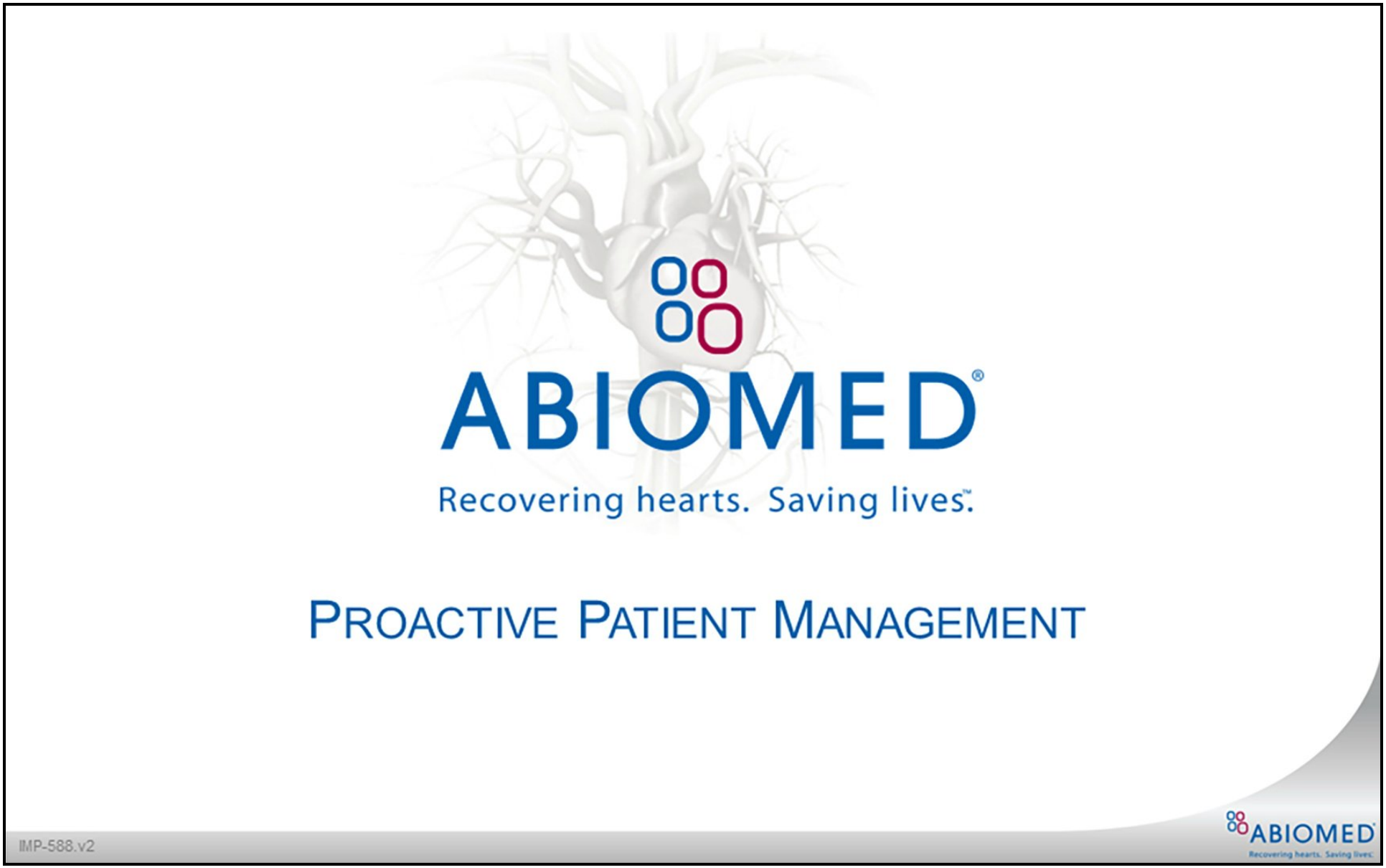
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PROACTIVE PATIENT MANAGEMENT
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TOPICS

- ICU Check-In
- P-A-P Method for Proactive Support
- Diagnose and Resolve
- Patient Scenarios

Approximate duration: 30 minutes

Proactive Patient Management

IMPELLA® DEVICE INDICATION & SAFETY INFO.

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 ≤ 6 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.*

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 ***http://www.abiomed.com/important-safety-information*** to learn more.

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RIGHT-SIDE SUPPORT – INDICATION & SAFETY INFO.

INDICATIONS FOR USE

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-infomation*** to learn more.

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LEARNING OBJECTIVES

- Explain P-A-P as a proactive tool to support Impella® patients
- Identify questions to ask to determine good P-A-P
- Recognize patient scenarios demonstrating appropriate P-A-P

Proactive Patient Management

How do I proactively support an Impella® Patient?

ICU Check-In

- Assess patient
- Complete check-in procedure
- Use the Clinical Support Center (CSC) for check-in and questions

P-A-P Method

- Use P-A-P method to stay on top of potential issues
- Follow general patient management practices

Diagnose and Resolve

- Troubleshoot and manage AIC alarms
- Diagnose and resolve issues

=

Optimal Patient Care

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ICU CHECK-IN

Proactive Patient Management

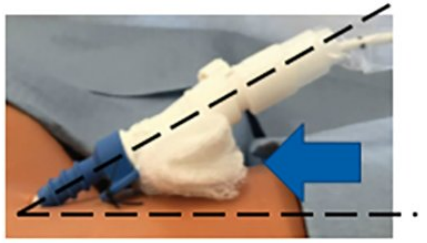
ICU Patient Check-In: Assessment

Patient Check-In:

- Call the Clinical Support Center or local Abiomed® Representative to check in patient
- Ensure access angle of entry is maintained
- Record CM marking on the Impella® catheter closest to the sheath
- Ensure Tuohy-Borst valve is locked
- Ensure volume status is assessed and adequate (target CVP ≥ 10 mmHg if frequent suction alarms)
- Record urinary output for color and amount

