Impella®
The World's Smallest Heart Pump

Quick Reference and Troubleshooting Guide

- Impella® Heart Pump with Automated Impella® Controller Function
- Impella Heart Pump Positioning
- Purge System Management

This is not a replacement for the Instructions for Use Manual

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This troubleshooting guide is for use with the Automated Impella Controller with Software v6 and higher

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Indications and Safety Information

INDICATIONS FOR USE

High-Risk PCI

The Impella 2.5®, Impella CP® and Impella CP® with SmartAssist® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, Impella CP, and Impella CP with SmartAssist Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Cardiogenic Shock

The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0® and Impella LD® Catheters, in conjunction with the Automated Impella® Controller (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

Important Risk Information for Impella devices

CONTRAINDICATIONS

The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0 and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade*

*** This condition is a contraindication for the cardiogenic shock indication only.**

Indications and Safety Information

POTENTIAL ADVERSE EVENTS
Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices. Visit ***www.abiomed.com/important-safety-information*** to learn more.

Impella RP®
The Impella RP® System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

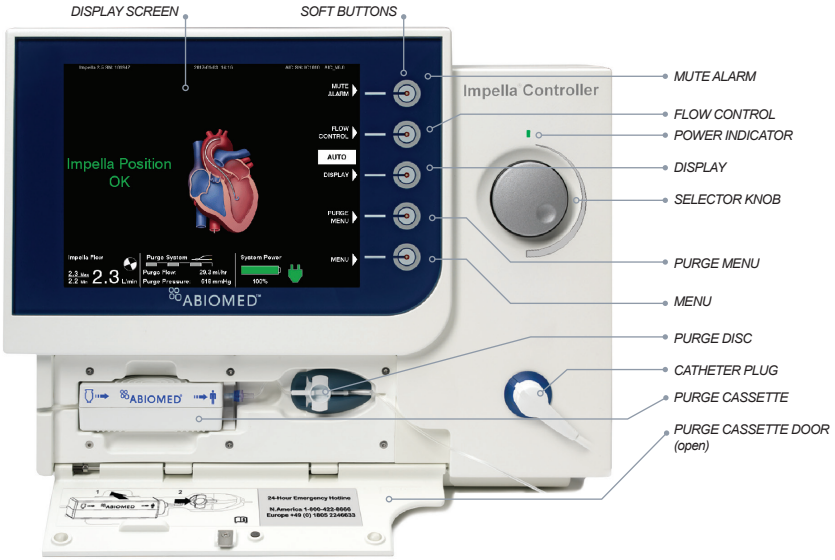
Important Risk Information for Impella RP System

CONTRAINDICATIONS
The Impella RP System is contraindicated for patients with the following conditions: Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP device. Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid or pulmonary valve. Mural thrombus of the right atrium or vena cava. Anatomic conditions precluding insertion of the pump. Presence of a vena cava filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter.

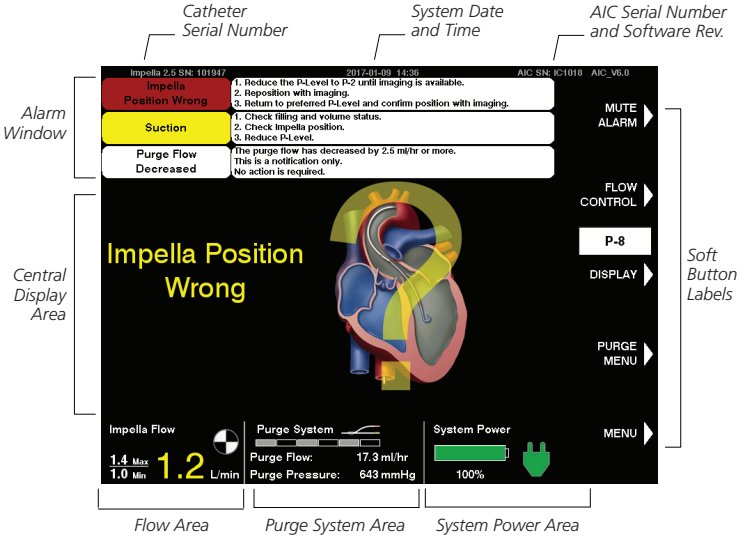
POTENTIAL ADVERSE EVENTS
The potential adverse effects (eg, complications) associated with the use of the Impella RP System: Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device malfunction, Hemolysis, Hepatic failure, Insertion site infection, Perforation, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system) complication, Tricuspid valve injury, Vascular injury, Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella RP. Visit ***www.abiomed.com/important-safety-information*** to learn more.

