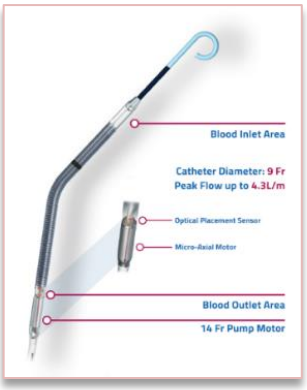
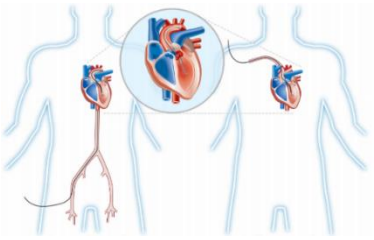
# KEY TAKEAWAYS

The Impella CP with SmartAssist heart pump is approved for use in high-risk percutaneous coronary intervention and cardiogenic shock. The Impella heart pumps are catheter-based devices providing hemodynamic support while allowing the heart to rest.

## IMPELLA CP WITH SMARTASSIST - TECHNOLOGY OVERVIEW



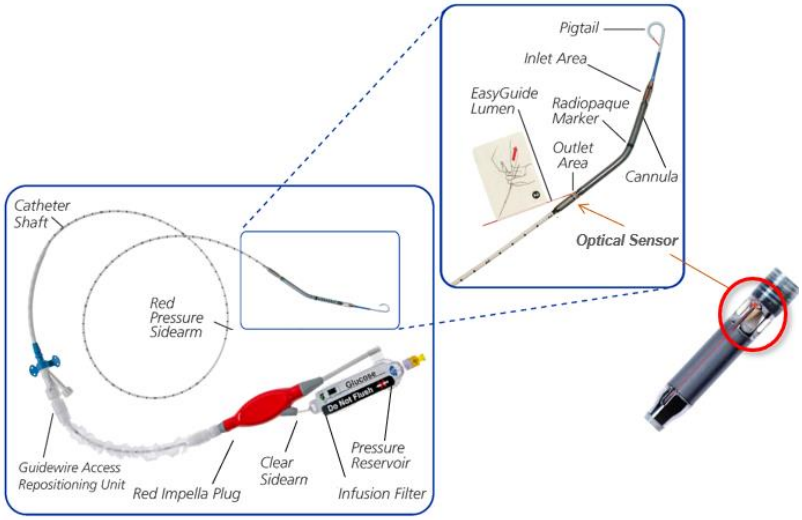
**Femoral Insertion** **Axillary Insertion**

The Impella CP with SmartAssist catheter is inserted percutaneously through the femoral artery or surgically through the axillary artery 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 left 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:

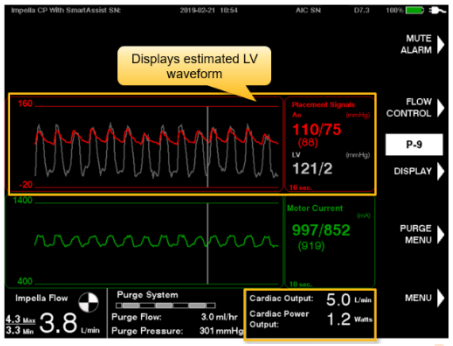
- an interface for monitoring and controlling the Impella heart pumps
- purge fluid to the Impella devices
- backup power (when fully charged, can operate on its battery for at least 60 mins.)

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 Ao placement Signal and LV placement signal 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 **AO Placement Signal is aortic**, **the LV placement signal is ventricular,** and 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 CP WITH SMARTASSIST – PATIENT MANAGEMENT

## ICU Checklist

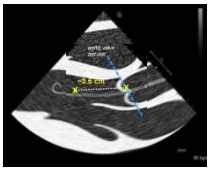
Follow these ICU proactive actions and processes to ensure successful Impella® patient management.

**ICU Patient Check-In: Assessment**

- ☐ Record the centimeter marking on the Impella catheter closest to the sheath
- ☐ Ensure the access angle of entry is maintained
- ☐ Record the urinary output, both color and amount
- ☐ Check the Tuohy-Borst valve to be sure it is locked tightly on the repositioning sheath
- ☐ 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 (catheter is 3.5 cm from the aortic annulus)
  *Preferred view of the Impella catheter in the left ventricle: Parasteral long axis (TTE)
- ☐ 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 in contraindicated.
  *D5W with 25U/mL or 50U/mL is acceptable; ** Sodium Bicarbonate 50mEq/1L is acceptable
- ☐ Address any alarms on the Automated Impella Controller (AIC)



Verify position to confirm inlet is 3.5 cm from annulus

## AIC Monitoring and Troubleshooting

Top of each AIC screen shows battery status. When fully charged, the battery will last at least 60 minutes.

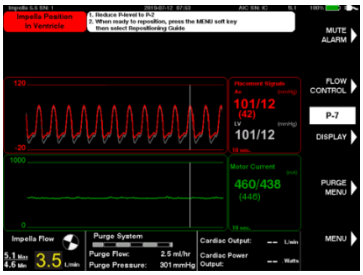


ABIOMED

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.

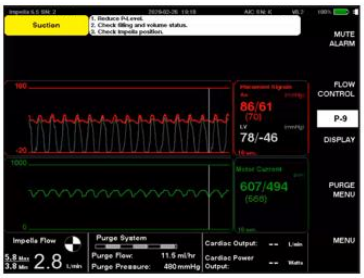
**Impella Placement Alarms**



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.

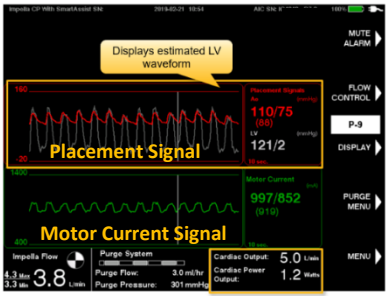
**Suction Alarms**



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 assessing 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 or with change in hemodyanic status.
Note: Metrics are for informational purposes only and are not intended for diagnostic use. Values must be verified independently using an approved diagnostic

## 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)

***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

- Maintain the head of the bed no greater than 30°
- Consider using a knee immobilizer
- Monitor pedal pulses
- Perform dressing changes per hospital protocol
- Assess access site for bleeding and hematoma

### 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.

## 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

Impella CLINICAL SUPPORT CENTER 24/7

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.