Impella CLINICAL SUPPORT CENTER 24/7

1-800-422-8666



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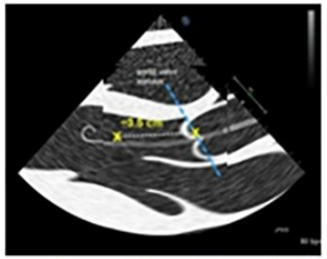
ICU Patient Check-In: Procedures

- Conduct baseline Echo to verify position

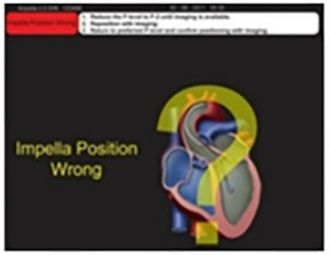


Correctly positioned Impella® (TTE)

Confirm the following supplies are available to complete the Check-In:

- Purge fluid (D5W with 50 units of heparin/mL is recommended)
- Pressurized NS bag with tubing for the transfer to standard configuration

- Transfer to Standard Configuration is complete
  Roller Clamp is open wide on the NS pressure bag and pressurized to 300-350 mmHg



- Alarms are addressed and action taken

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General Patient Considerations

- Do not raise the head of the bed to higher than a 30-degree angle.
- Use knee immobilizer as needed to maintain access site straight.
- Perform dressing changes per hospital protocol, using aseptic technique.
- Assess access site for bleeding and hematoma.
- Be careful not to pull on the Impella® Catheter when transferring a patient from one bed to another.
- Monitor pedal pulses.
- Maintain an ACT of 160 – 180 or an equivalent pTT.

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P-A-P METHOD FOR PROACTIVE SUPPORT

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INTRODUCING P-A-P

Preload	The pressure or volume in the ventricle at end diastole
Afterload	The pressure the ventricle must overcome to eject blood
Positioning	Correct positioning is vital to its function and patient outcomes

The Impella® device is Preload dependent and Afterload sensitive

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WHY P-A-P?

Patient Safety

- P-A-P method helps you stay on top of potential issues
- Reduces the likelihood of suction and adverse events
- Reduces the likelihood of positioning issues

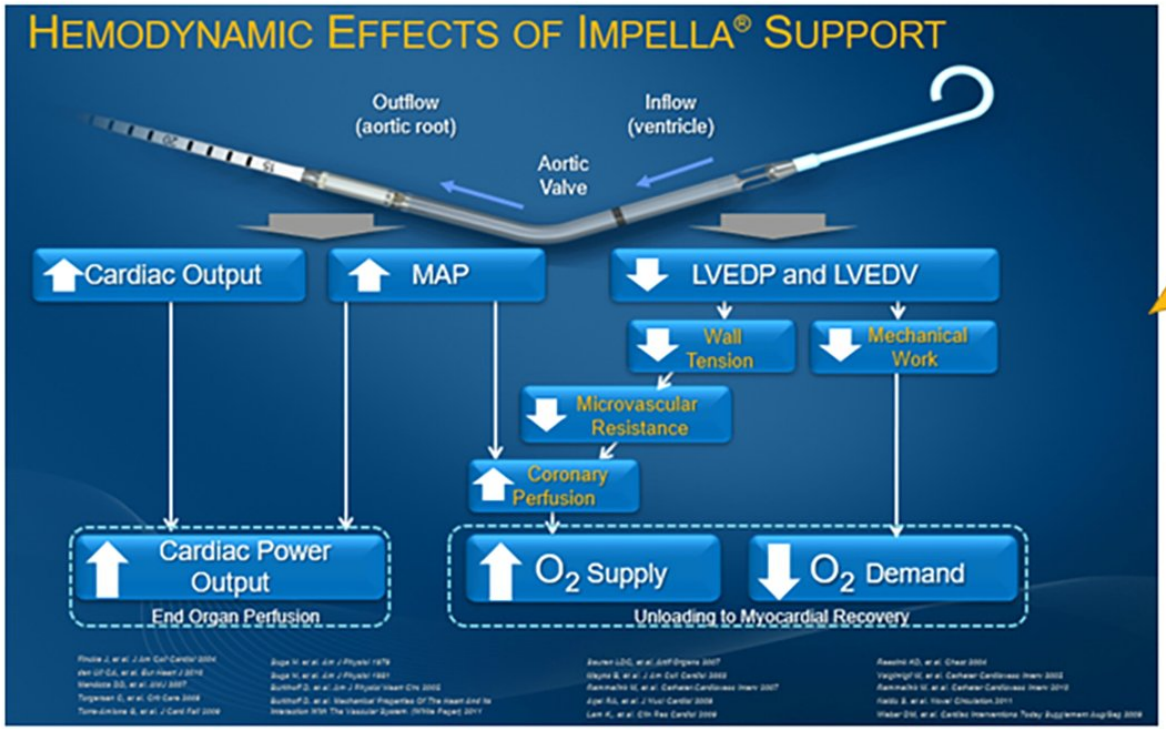
Optimal Patient Outcomes

- Optimal pump performance
- Proper P-A-P promotes better outcomes
- Promotes blood compatibility

WHY P-A-P?

Hemodynamic Support

- Allows for the Impella® device to provide optimal hemodynamic support and end organ perfusion
- Promotes myocardial recovery – **unloading the left ventricle lets the heart rest**



With adequate **P**reload and proper **P**osition, the Impella® heart pump offers all of these hemodynamic benefits.

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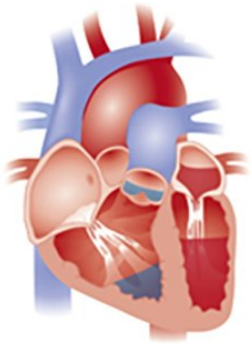
PRELOAD

Impella® is preload dependent.



What if there is inadequate preload?

- Increased likelihood of suction alarms
- RBC shearing may become a concern

Why is there inadequate preload?

