Impella® 2.5
with the Impella® Controller

Circulatory Support System

INSTRUCTIONS FOR USE & CLINICAL REFERENCE MANUAL

(European Union and Canada only)

ABIOMED®

Recovering hearts. Saving lives.™

IMPORTANT NOTICE: Read this entire manual before using the Impella® Controller and Impella® 2.5 Circulatory Support System (Impella® 2.5 System). The Impella® 2.5 System is to be used only in accordance with this manual. This manual is only applicable to Impella® systems using the Impella® Controller.

Information contained in this document is subject to change without notice.

IMPELLA® 2.5
WITH THE IMPELLA® CONTROLLER
INSTRUCTIONS FOR USE
& CLINICAL REFERENCE MANUAL

(EUROPEAN UNION AND CANADA ONLY)

Rx Only

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INTRODUCTION

PURPOSE OF MANUAL

This Instructions for Use & Clinical Reference Manual is designed for healthcare professionals. It contains clinical and technical information to guide healthcare professionals in their use of the Impella® 2.5 Catheter with the Impella® Controller. The Impella® 2.5 System performs life-sustaining functions. To use the system you must understand and follow these instructions. The Impella® 2.5 System may be used only for its intended purpose.

MANUAL OVERVIEW

This manual provides instructions for use of the Impella® 2.5 Catheter with the Impella® Controller. The following summarizes the contents of each section of the manual.

- **Section 1: Warnings and Cautions** discusses the warnings and cautions pertaining to the use of the Impella® 2.5 Catheter with the Impella® Controller.
- **Section 2: Intended Use, Contraindications, and Possible Complications** discusses the intended use of the Impella® 2.5 Catheter with the Impella® Controller, contraindications, and possible complications that may be associated with the use of the system.
- **Section 3: The Impella® 2.5 Catheter and Impella® Controller** provides an overview of the system and describes its major components and features.
- **Section 4: Using the Impella® Controller** describes the controls and various screen types on the Impella® Controller.
- **Section 5: Using the Impella® Controller with the Impella® 2.5 Catheter** provides the procedures for using the Impella® 2.5 System.
- **Section 6: Patient Management Topics** provides key information on various topics related to management of patients with the Impella® 2.5 Catheter and Impella® Controller.
- **Section 7: Impella® Controller Alarms** provides a listing of Impella® Controller alarms as well as information on what to do to resolve them.
- **Section 8: General System Information** contains information including definitions for key terms that appear in the manual, descriptions of the abbreviations and symbols that appear on Impella® 2.5 Catheter and Impella® Controller components and packaging, technical information pertaining to the Impella® 2.5 Catheter and Impella® Controller, and instructions on cleaning and storing system components as well as disposing of components and returning components to Abiomed.
- **Appendices** at the end of the manual provide supplemental information about topics including the Impella® Limited Service Warranty; technical safety inspection, maintenance and repair; Abiomed-approved guidewires and introducers; and the Impella® Controller menu structure.

1 WARNINGS AND CAUTIONS

WARNINGS

The Impella® 2.5 System is intended for use only by personnel trained in accordance with the Abiomed® Training Program.

Fluoroscopy is required to guide placement of the Impella® 2.5 Catheter. The small placement guidewire must be reliably observed at all times.

Be sure that the stopcock on the peel-away introducer or repositioning sheath is always kept in the closed position. Significant bleed back can result if the stopcock is open.

Avoid manual compression of the inlet and outlet areas of the cannula assembly.

The sterile components of the Impella® 2.5 System can be used only if the sterilization indicators show that the contents have been sterilized, the packaging is not damaged, and the expiration date has not elapsed.

Do ***NOT*** resterilize or reuse the Impella® 2.5 Catheter. It is a disposable device and is intended for single use only. Reuse, reprocessing, or resterilization may compromise the structural integrity of the catheter and/or lead to catheter failure which, in turn, may result in patient injury, illness, or death.

Retrograde flow will occur across the aortic valve if the Impella® 2.5 Catheter is set at performance level P0.

To prevent malfunction of the locking mechanism of the 13 Fr peel-away introducer, do ***NOT*** hold the hemostatic valve while inserting into the artery.

To prevent failure of the 13 Fr peel-away introducer, remove the 13 Fr peel-away introducer prior to transport when activated clotting time (ACT) is less than 150 seconds.

Do ***NOT*** use saline in the purge system.

Do ***NOT*** use an Impella® 2.5 System if any part of the system is damaged.

To prevent the risk of explosion, do ***NOT*** operate the Impella® 2.5 System near flammable anesthetics.

If at any time during the course of support with the Impella® 2.5 Catheter, the Impella® Controller alarms "Purge Pressure Low" or "Purge System Open," follow the instructions presented in section 5 of this manual.

Do ***NOT*** subject a patient who has been implanted with an Impella® 2.5 Catheter to magnetic resonance imaging (MRI). The strong magnetic energy produced by an MRI machine may cause the Impella® 2.5 System components to stop working, and result in injuries to the patient. An MRI may also damage the electronics of the Impella® 2.5 System.

During defibrillation, do ***NOT*** touch the Impella® 2.5 Catheter, cables, or Impella® Controller.

Power the Impella® Controller using its internal battery if the integrity of the protective earth conductor is questionable.

Warnings

Warnings alert you to situations that can cause death or serious injury. The red symbol ⚠ appears before warning messages.

