)
- Call the Clinical Support Center or local Abiomed representative to check in patient

ICU Patient Check-In: Procedures

- Order a baseline echo to verify proper position (inlet area is 5 cm from the aortic annulus)
*Preferred echo views: Parasternal long axis (TTE), Mid-Esophageal Long Axis (TEE)
- Confirm D5W with heparin 25 U/mL* is on-hand as the purge fluid. Sodium Bicarbonate 25 mEq/1L is the preferred replacement for heparin in the purge solution within the indicated duration of use for patients who are intolerant to heparin or in whom heparin is contraindicated.
*D5W with 25U/mL or 50U/mL is acceptable
- Address any alarms on the Automated Impella Controller (AIC)



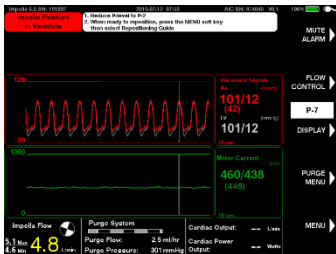
Verify position to confirm inlet is 5 cm from annulus

AIC Monitoring and Troubleshooting

To ensure that patients receive the benefits of Impella support, the Impella device must be correctly positioned across the aortic valve. Monitor the Automated Impella Controller (AIC) Placement screen and respond to alarms.

Alarms may include incorrect position, suction, and purge alarms. To address alarms, follow the on-screen prompts in the alarm window.

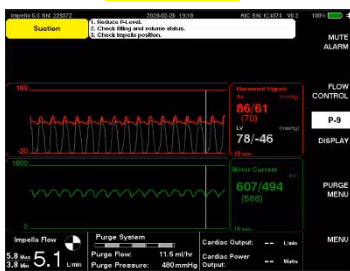
Impella Placement Alarms



For **incorrect position alarms**, reduce the Impella flow to P-2; then, reposition the Impella device under imaging guidance.

Note: Placement monitoring may be suspended at low flow rates. In cases of low native heart pulsatility, monitor the position using patient hemodynamics and echo.

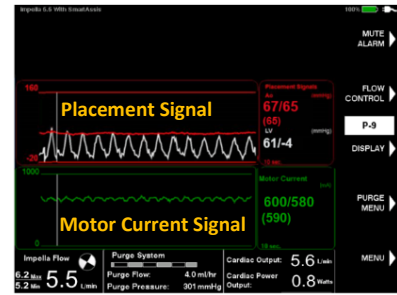
Suction Alarms



For **suction alarms**, reduce the Impella flow by 1-2 P-levels (do not drop below P-2).

Assess volume and consider adding if CVP or PCWP <10 mmHg; confirm RV function; evaluate position and reposition the Impella device under imaging guidance if necessary.

Watch for signs of impending suction, including:
 1) lower than expected flows, 2) reduced mean motor current, and 3) reduction in patient's blood pressure.



The SmartAssist® Placement Screen provides information to be used for trending purposes and to aid in measuring end organ perfusion. These include: Ao and LV Placement Signals, Cardiac Output (CO)* and Cardiac Power Output (CPO).

*CO is displayed after entering a reference measurement and needs to be re-entered every 8 hrs.

**Metrics are for informational purposes only and are not intended for diagnostic use. Values must be verified independently using an approved diagnostic device and must not be used for patient monitoring.

Patient Management

Impella Patient Care

- For insertion, administer heparin for ACT at least 250 seconds
- For support, maintain ACT at 160-180 seconds
- Complete ICU Check-In above
- Conduct routine echo (TTE) to confirm Impella position
- Monitor placement signal and motor current waveforms on the AIC and address any alarms
- Monitor for right heart failure (reduced Impella flows, suction alarms, elevated filling/PA pressures, signs of liver failure, reduced PAPI score)
- Monitor patient hemodynamics

Good to Know

- The Impella heart pump is *preload dependent*, low CVP could precipitate a suction alarm.
- The Impella heart pump is *afterload sensitive*, high SVR can lead to reduced flows.




General Patient Care

- Perform dressing changes per hospital protocol
- Assess access site for bleeding and hematoma
- Do not pull on the Impella device when transferring a patient from one bed to another
- Check Tuohy-Borst is properly tightened (daily or every shift change)

Hemolysis

Obstructions in the Impella catheter may lead to hemolysis, which may include obstruction in inflow, within cannula, or outflow.



If hemolysis is suspected, address any active position or suction alarms, use echo to look for obstructions, and consider giving volume if suspected hemolysis is accompanied by a CVP or wedge pressure < 10 mmHg.

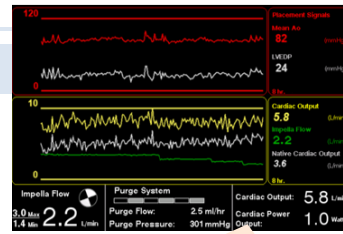


If CPR is indicated for a patient being supported with the Impella device, initiate CPR per hospital protocol and reduce the Impella flow to P-2. For defibrillation, it is not necessary to reduce P-level. *Note* during resuscitation, placement monitoring and flow calculations will not be accurate.

Weaning and Explant

To initiate weaning a patient from Impella support:

1. Press FLOW CONTROL and decrease flow rate by 2 P-level increments
2. Assess native heart recovery with Trend Screen as P-levels decrease
3. Maintain Impella support at P-2 until hemodynamics are stable
4. Reduce Impella flow to P-1 and pull the catheter into the aorta
5. When ACT < 150 seconds, reduce to P-0 and remove the Impella device
6. Apply manual compression per hospital protocol



As P-levels decrease, observe Trend Screen for stable LVEDP and MAP; trends showing total CO compared to native CO

Helpful Links - ICU



ALARMS



CARDIAC OUTPUT



DRESSING CHANGE



AIC PLACEMENT



CALCULATE TOTAL HEPARIN RATE



PURGE CASSETTE AND FLUID BAG



PURGE FLUID BAG



SUCTION TROUBLESHOOTING



IMPELLA POSITION WITH ECHO



HEPARIN-FREE PURGE

Resources



Contact the 24/7 Abiomed Clinical Support Center **1-800-422-8666**

- Clinical & technical expertise
- ICU patient check-in & proactive daily monitoring
- Patient transfer notification

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit www.abiomed.com/important-safety-information.