Patient may be:

- Receiving diuretics
- On continuous dialysis
- Bleeding
- Right heart dysfunction

Learn more ▶ Recommendations for Preload

- ☑ CVP >10 mmHg
- ☑ PCWP ≥ 10 mmHg
- ☑ Monitor volume status through PA catheter

This is important for proper preload maintenance as well as overall hemodynamic monitoring.

Reminder:

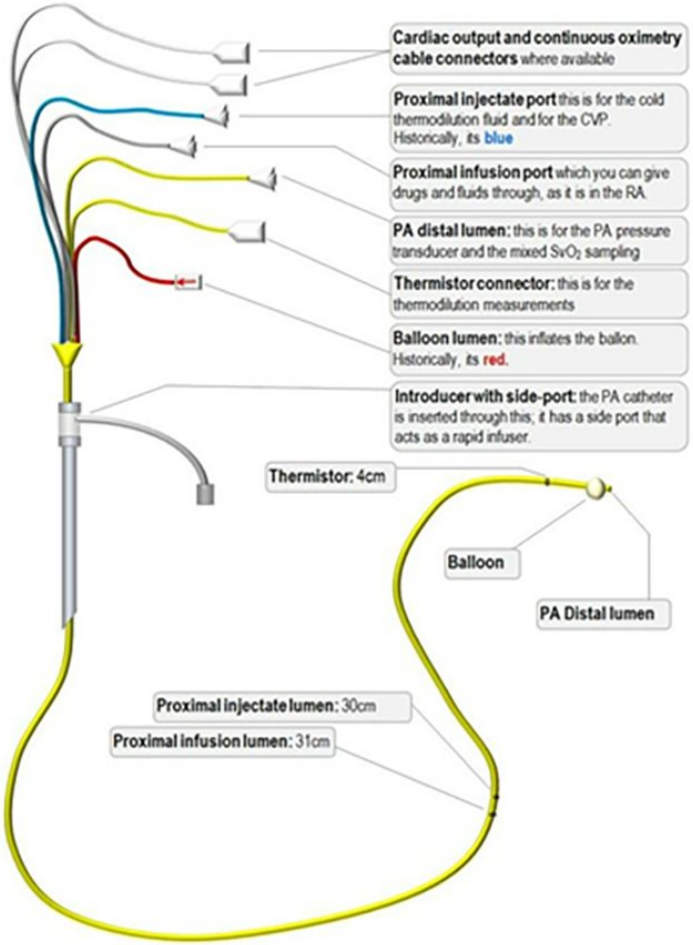
- If there are signs of hemolysis and/or suction alarms, CVP and/or PCWP should be >10 mmHg
- If CVP and/or PCWP is < 10 mmHg and there are no issues, there is no reason to recommend additional volume.

How to Maintain Proper Preload

Use of a pulmonary artery (PA) catheter is strongly encouraged with Impella® patients.

PCWP is a measure of left ventricular preload and the most reliable indicator of volume status.

If PCWP is not available, CVP could also be monitored.



1. Chatterjee K. Circulation 2009;119(1):147-152.
2. Evans DC, et al. Scand J Surg. 2009;98(4):199-208.

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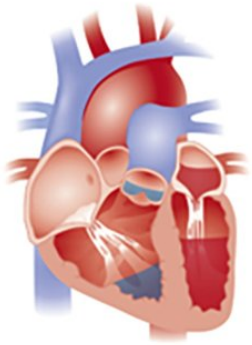
AFTERLOAD

Impella® is afterload sensitive.



What if there is high afterload?

- Impella device flows may be lower than expected

Why is there high afterload?

- Physiologic effects
- Use of vasopressors
- Concurrently on V-A ECMO

Learn more ▶ Recommendations for Afterload

- ☑ Monitor MAP (Mean Arterial Pressure) and Systemic Vascular Resistance (SVR)
- ☑ MAP goal, while on Impella device: 60 - 80 mmHg

Medical therapy, such as inotropes and/or vasopressors may be reduced with appropriate Impella support which can also lead to decreased mortality rates.

How to Maintain Proper Afterload

If patient is hemodynamically stable, reduce the use of vasopressors when possible.

In situations of high arterial pressures, due to chronic conditions, vasodilators may assist in reducing afterload.

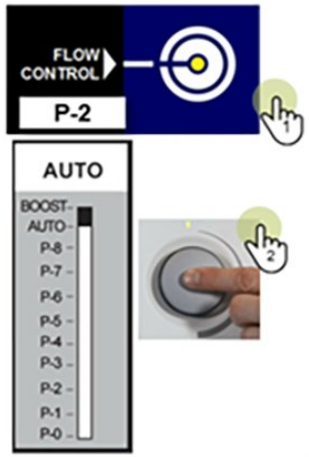
If a patient remains on V-A ECMO while on Impella® support, it will be necessary to reduce P-level to account for the lower flows from the device.

Vasopressors

Constrict blood vessels, increasing blood pressure

Vasodilators

Dilate blood vessels, decreasing blood pressure



Proactive Patient Management

P-Level and Flow Rate

Impella CP®

P-8 3.1 – 3.4

Impella 5.0, Impella LD	Performance Level	*Flow Rate (L/min)
Impella® Catheter motor is stopped	P-0	0.0
Flow rate increases as the P-level increases	P-1	0.0 – 1.4
	P-2	0.5 – 2.6
	P-3	0.5 – 3.1
	P-4	0.9 – 3.4
	P-5	1.4 – 3.7
	P-6	1.8 – 4.0
	P-7	2.6 – 4.4
	P-8	3.4 – 4.7
	P-9	4.2 – 5.3

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

Impella CP	P-level	*Flow Rate (L/min)	Revolutions Per Minute (rpm)
Impella® Catheter motor is stopped	P-0	0.0	0
Flow rate increases as the P-level increases	P-1	0.0 – 0.9	23,000
	P-2	1.1 – 2.1	31,000
	P-3	1.6 – 2.3	33,000
	P-4	2.0 – 2.5	35,000
	P-5	2.3 – 2.7	37,000
	P-6	2.5 – 2.9	39,000
	P-7	2.9 – 3.3	42,000
Recommended maximum P-level for continuous use	P-8	3.1 – 3.4	44,000
Used to confirm stable position after placement; can be used to provide maximum flow for up to 5 minutes. After 5 minutes, the controller will automatically default to AUTO or P-8.	BOOST	3.3 – 3.7	46,000