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the electromagnetic compatibility (EMC) information provided in section 8 of this manual.
- During transport, the Impella® Controller may be exposed to stronger electromagnetic disturbance than during in-hospital use. Strong electromagnetic disturbance may cause the Impella® Controller to display soft button menu selections that were not selected by the user. Operators should be aware that, under these conditions, the operating parameters are not affected. No user intervention is required. Monitor Impella® 2.5 Catheter flow and patient hemodynamics to confirm normal operation. The condition will resolve itself once the Impella® Controller is no longer exposed to the disturbance.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- Use of cables, other than those sold by Abiomed, may result in increased emissions or decreased immunity of the Impella® Controller.
- The Impella® Controller uses RFID (radio frequency identification) to identify and communicate with the purge cassette. Other equipment may interfere with the Impella® Controller even if that other equipment complies with CISPR emission requirements.
- Infusion through the sideport of the introducer can be done only after all air is removed from the introducer. If performed, the infusion should be done for flushing purposes only and ***NOT*** for delivering therapy or monitoring blood pressure.

CAUTIONS

Cautions

Cautions indicate situations in which equipment may malfunction, be damaged, or cease to operate. The yellow symbol ⚠ appears before caution messages.

- Handle with care. The Impella® 2.5 Catheter can be damaged during removal from packaging, preparation, insertion, and removal. Do ***NOT*** bend, pull, or place excess pressure on the catheter or mechanical components at any time.
- Patients with aortic stenosis or other abnormal aortic valve performance may be compromised by the use of the Impella® 2.5 Catheter. Patients with aortic valve disease should be observed for aortic insufficiency.
- Use only original accessories and replacement parts supplied by Abiomed.
- Do ***NOT*** use damaged or contaminated connector cables.
- To prevent device failure, do ***NOT*** start the Impella® 2.5 Catheter until the guidewire has been removed.
- Do ***NOT*** remove the Impella® 2.5 Catheter over the length of the guidewire.
- When replacing the purge cassette, the replacement process must be completed within 2 minutes. The Impella® 2.5 Catheter may be damaged if replacement takes longer than 2 minutes.

To prevent malfunction of the Impella® Controller, avoid long-term exposure to direct sunlight and excessive heat (40°C).

To prevent overheating and improper operation, do ***NOT*** block the cooling vents of the Impella® Controller while it is operating.

Do ***NOT*** kink or clamp the Impella® 2.5 Catheter or the 13 Fr peel-away introducer.

The Li-Ion batteries must be charged for 5 hours prior to system operation in order to meet the runtime requirement of 1 hour. Failure to do so will yield a shorter runtime. After being unplugged, the Impella® Controller will operate for at least 60 minutes after the batteries have been fully charged.

Minimize exposure of Impella® 2.5 System components to sources of electromagnetic interference (EMI). Exposure to sources of EMI, such as cell phones and two-way radios, may cause operational interference. To clear interference, either increase the distance between system components and the EMI source or turn off the EMI source.

Operation of Impella® 2.5 System components may interfere with the operation of other devices. If interference occurs, increase the distance between the device and system components.

Have a backup Impella® Controller available in the unlikely event of controller failure.

Do ***NOT*** use the bed mount as a handle.

Do ***NOT*** alter the Impella® 2.5 Introducer kit in any way.

Aspiration and saline flushing of the Impella® 2.5 Introducer kit sheath, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation.

Indwelling introducer sheaths should be internally supported by a catheter, electrode, or dilator.

Dilators, catheters, and pacing leads should be removed slowly from the sheath. Rapid removal may damage the valve, resulting in blood flow through the valve.

Never advance the guidewire or sheath when resistance is met. Determine the cause of resistance using fluoroscopy and take remedial action.

When injecting or aspirating through the sheath, use the sideport only.

2 INTENDED USE, CONTRAINDICATIONS, AND POSSIBLE COMPLICATIONS

INTENDED USE (EU AND CANADA)

The Impella® 2.5 (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 5 days for the following indications, as well as others:

- The Impella® 2.5 is a circulatory support system for patients with reduced left ventricular function, eg, post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction, or for myocardial protection after acute myocardial infarction
- The Impella® 2.5 may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome
- Support during high risk percutaneous coronary intervention (PCI)
- Post PCI

CONTRAINDICATIONS (EU AND CANADA)

Patients with aortic stenosis or other abnormal aortic valve performance may be compromised by the use of the Impella® 2.5 Catheter. Patients with aortic valve disease should be observed for aortic insufficiency.

CONTRAINDICATIONS IN THE EUROPEAN UNION

- Mechanical aortic valves, severe aortic valvular stenosis or valvular regurgitation
- Hematological disorder causing fragility of the blood cells or hemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrotomy or severe anomaly of the ascending aorta and/or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) after myocardial infarction
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PAOD) is a relative contraindication

CONTRAINDICATIONS IN CANADA

- Prosthetic aortic valves, severe aortic valvular stenosis or valvular regurgitation
- Hematological disorder causing fragility of the blood cells or hemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrotomy or severe anomaly of the ascending aorta and/or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) after myocardial infarction
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Peripheral arterial occlusion disease (PAOD)

POSSIBLE COMPLICATIONS (EU AND CANADA)

There are risks of complications with every procedure using a blood pump. These include among others:

- Hemolysis
- Bleeding
- Immune reaction
- Embolism, thrombosis
- Vascular injury through to angionecrotomy
- Positioning problems
- Infection and septicemia
- Dislocation of the pump
- Cardiovalvular injuries due to extreme movement of the suction cannula in relation to the cardiac valve or as a result of attachment by suction of the pump to the valve system following incorrect positioning
- Endocardiac injuries as a result of attachment of the pump due to suction
- Pump failure, loss of pump components following a defect
- Patient dependency on the pump after use for support

3 THE IMPELLA® 2.5 CATHETER AND IMPELLA® CONTROLLER

OVERVIEW

The Impella® 2.5 Catheter is an intravascular microaxial blood pump that supports a patient's circulatory system. The Impella® 2.5 Catheter is inserted percutaneously through the femoral artery and into the left ventricle (see Figure 3.1).