Automated Impella® Controller Features



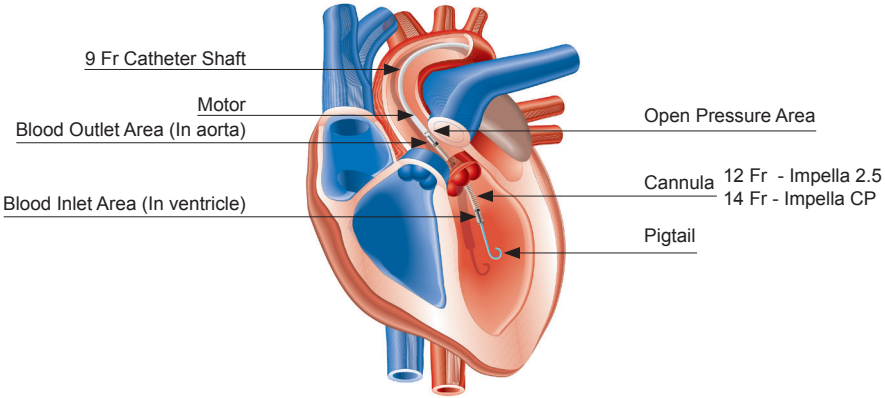
Automated Impella® Controller Home screen



Impella 2.5®
Impella CP®

Heart Pumps

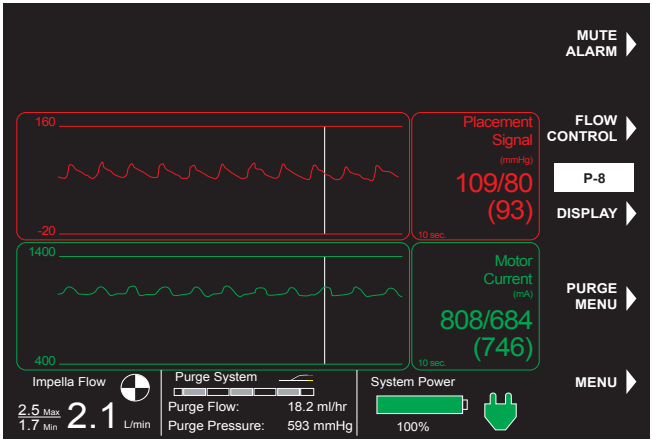
Impella 2.5® or Impella CP® Device in the Heart



Correct Impella 2.5® or Impella CP® Device Placement

Placement Signal:
Aortic

Motor Current:
Pulsatile



Modes of Operation

(Expected mean flow rate relative to P-Level)

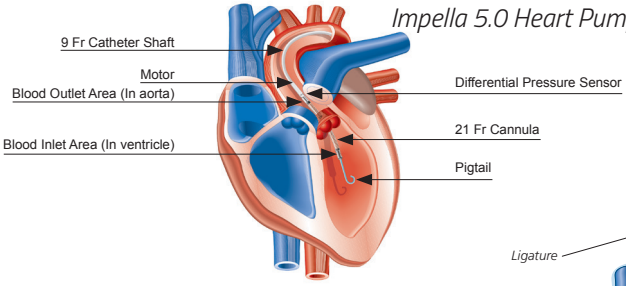
P-Level	Impella 2.5 *Flow (L/min)	Impella CP *Flow (L/min)
P-0	0.0	0.0
P-1	0.0 – 1.1	0.0 – 1.9
P-2	0.8 – 1.5	1.1 – 2.1
P-3	1.1 – 1.7	1.6 – 2.3
P-4	1.3 – 1.8	2.0 – 2.5
P-5	1.5 – 1.9	2.3 – 2.7
P-6	1.7 – 2.1	2.5 – 2.9
P-7	1.8 – 2.2	2.9 – 3.3
P-8	2.1 – 2.4	3.1 – 3.4
P-9	2.1 – 2.5	3.3 – 3.7

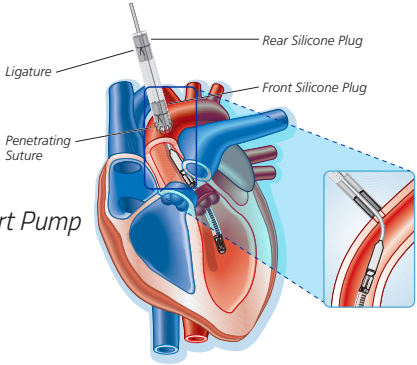
**Flow rate can vary due to suction or incorrect positioning.*