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

Impella 2.5	P-level	*Flow Rate (L/min)	Revolutions Per Minute (rpm)
Impella® Catheter motor is stopped	P-0	0.0	0
Flow rate increases as the P-level increases	P-1	0.0 – 1.1	25,000
	P-2	0.8 – 1.5	35,000
	P-3	1.1 – 1.7	38,000
	P-4	1.3 – 1.8	40,000
	P-5	1.5 – 1.9	43,000
	P-6	1.7 – 2.1	45,000
	P-7	1.8 – 2.2	47,000
Recommended maximum P-level for continuous use	P-8	2.1 – 2.4	50,000
Used to confirm stable position after placement; can be used to provide maximum flow for up to 5 minutes. After 5 minutes, the controller automatically defaults to AUTO or P-8.	BOOST	2.1 – 2.5	51,000

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

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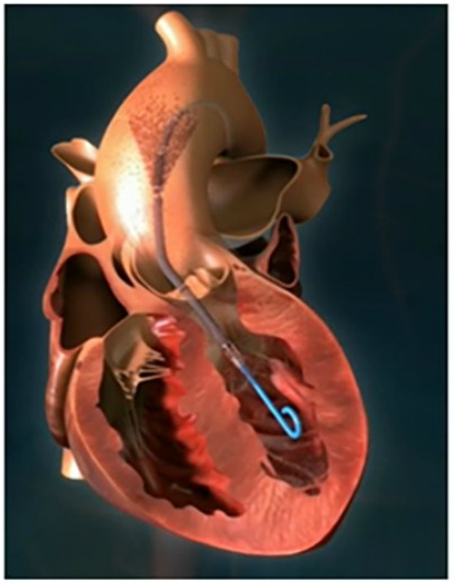
POSITIONING

Correct Impella® positioning is vital to its function and patient outcomes.

What if the Impella® catheter is malpositioned?

- Patient is not receiving any benefit from the Impella device
- RBC shearing may become a concern



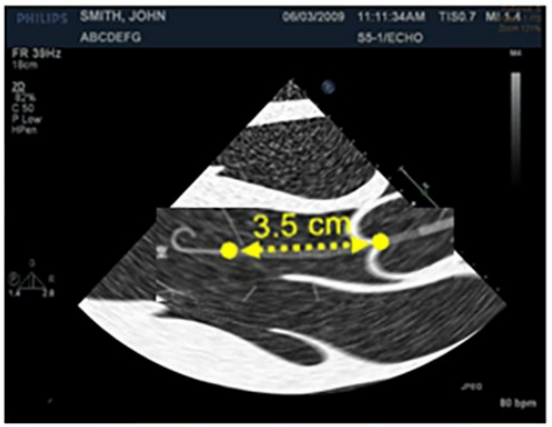
Learn more ▶ Recommendations for Positioning

- ☑ Monitor Impella® position with placement signal and motor current waveforms
- ☑ Prevent inward migration by removing catheter slack during insertion and locking catheter down with anchoring ring
- ☑ Reposition via Echo if needed

How to ensure Proper Positioning

Monitor Position

- Note the cm marking of the catheter at the Tuohy when tightened
- Monitor Motor Current – is it pulsatile?
- Get baseline echo after transfer to the unit
- If evidence of blood damage, reposition even if position appears perfect under echo



Prevent Inward Migration

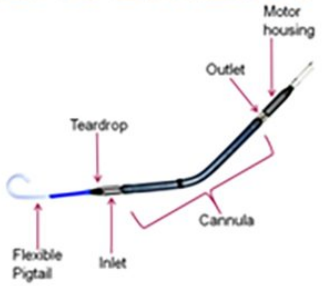
- Remove slack when at a higher performance level
- Position mid-inlet cage 3.5 cm from aortic annulus
- Tighten the Tuohy valve
- Recommend use of a knee immobilizer

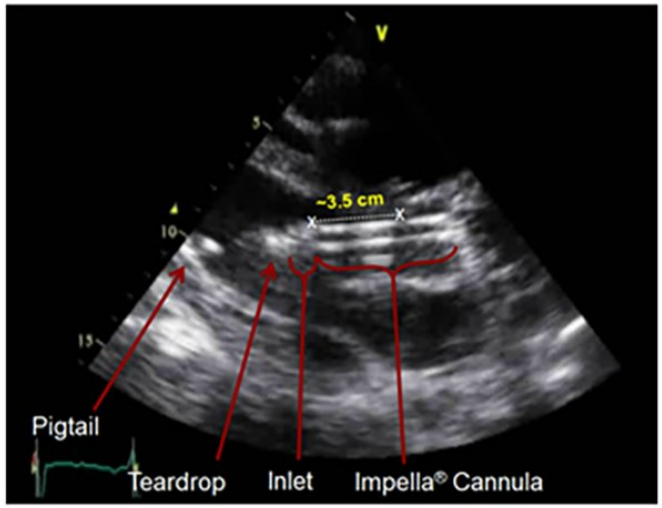
Cultivate a Culture of Understanding Catheter Migration