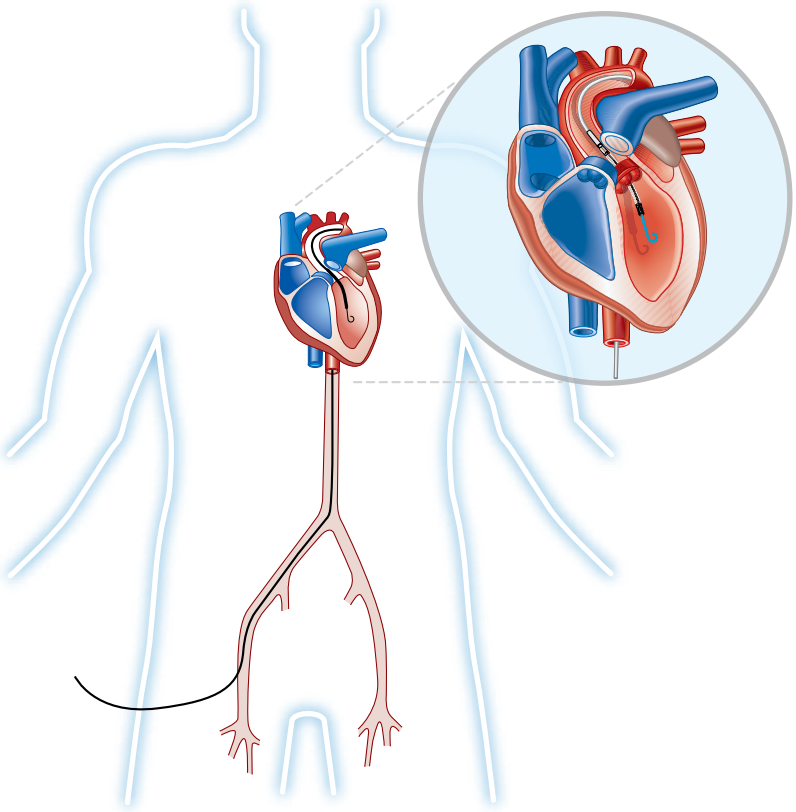


Figure 3.1 Impella® 2.5 Catheter in the Heart

When properly positioned, the Impella® 2.5 Catheter delivers blood from the inlet area, which sits inside the left ventricle, through the cannula, to the outlet opening in the ascending aorta. Physicians and device operators monitor the correct positioning and functioning of the Impella® 2.5 Catheter on the display screen of the Impella® Controller.

This section describes the components of the Impella® 2.5 Catheter and the Impella® Controller, as well as the accessory components.

REUSABLE SYSTEM COMPONENTS

The Impella® 2.5 System consists of the following reusable components:

- Impella® Controller—provides the user interface, alarm indications, and portable battery
- Impella® Controller cart—for easy transport of the Impella® Controller

SINGLE-USE SYSTEM COMPONENTS

The Impella® 2.5 System also includes the following single-use components:

- Impella® 2.5 Catheter
- Purge cassette
- Introducer kit
- 0.018 inch, 260 cm placement guidewire
- Connector cable

IMPELLA® 2.5 SET-UP AND INSERTION KIT

The components of the Impella® 2.5 System are packaged into a single box called the Impella® 2.5 Set-up and Insertion kit. Table 3.1 describes the contents of this kit.

Table 3.1 Impella® 2.5 Set-up and Insertion Kit Components

The Impella® 2.5 Set-up and Insertion kit contains the following:

- Impella® 2.5 Catheter
- 0.018 inch, 260 cm placement guidewire
- Connector cable
- Purge cassette
- Introducer kit
  - » 13 Fr peel-away introducer
  - » 13 Fr dilator
  - » 18 G Seldinger needle
  - » 10 cc syringe
  - » 0.035 inch stiff access guidewire

SYSTEM CONFIGURATIONS

Figure 3.2 illustrates how the Impella® Controller connects to the Impella® 2.5 Catheter and accessory components in the initial set-up configuration.

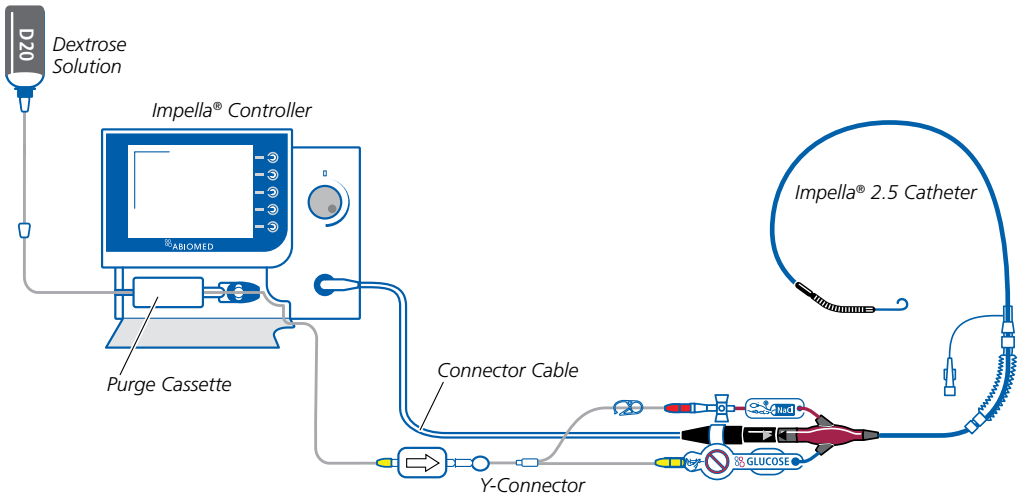


Figure 3.2 Set-up Configuration of the Impella® Controller, Impella® 2.5 Catheter, and Accessories

Figure 3.3 illustrates the standard configuration of the Impella® 2.5 Catheter, Impella® Controller, and accessory components.