Impella 5.0®
Impella LD®

Heart Pumps

Impella 5.0® and Impella LD® Devices in the Heart

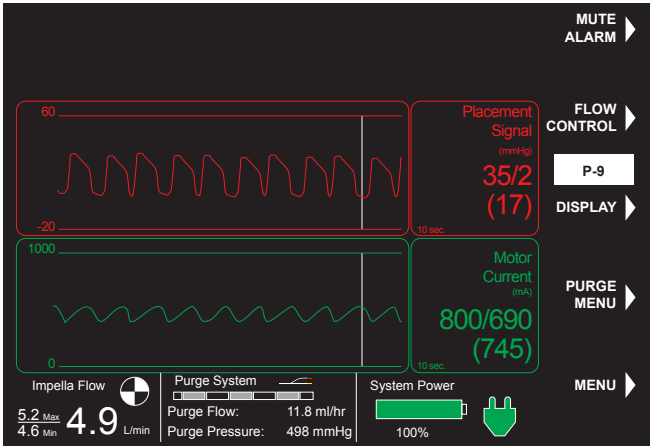




Correct Impella 5.0® and Impella LD® Device Placement

Placement Signal:
Pulsatile

Motor Current:
Pulsatile



Modes of Operation

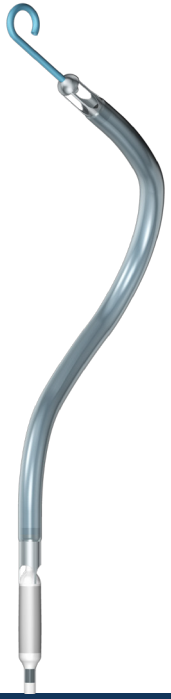
(Expected mean flow rate relative to P-Level)

P-Level	Flow Rate L/min MAP 60-100	*Flow Rate (L/min)	Revolutions Per Minute (rpm)
P-0	0.0	0.0	0
P-1	0.0 – 0.1	0.0 – 1.4	10,000
P-2	0.7 – 2.1	0.5 – 2.6	17,000
P-3	1.2 – 2.7	0.5 – 3.1	20,000
P-4	1.9 – 3.1	0.9 – 3.4	22,000
P-5	2.8 – 3.5	1.4 – 3.7	24,000
P-6	3.3 – 3.8	1.8 – 4.0	26,000
P-7	3.7 – 4.1	2.6 – 4.4	28,000
P-8	4.1 – 4.5	3.4 – 4.7	30,000
P-9	4.7 – 5.1	4.2 – 5.3	33,000

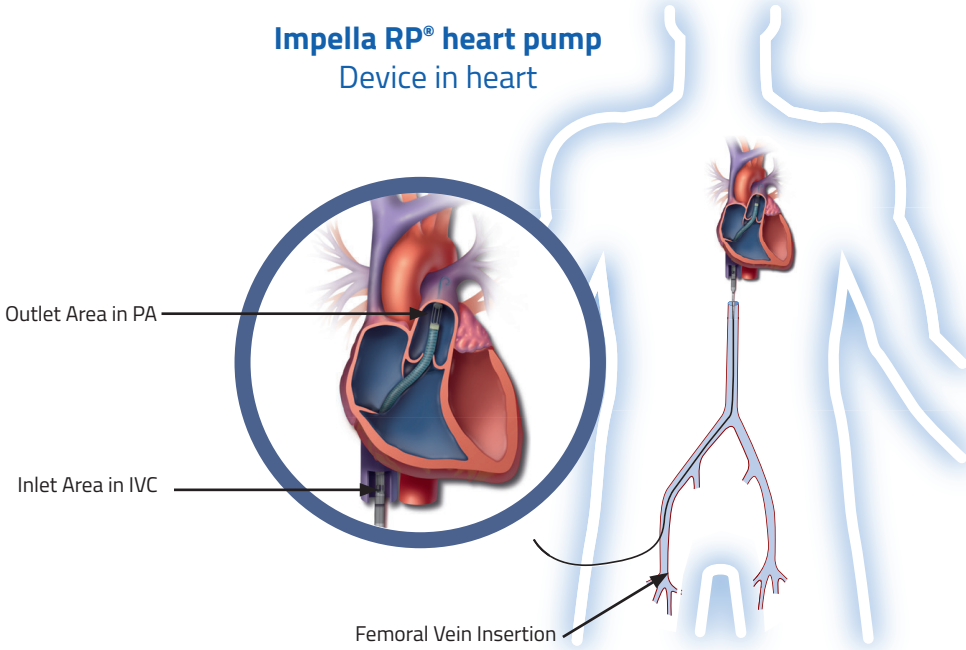
**Flow rate can vary due to suction or incorrect positioning.*