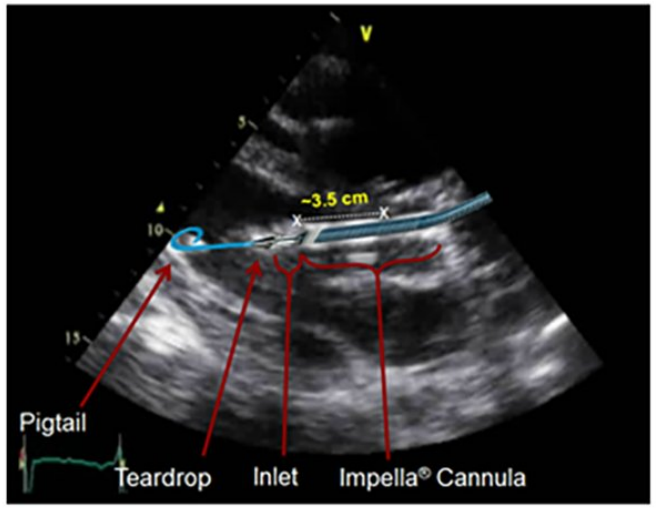
ECHO AND IMPELLA® : PROPER PLACEMENT

Verify Proper Catheter Placement

- ✓ Stable position in mid-ventricular space
- ✓ Catheter directed toward apex, pigtail free of mitral subvalvular structures
- ✓ Inlet clear of MV structures and LV walls
- ✓ Distance from aortic valve annulus to distal end of inlet cage approx. 3.5 cm
- ✓ Outlet in the aorta, well above the aortic valve







Preferred view for TTE: Parasternal long axis view

Tips and Tricks

- For the most accurate measurements, be sure you are able to view the catheter throughout the length of the measurement (off-axis views may be required)
- Reverberation/comet-tail artifacts posterior to inlet and teardrop may help locate these components
- Utilize color flow Doppler to visualize outflow in ascending aorta

Because TTE and TEE views provide 2D images, visualizing catheter position in multiple views is recommended.

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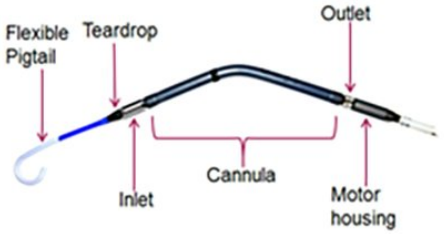
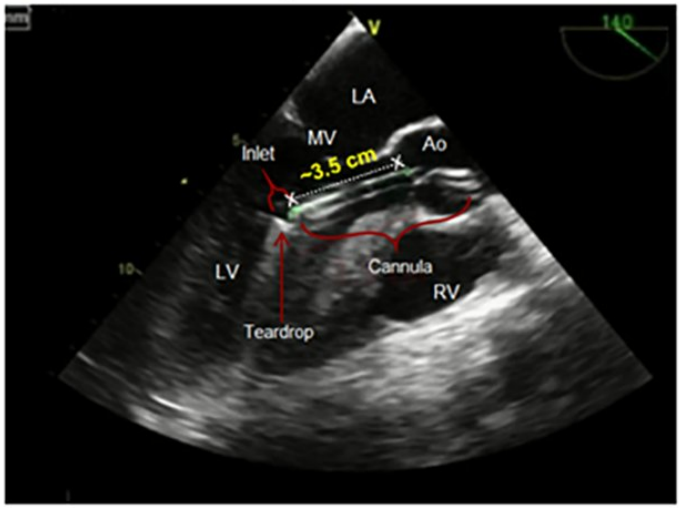
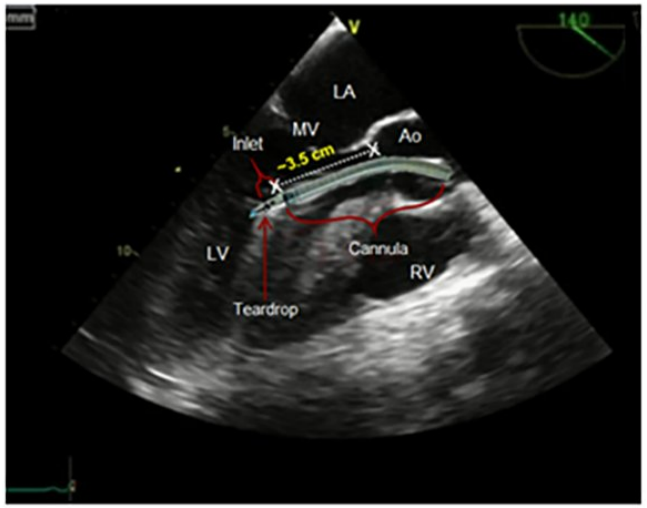
ECHO AND IMPELLA® : PROPER PLACEMENT (TEE)

Verify Proper Catheter Placement

- ✓ Stable position in mid-ventricular space
- ✓ Catheter directed toward apex, pigtail free of mitral subvalvular structures
- ✓ Inlet clear of MV structures and LV walls
- ✓ Distance from aortic valve annulus to distal end of inlet cage approximately 3.5 cm
- ✓ Outlet in the aorta, well above the aortic valve







Preferred view for TEE: Mid-esophageal long axis view

Tips and Tricks

- For the most accurate measurements, be sure you are able to view the catheter throughout the length of the measurement (off-axis views may be required)
- Reverberation/comet-tail artifacts posterior to inlet and teardrop may help locate these components
- Utilize color flow Doppler to visualize outflow in ascending aorta

Because TTE and TEE views provide 2D images, visualizing catheter position in multiple views is recommended.

P-A-P FOR PROACTIVE SUPPORT
PATIENT SCENARIOS

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QUESTIONS TO ASK TO DETERMINE GOOD P-A-P

- Which Impella® device is being used?
- Are the flows for the current P-level within the acceptable range for this device?
- What is **P**reload?
- What is the **A**fterload?
- Does motor current indicate proper **P**osition?
- Should **P**osition be assessed?
- Should any changes be made?

Impella CP	P-level	*Flow Rate (L/min)	Revolutions Per Minute (rpm)
Impella® Catheter motor is stopped	P-0	0.0	0
Flow rate increases as the P-level increases	P-1	0.0 – 0.9	23,000
	P-2	1.1 – 2.1	31,000
	P-3	1.6 – 2.3	33,000
	P-4	2.0 – 2.5	35,000
	P-5	2.3 – 2.7	37,000
	P-6	2.5 – 2.9	39,000
	P-7	2.9 – 3.3	42,000
Recommended maximum P-level for continuous use	P-8	3.1 – 3.4	44,000
Used to confirm stable position after placement; can be used to provide maximum flow for up to 5 minutes. After 5 minutes, the controller will automatically default to AUTO or P-8.	BOOST	3.3 – 3.7	46,000

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

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DO WE HAVE GOOD P-A-P?