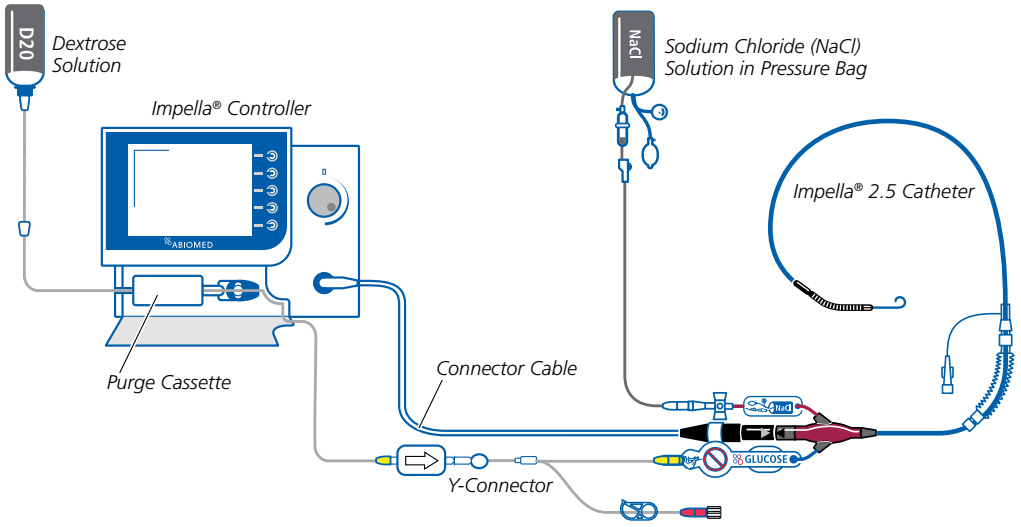


Figure 3.3 Standard Configuration of the Impella® Controller, Impella® 2.5 Catheter, and Accessories

IMPELLA® 2.5 CATHETER

The Impella® 2.5 Catheter is an intravascular microaxial blood pump that delivers up to 2.5 liters of blood per minute from the left ventricle into the aorta. Figure 3.4 illustrates the Impella® 2.5 Catheter. Table 3.2 describes each component from the pigtail at one end to the check valve on the other end.

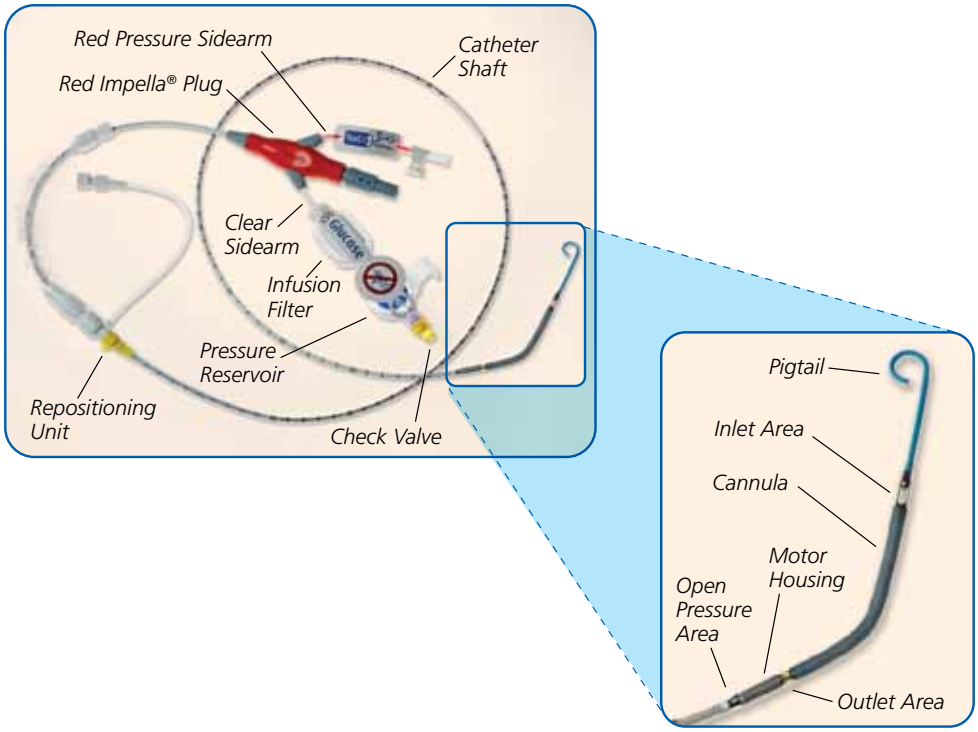


Figure 3.4 Impella® 2.5 Catheter

Table 3.2 Impella® 2.5 Catheter Components

Component	Description
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.
Inlet area	The inlet area, located at the distal tip of the cannula, has four openings (windows) that allow blood to be drawn into the inlet and channeled through the cannula.
Cannula	The 12 Fr cannula has a spiral-shaped reinforced body that is shaped in a 45-degree angle. The cannula is made of nitinol and covered in polyurethane.