Impella RP®

Heart Pump



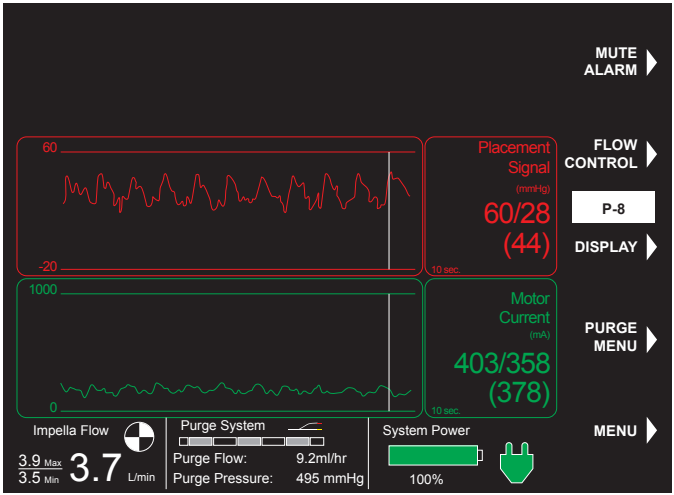
Impella RP® heart pump
Device in heart



Correct Impella RP® Device Placement

Placement Signal:
Pulsatile

Motor Current:
Pulsatile



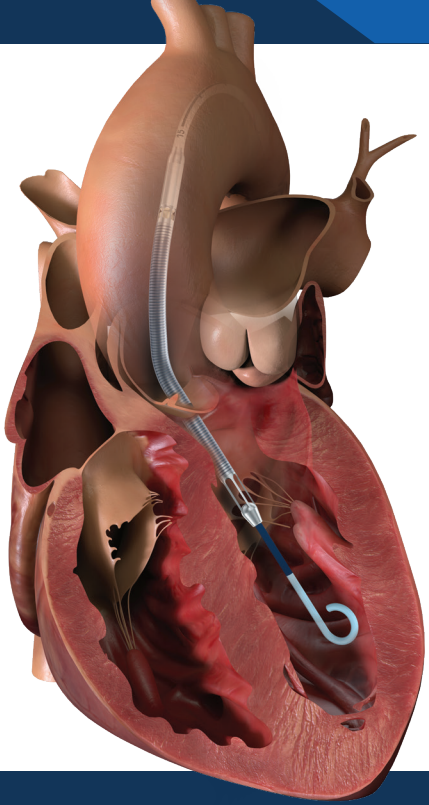
Modes of Operation

(Expected mean flow rate relative to P-Level)

P-Level	*Flow Rate (L/min)
P-0	0.0
P-1	0.0 – 1.2
P-2	0.0 – 1.6
P-3	0.0 – 2.0
P-4	1.3 – 2.9
P-5	1.6 – 3.1
P-6	2.4 – 3.5
P-7	3.0 – 4.0
P-8	3.4 – 4.2
P-9	3.9 – 4.4

**Flow rate depends on preload and afterload and can vary due to suction or incorrect positioning.*

IMAGING THE IMPELLA DEVICES

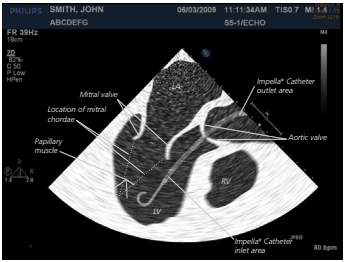


Correct Left-sided Impella® Device Position as Seen on TEE/TTE

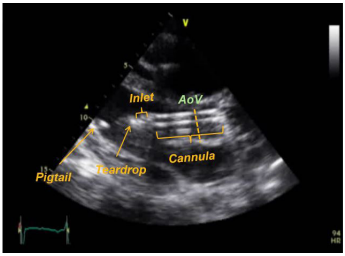
Checklist for proper positioning:

- Catheter inlet area 3.5 cm below aortic valve annulus.
- Catheter outlet area well above aortic valve.
- Catheter angled toward the left ventricular apex away from the heart wall and not curled up or blocking the mitral valve.