Automated Impella® Controller (AIC) Placement Screen

Patient Monitor Screen

Impella CP	P-level	*Flow Rate (L/min)	Revolutions Per Minute (rpm)
Impella® Catheter motor is stopped	P-0	0.0	0
Flow rate increases as the P-level increases	P-1	0.0 – 0.9	23,000
	P-2	1.1 – 2.1	31,000
	P-3	1.6 – 2.3	33,000
	P-4	2.0 – 2.5	35,000
	P-5	2.3 – 2.7	37,000
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Recommended maximum P-level for continuous use	P-8	3.1 – 3.4	44,000
Used to confirm stable position after placement; can be used to provide maximum flow for up to 5 minutes. After 5 minutes, the controller will automatically default to AUTO or P-8.	BOOST	3.3 – 3.7	46,000

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

✓ *Demonstrates adequate P-A-P*

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Do We Have Good P-A-P? Patient Scenario 1

Automated Impella® Controller (AIC) Placement Screen

Patient Monitor Screen

Impella 5.0, Impella LD	Performance Level	*Flow Rate (L/min)
Impella® Catheter motor is stopped	P-0	0.0
Flow rate increases as the P-level increases	P-1	0.0 – 1.4
	P-2	0.5 – 2.6
	P-3	0.5 – 3.1
	P-4	0.9 – 3.4
	P-5	1.4 – 3.7
	P-6	1.8 – 4.0
	P-7	2.6 – 4.4
	P-8	3.4 – 4.7
	P-9	4.2 – 5.3

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

No, this does not demonstrate adequate P-A-P

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Do We Have Good P-A-P? Patient Scenario 2

Automated Impella® Controller (AIC) Placement Screen

Impella CP	P-level	*Flow Rate (L/min)	Revolutions Per Minute (rpm)
Impella® Catheter motor is stopped	P-0	0.0	0
Flow rate increases as the P-level increases	P-1	0.0 – 0.9	23,000
	P-2	1.1 – 2.1	31,000
	P-3	1.6 – 2.3	33,000
	P-4	2.0 – 2.5	35,000
	P-5	2.3 – 2.7	37,000
	P-6	2.5 – 2.9	39,000
	P-7	2.9 – 3.3	42,000
Recommended maximum P-level for continuous use	P-8	3.1 – 3.4	44,000
Used to confirm stable position after placement; can be used to provide maximum flow for up to 5 minutes. After 5 minutes, the controller will automatically default to AUTO or P-8.	BOOST	3.3 – 3.7	46,000

* Flow rate can vary due to suction or incorrect positioning

No, this does not demonstrate adequate P-A-P

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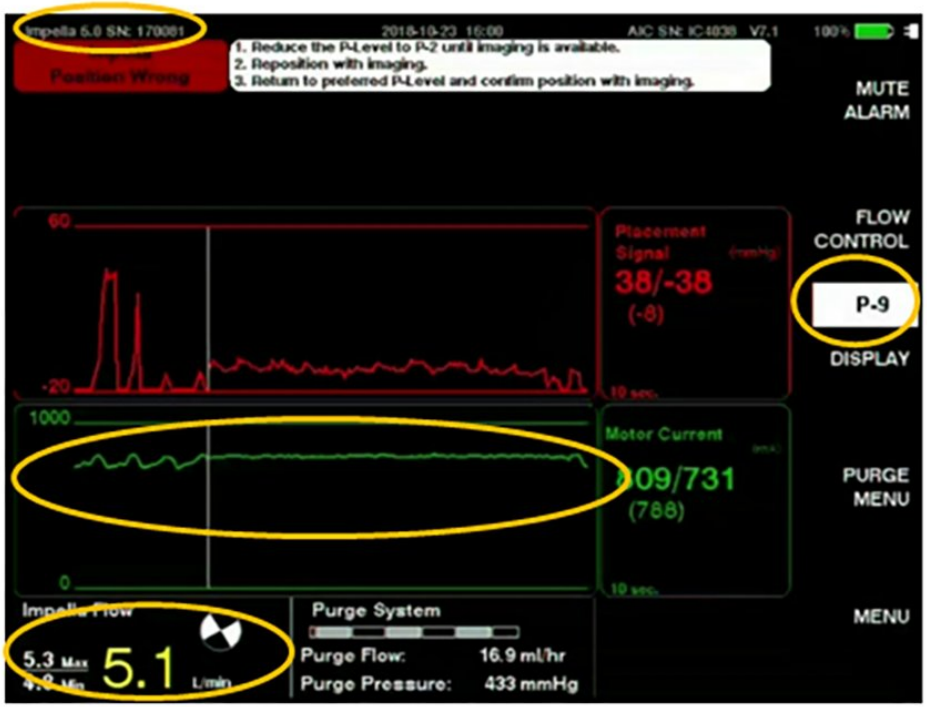
Do We Have Good P-A-P? Patient Scenario 3



Automated Impella® Controller (AIC) Placement Screen

Patient Monitor Screen

Impella 5.0, Impella LD	Performance Level	*Flow Rate (L/min)
Impella® Catheter motor is stopped	P-0	0.0
Flow rate increases as the P-level increases	P-1	0.0 – 1.4
	P-2	0.5 – 2.6
	P-3	0.5 – 3.1
	P-4	0.9 – 3.4
	P-5	1.4 – 3.7
	P-6	1.8 – 4.0
	P-7	2.6 – 4.4
	P-8	3.4 – 4.7
	P-9	4.2 – 5.3

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

No, this does not demonstrate adequate P-A-P

IMP-588.v2

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DIAGNOSE AND RESOLVE

Proactive Patient Management

DIAGNOSE AND RESOLVE ISSUES

ICU Check-In

- Assess patient
- Complete check-in procedure
- Use the Clinical Support Center (CSC) for check-in and questions