Table 3.2 Impella® 2.5 Catheter Components (continued)

Component	Description
Outlet area	The proximal end of the cannula is attached to the outlet area where the blood exits the cannula.
Motor housing	The motor housing is 12 Fr in diameter and consists of an encapsulated motor.
Open pressure area	The open pressure area is an opening located between the motor housing and the distal end of the catheter shaft.
Catheter shaft	A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, a pressure measurement lumen, and an electrical cable. The catheter shaft has longitudinal and transversal marks: • The longitudinal mark along the inner radius shows correct position of the 0.018 inch, 260 cm placement guidewire once backloaded on the Impella® 2.5 Catheter. • The transversal marks at 1 cm intervals with numbers every 5 cm aid in proper positioning.
Repositioning unit	The repositioning unit consists of a sheath and an anticontamination sleeve with an anchoring ring. • The sheath (with hemostatic valve) is graduated from 9 Fr to 13 Fr. It is located on the catheter shaft and allows repositioning of the catheter. • The anchoring ring of the anticontamination sleeve secures the sheath to the catheter.
Red Impella® plug	The red Impella® plug at the proximal end of the catheter connects the catheter to the Impella® Controller through a connector cable. It contains: • A pressure transducer that translates pressure for the pressure lumen proximal to the motor • Memory that retains operating parameters in case the patient needs to be transferred to another controller • The placement signal lumen that allows for pressure and waveform displays It has two sidearms: a red pressure sidearm and a clear sidearm.
Red pressure sidearm	The red pressure sidearm is attached to a standard pressure bag and is used to prime the line of the pressure measurement system.
Clear sidearm	The clear sidearm is attached to the purge cassette tubing. It leads to the infusion filter, the pressure reservoir, and the check valve.
Infusion filter	The infusion filter prevents bacterial contamination and air from entering the purge lumen.
Pressure reservoir	The pressure reservoir includes a flexible rubber diaphragm that provides additional filling volume by means of an expansion chamber during purge solution change.
Check valve	The yellow check valve ensures that purge fluid does not flow in the reverse direction when the purge solution is exchanged.

Repositioning Sheath: Inner vs Outer Diameter

The repositioning sheath has a graduated inner diameter of 9 Fr to 13 Fr. The outer diameter is graduated from 11 Fr to 15 Fr.

IMPELLA® CONTROLLER

Impella® Controller Battery Power

The controller can operate on its internal lithium-ion (Li-Ion) battery for at least 60 minutes when fully charged.

The Impella® Controller (see Figure 3.5) provides three vital functions to the operation of the Impella® 2.5 Catheter:

- The controller provides an interface for monitoring and controlling the function of the Impella® 2.5 Catheter
- The controller provides a fluid purge to the Impella® 2.5 Catheter
- The controller provides backup power when the Impella® 2.5 System is operated away from AC power

The controller weighs 26 lbs (11.8 kg) and can operate on its internal battery for at least 60 minutes when fully charged.

Impella® Controller operation is described in detail in section 4 of this manual.

Figure 3.5 Impella® Controller – Front View

PURGE CASSETTE

Do not use saline in the purge system.

The purge cassette delivers rinsing fluid to the Impella® 2.5 Catheter. The purge fluid (typically 20% dextrose solution) flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor. When the purge cassette is properly installed in the Impella® Controller, the words on it are upright and facing you. The image of the purge fluid appears on the left with arrows pointing toward the image of the person on the right. Figure 3.6 illustrates the purge cassette and related components. Table 3.3 describes each component.

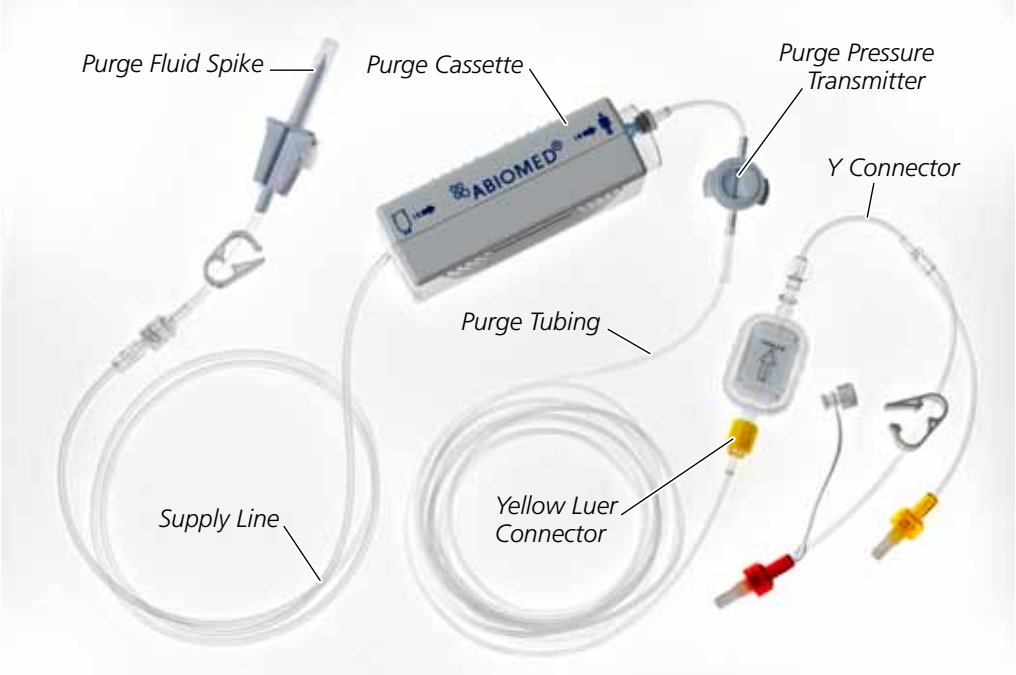


Figure 3.6 Purge Cassette

Y connector for Set-up Configuration

The Y connector attached to the purge tubing is used for the initial set-up configuration of the Impella® 2.5 System. Switch to the standard configuration as soon as practical.