TEE of Impella Catheter



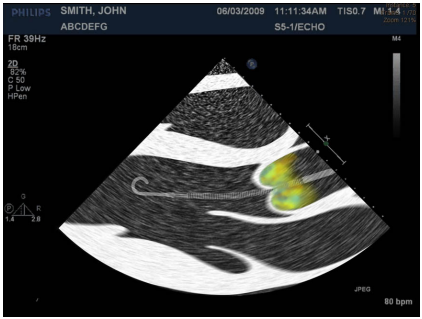
TTE of Impella Catheter



Left-sided Impella® Device as Seen on Color Doppler Echocardiography

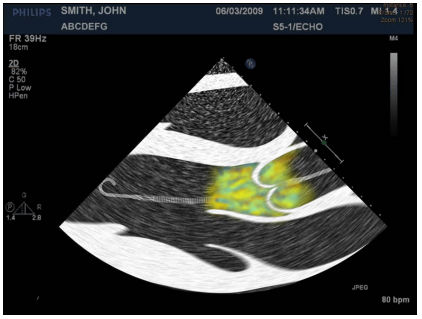
CORRECT:

Dense mosaic pattern of turbulence above the aortic valve near the outlet area of the catheter.



INCORRECT:

Dense mosaic pattern of turbulence beneath the aortic valve indicating the catheter is too far into the ventricle or entangled in papillary muscle.



TROUBLESHOOTING

TROUBLESHOOTING: Device Position in Ventricle

(Impella 2.5® and Impella CP® Devices)

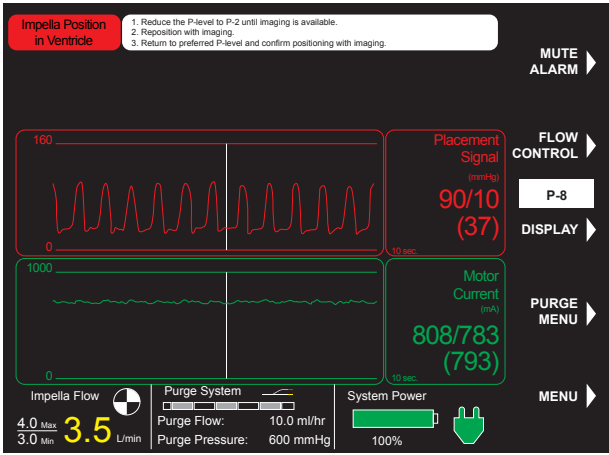
Patient not benefiting from given flow

Placement Signal:
Ventricular

Motor Current:
Flat

Actions

1. Reduce Flow Rate to P-2.
2. Using echo guidance, reposition the pump until the inlet area measures 3.5 cm below the aortic valve annulus.
3. Resume previous P-level setting.
4. Lock Tuohy Valve.



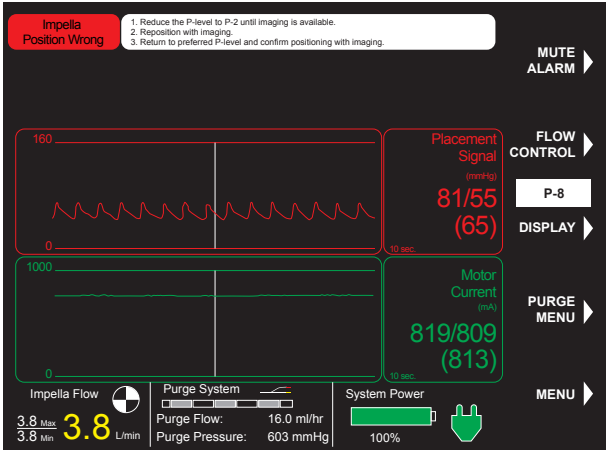
TROUBLESHOOTING: Pump Position Wrong
(Impella 2.5® and Impella CP® Devices)

Placement Signal:
Aortic

Motor Current:
Flat

Actions

1. Reduce Flow Rate to P-2.
2. Using echo guidance, reposition the pump until the inlet area measures 3.5 cm below the aortic valve annulus.
3. Resume previous P-level setting.
4. Lock Tuohy Valve.