P-A-P Method

- Use P-A-P method to stay on top of potential issues
- Follow general patient management practices

Diagnose and Resolve

- Troubleshoot and manage AIC alarms
- Diagnose and resolve issues

=

Optimal Patient Care

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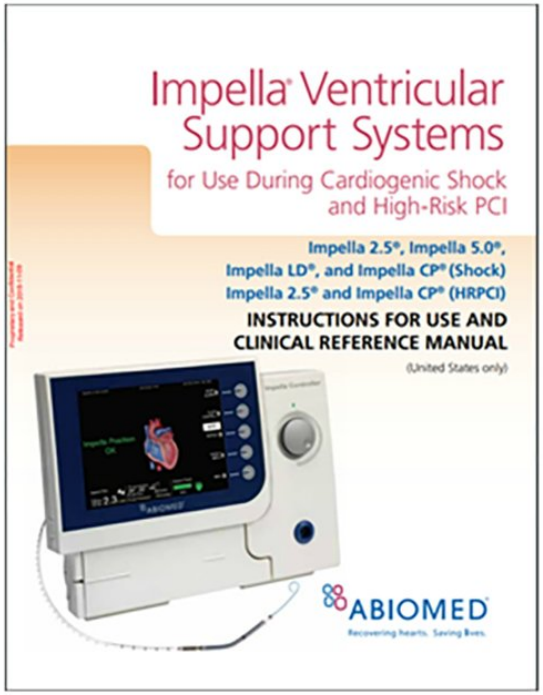
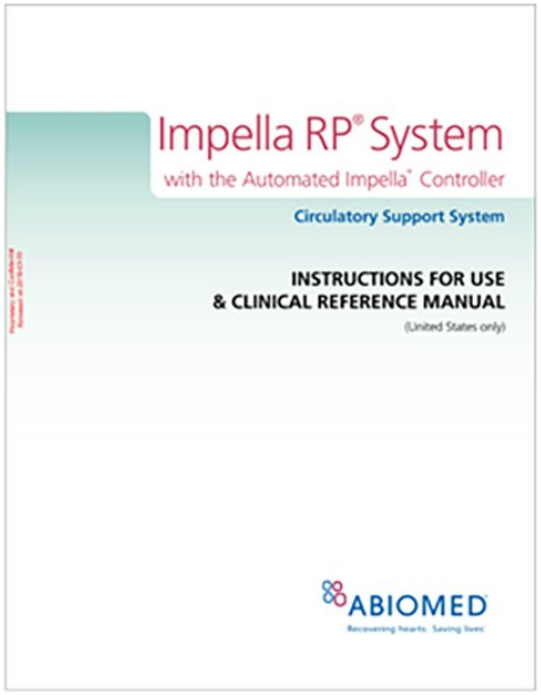
RESOURCES

RESOURCES





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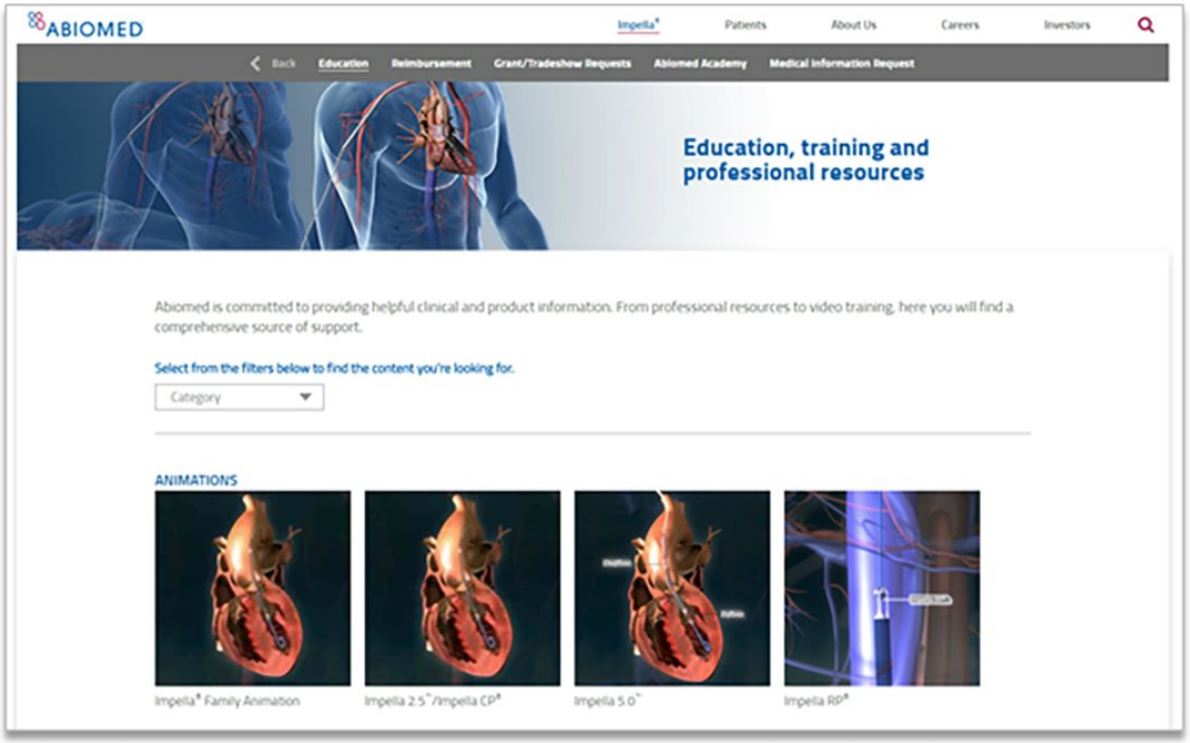

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RESOURCES - IMPELLA® APP

IMP-588.v2

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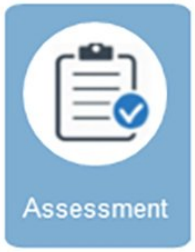
RESOURCES