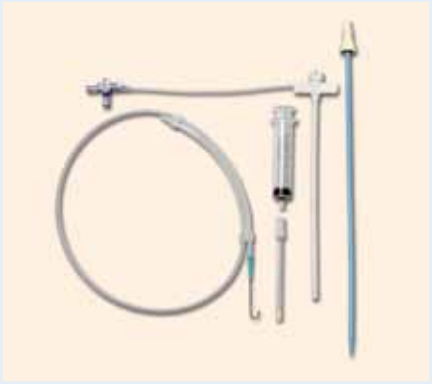
Table 3.3 Purge Cassette Components

Component	Description
Purge fluid spike	One end spikes the purge fluid bag and the other end connects the bag to the purge cassette supply line
Supply line	Carries fluid from the purge fluid bag to the purge cassette
Purge cassette	Contains the components for delivering the purge fluid; maintains the pressure barrier between the blood and the motor to prevent blood from entering the motor
Purge pressure transmitter	Transmits pressure to the controller based on the purge pressure in the purge tubing; a sensor in the controller measures the pressure so that it can be displayed on the screen and used by the purge pressure algorithm to maintain the purge pressure
Purge tubing	Carries purge fluid from the purge cassette to the Impella® 2.5 Catheter
Yellow luer connector	Connects the purge tubing to the Y connector at case start and to the check valve (yellow luer lock) on the Impella® 2.5 Catheter during system change
Y connector	Adapter that connects the purge tubing to the sidearms of the Impella® 2.5 Catheter during case start. The Y connector consist of: • Yellow luer that connects to the clear sidearm • Red luer that connects to the red sidearm • Cap for the red luer when it is disconnected from the sidearm for transfer to the standard configuration • Clamp for the purge tubing leading to the red sidearm • Rectangular antibacterial air filter

ACCESSORIES

Table 3.4 illustrates and describes the accessories used with the Impella® 2.5 Catheter and Impella® Controller.

Table 3.4 Impella® 2.5 Catheter and Impella® Controller Accessories

Component	Description
	The white connector cable connects the Impella® 2.5 Catheter to the Impella® Controller. Clips on the cable are used to secure the purge tubing to the cable. • The socket at the black end of the cable connects to the Impella® 2.5 Catheter plug. • The white plug at the opposite end of the cable is inserted into the blue catheter plug on the front of the Impella® Controller.
Figure 3.7 White Connector Cable	
	The introducer kit is used to position the Impella® 2.5 Catheter. It contains: • 13 Fr peel-away introducer—with hemostatic valve for tight fit around components and single-step "break-away" configuration • 13 Fr dilator—easy to insert and remove with soft design for atraumatic approach into femoral artery • 18 G Seldinger needle • 10 cc syringe • 0.035 inch stiff access guidewire
Figure 3.8 Introducer Kit	
	The 0.018 inch, 260 cm placement guidewire is used for the placement of the catheter. The guidewire has a radiopaque, shapable tip.
Figure 3.9 0.018 inch, 260 cm Placement Guidewire	

Guidewire Use

It is important to use only the guidewire supplied with the system or an Abiomed-approved alternative. Refer to Appendix C for more information about Abiomed-approved guidewires.

Component	Description
	Hospital Provided: Dextrose solution (typically 20% dextrose in water with 50 IU/mL of heparin) is used as the purge fluid through the Impella® 2.5 Catheter.

Figure 3.10 Dextrose Solution

	The Impella® Controller cart holds the Impella® Controller. The cart has wheels for easy transport of the controller and a storage basket. (For more information, including assembly instructions, refer to the Impella® Controller cart instructions for use.)

Figure 3.11 Impella® Controller Cart

4 USING THE IMPELLA® CONTROLLER

OVERVIEW

The Impella® Controller is the primary user control interface for the Impella® 2.5 Catheter. It controls the Impella® 2.5 Catheter performance, monitors the catheter for alarms, and provides real-time catheter position information regarding the location of the catheter across the aortic valve. The controller can be powered by AC power or can operate on internal battery power for at least 60 minutes when fully charged.

This section of the manual discusses Impella® Controller features and displays.

IMPELLA® CONTROLLER FEATURES

IMPORTANT NOTE: The underside of the Impella® Controller has a battery switch to turn on the batteries. This switch is turned off for shipping purposes. Before operating the Impella® Controller for the first time, make sure you turn this switch on. If the battery switch is not turned on, the Impella® Controller will not be able to operate on battery power.

Figure 4.1 illustrates the features on the front of the Impella® Controller. These features are described in Table 4.1.