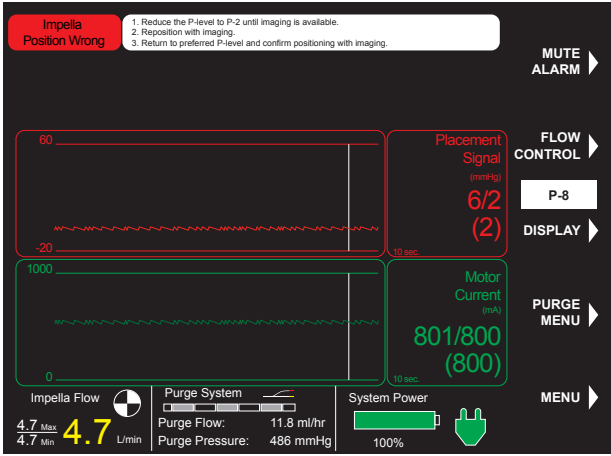
TROUBLESHOOTING: Pump Position Wrong
(Impella 5.0® and Impella LD® Devices)

Placement Signal:
Flat

Motor Current:
Flat

Actions

1. Reduce Flow Rate to P-2.
2. Using echo guidance, reposition the pump until the inlet area measures 3.5 cm below the aortic valve annulus.
3. Resume previous P-level setting.
4. Lock Tuohy Valve.



TROUBLESHOOTING: Suction (all devices)

Suction

1. Check filling and volume status.
2. Check Impella position
3. Reduce P-Level.

What is it?	What to look for	What to do
Causes of suction: ▪ Low Volume ▪ Incorrect position ▪ Inadequate LV filling due to RV failure **Effects of suction:** ▪ Lower than expected Impella flow ▪ Patient may not fully benefit from Impella support ▪ Potential for hemolysis	▪ Impella Flow Reduced alarm ▪ Suction alarm ▪ Lower than expected flow rates ▪ Reduced mean motor current ▪ Lower patient blood pressure	1. Drop 1 or 2 P-levels or until Suction breaks. 2. Assess volume status 3. Evaluate catheter position with imaging; reposition if necessary 4. Confirm RV function 5. Return flow rate to pre-alarm setting when suction resolved

When running in Auto Mode (Impella 2.5 and Impella CP), the **Impella Flow Reduced** advisory should prompt action to resolve the suction condition. These actions should include, but are not limited to, checking Impella position, assessing left sided filling / volume status, and manually reducing the Impella flow level.

TROUBLESHOOTING: Purge Pressure High

Purge Pressure High

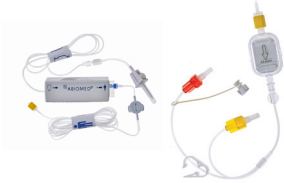
1. Check purge tubing for kinks.
2. Decrease concentration of dextrose in purge solution.

	Where to look	What to look for	What to do
1		Are there any kinks: ▪ In the purge tubing? ▪ In the clear sidearm? ▪ Anywhere along the catheter?	Straighten the tubing, clear sidearm, or catheter.
2		Is the purge fluid concentration too high?	Ensure D5W with Heparin is being used.
3		If unable to resolve high purge pressure, monitor for increases in motor current which can indicate impending pump failure.	May need to replace pump

TROUBLESHOOTING: Purge Pressure Low

Purge Pressure Low

1. Check purge system tubing for leaks.
2. Increase concentration of dextrose in purge solution.
3. Replace purge cassette.

	Where to look	What to look for	What to do
1		Are there any leaks: ▪ In the purge cassette connections? ▪ In the Y connector? ▪ In the luer connections to the catheter?	Tighten any loose connections. Replace purge cassette if leaking.
2		Is the purge fluid concentration too low?	Increase the purge fluid concentration.
3		If unable to resolve low purge pressure, monitor for increases in motor current which can indicate impending pump failure.	May need to replace pump

IMPELLA DEVICE INSTRUCTIONS FOR USE PRODUCT MANUALS

For quick access to the Impella heart pump instructions for use manuals please visit:
www.abiomed.com/impella-device-instructions-for-use

Please be aware of the software versions.

If you have any questions please contact your local field representative or contact the Impella Clinical Support Center.

1-800-422-8666 (US)

24/7 Impella Clinical Support and Technical Expertise

1-800-422-8666 (US)

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