Impella
CLINICAL
SUPPORT
CENTER
24/7
1-800-422-8666
24/7 Impella clinical & technical expertise
ICU patient check-in & proactive daily monitoring
Patient transfer notification
IMP-901-16
ABIOMED

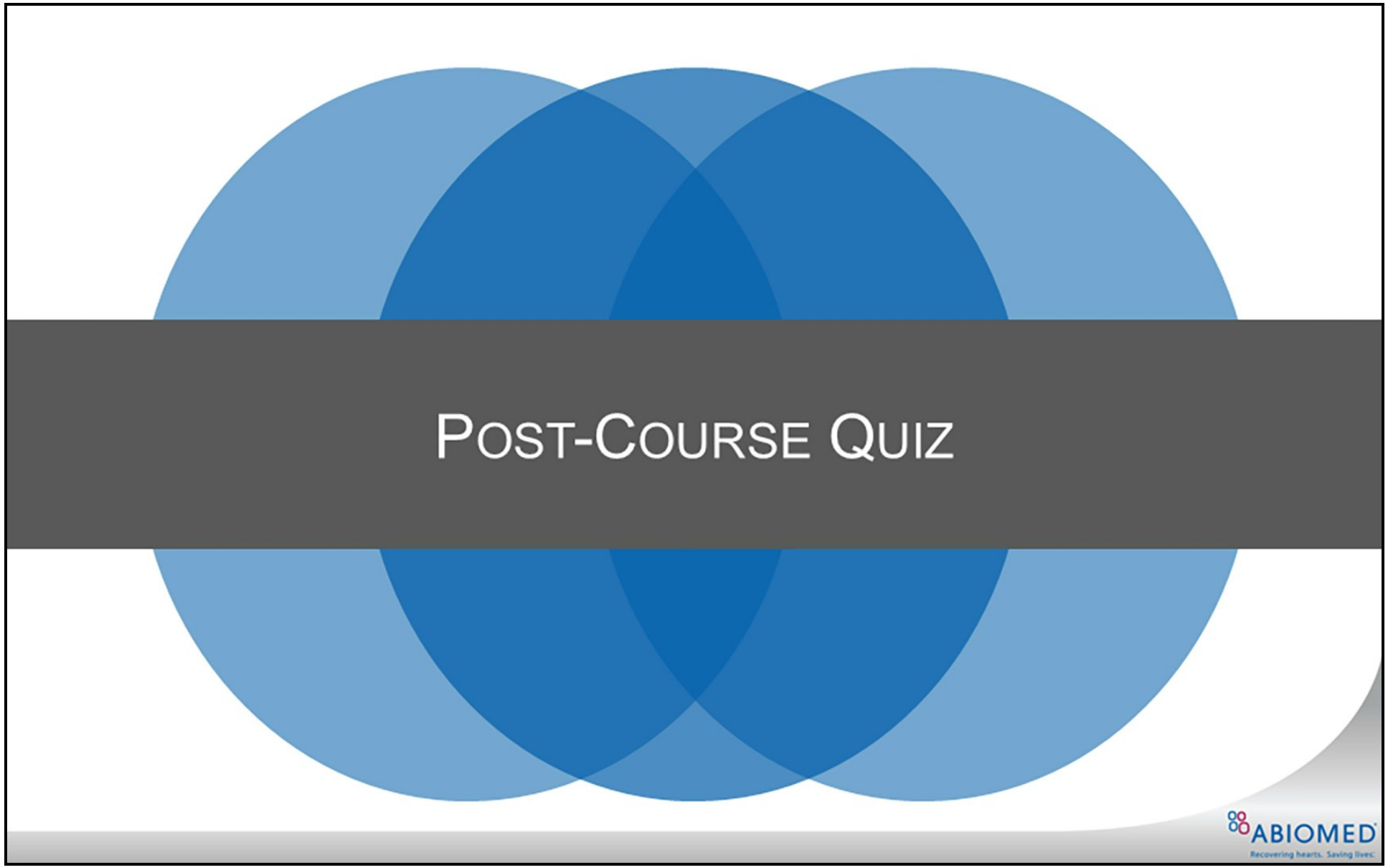
NEXT STEPS

Review any section of this course as needed.



Take a brief quiz to earn CEU credits

THANK YOU


POST-COURSE QUIZ
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QUIZ

1. The first line of defense to best outcomes is:
   a) Reading articles about the Impella®
   b) Using the ICU Check In Procedure
   c) Performing a chest x-ray when patient arrives to the ICU
   d) Having the assistance of another RN when the patient arrives to the ICU
2. The A in the acronym P-A-P stands for
   a) Afterload
   b) Always
   c) Arterial
   d) Advanced
3. Improper Position of the Impella device can lead to a decrease in hemodynamic support.
   a) True
   b) False
4. Inadequate preload can lead to: (select all that apply)
   a) Shearing of the RBCs
   b) Suction events
   c) Improper positioning of the Impella device
   d) Increased flows from the Impella device
5. Some causes of inadequate preload include: (select all that apply)
   a) Receiving diuretics
   b) On continual dialysis
   c) Bleeding
   d) Concurrently on ECMO
6. The best way to monitor for adequate preload is:
   a) Monitoring for suction events
   b) Determining if the MAP is high enough
   c) Use of a PA catheter
   d) Visualizing a decrease in urine output
7. Causes of high afterload include: (select all that apply)
   a) Diuretics
   b) Vasodilators
   c) Vasopressors
   d) V-A ECMO
8. While monitoring the Automated Impella® Controller (AIC), proper position is determined by the:
   a) Purge Pressure
   b) Purge Flow
   c) Lack of alarms
   d) Motor Current
9. Causes of inadequate flow from the Impella® device include: (select all that apply)
   a) Increased afterload
   b) Decreased afterload
   c) Increased preload
   d) Decreased preload
10. If it is determined that the Impella device is out of position, a chest x-ray should be ordered to determine where the catheter lies in regards to the aortic valve
    a) True
    b) False