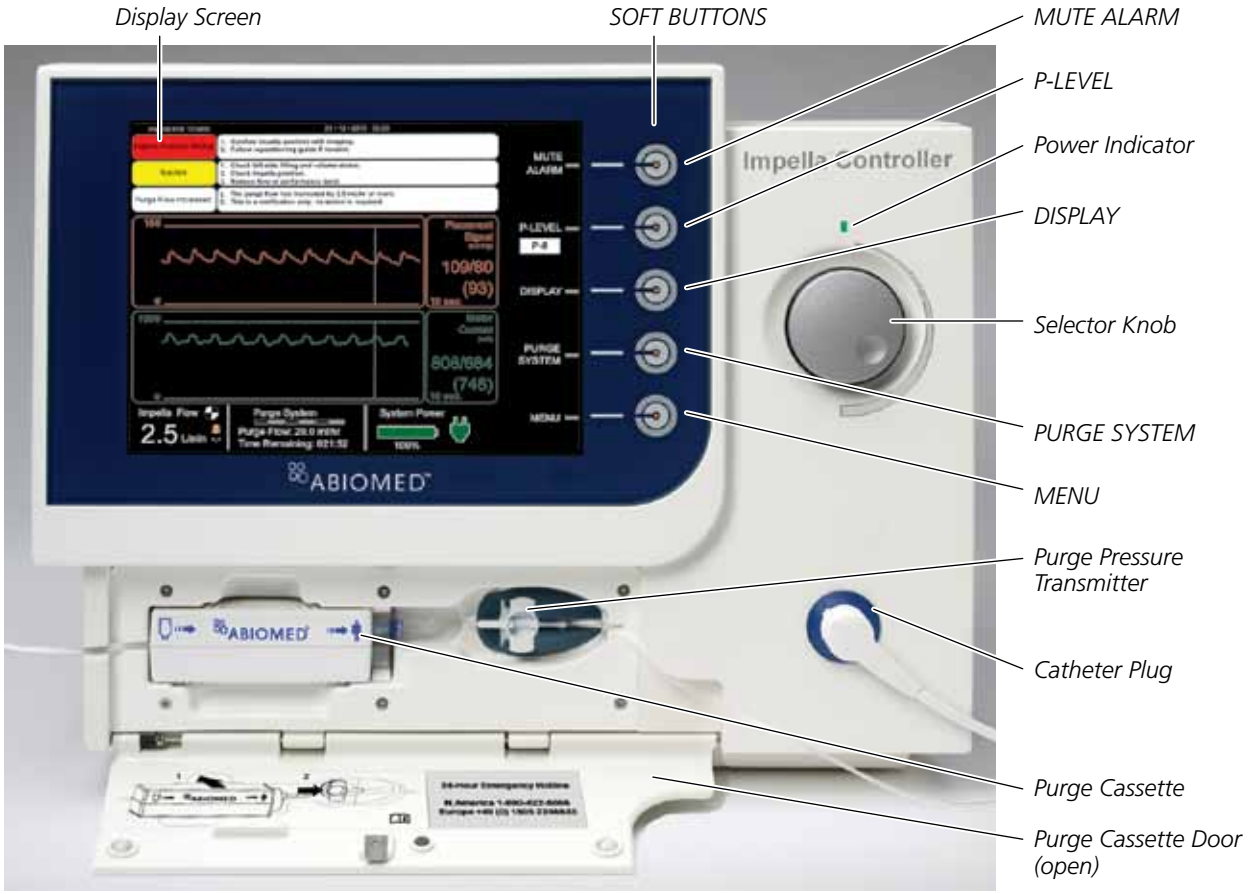


Figure 4.1 Impella® Controller Features – Front View

Table 4.1 Impella® Controller Front View Features

Feature	Description
Display screen	Displays user information, including the labels for the soft buttons. (Display screen elements described in detail later in this section.)
Soft buttons	Display, open, and close menus. The function for each soft button is defined by labels adjacent to the button on the display screen; function changes depending on the screen. (Soft button functions are described in Table 4.3.) When the Impella® 2.5 Catheter is running, the default soft button labels are as follows: • **MUTE ALARM** • **P-LEVEL** • **DISPLAY** • **PURGE SYSTEM** • **MENU**
Power indicator	LED light above the selector knob; indicates the power status of the Impella® Controller. • Green light—controller is on and plugged into AC power or running on battery power • Amber light—controller is off but plugged into AC power • No light—controller is off and not plugged into AC power
Selector knob	Rotating push button; turn clockwise and counterclockwise to navigate through menu items; push to make a selection.
Purge pressure transmitter	A flexible diaphragm on the purge cassette tubing that applies pressure to the sensor in the controller so that purge pressure can be measured.
Catheter plug	Connection point on the controller for the connector cable that connects to the Impella® 2.5 Catheter.
Purge cassette	Contains the components for delivering the purge fluid; maintains the pressure barrier between the blood and the motor to prevent blood from entering the motor. (The purge cassette and its components are described in section 3 of this manual.)
Purge cassette door	Spring-loaded door that opens to provide access to the purge cassette.

Selector Knob Function

Rotate *the selector knob on the controller to navigate through menu items.*
Push *the selector knob to confirm your selection.*

Figure 4.2 illustrates the features on the left and right sides of the Impella® Controller. These features are described in Table 4.2.

Figure 4.2 Impella® Controller Features – Side Views

Table 4.2 Impella® Controller Side View Features

Feature	Description
Bed mount	Metal bracket on the back of the controller; attaches controller to the cart or bed
Purge cassette door release	Button located on the left side of the controller; press to open the purge cassette door
RS-232 service jack	Interface for data transfer by Abiomed maintenance or service personnel
USB connector	Connection for data downloading by Abiomed maintenance or service personnel
AC fuses	Electrical safety device in the event of current overload
AC plug	Connection point on the controller for the AC power cord
Power switch	Button that turns the controller on or off • ON: Press and hold the power switch for 3 seconds • OFF: (1) Disconnect the Impella® 2.5 Catheter from the Impella® Controller (2) Press and hold the power switch for 3 seconds (3) A pop-up confirmation box will appear (4) Press **OK** using the selector knob to confirm that the controller should be turned off NOTE: Holding down the power switch for longer than 30 seconds during operation will cause the controller to initiate an emergency shutdown
Equipotential ground stud	Used to ground the Impella® Controller according to hospital procedures
Ethernet jack	Connection for downloading data or software upgrades

IMPELLA® CONTROLLER HOME SCREEN

The home screen displays operating parameters and information for the entire Impella® System. Figure 4.3 illustrates the Impella® Controller home screen. Each element of the display is described in Table 4.3.

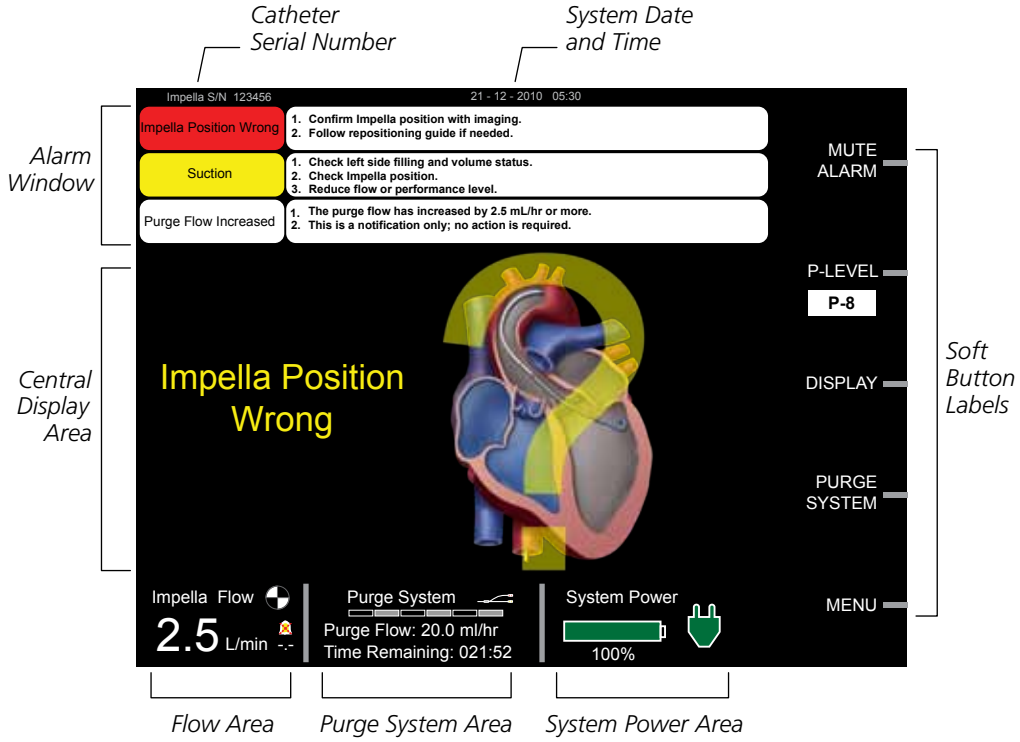


Figure 4.3 Impella® Controller Home Screen

Table 4.3 Impella® Controller Display Elements

Display Element	Description
Alarm window	The alarm window displays up to 3 alarms simultaneously, in order of priority from top to bottom. For each alarm, the alarm window displays: • Alarm header – displayed in the left column; window is color-coded red for critical alarms, yellow for serious alarms, white for advisory notifications, gray for resolved alarms • Alarm subhead (if applicable) – further describes the alarm condition • Detailed text – up to 3 lines of instructions for resolving the alarm condition are displayed in the right column of the alarm window next to the alarm header and subhead information (See section 7 of this manual for further discussion of alarms.)
Catheter serial number	Displayed in the upper left of the display screen if a catheter is connected to the controller.
System date and time	The current date (DD-MM-YYYY) and time (24-hour format; HH:MM) are displayed in the upper center of the screen display. (In this example it is December 21, 2010 at 5:30am.)

Table 4.3 Impella® Controller Display Elements (continued)

Display Element	Description
Mute alarm indicator	Displayed in place of the words "MUTE ALARM" when an alarm is silenced. (See section 7 of this manual for more information about the mute alarm function; Figure 7.1 illustrates the mute alarm indicator.) • Yellow bell with red X displayed when an alarm is muted • Not displayed when an alarm is active (but not muted) or when there are no active alarms
Soft button labels	The soft buttons on the Impella® Controller have corresponding labels adjacent to them on the display screen. These labels change depending on the type of screen displayed. (Refer to Appendix D in this manual for more details about the menu structure.) **MUTE ALARM** • Mutes (silences) active alarms **P-LEVEL** (or **NEXT**) • **P-LEVEL** – Allows you to set the performance level for the Impella® 2.5 Catheter • **NEXT** – Advances to the next screen **DISPLAY** (or **BACK**) • **DISPLAY** – Brings up the Display menu for viewing waveforms and navigating to other screen displays • **BACK** – Returns to the previous screen **PURGE SYSTEM** (or **EXIT**) • **PURGE SYSTEM** – Brings up the Purge System menu for changing the purge fluid, purge cassette, or purge system; de-airing the purge system; or transferring to the standard configuration • **EXIT** – Exits the current procedure **MENU** (or **Exit Repositioning Guide**) • **MENU** – Brings up a menu of options related to controller settings, alarm history, repositioning, and starting a case • **Exit Repositioning Guide** – Exits the repositioning guide
System power area	System power information is displayed to the right of the purge system information on the bottom of the display screen. Battery status – Bar within battery symbol indicates the overall remaining capacity of the batteries • Full green bar for fully charged battery • Partial green bar for battery that is at least 50% charged • Partial yellow bar for battery that is between 16% and 50% charged • Partial red bar for battery that is less than or equal to 15% charged • Moving gray bar for battery that is in charging mode • Numeric percentage of battery power remaining displayed below the battery icon AC plug indicator • Green plug indicates that the controller is running on AC power • Gray plug with a red X indicates no AC power detected and the controller is running on battery power

Table 4.3 Impella® Controller Display Elements (continued)

Display Element	Description
Purge system area	Information about the purge system is displayed to the right of the flow area at the bottom of the display screen. Purge system marquee—scrolls from left to right when purge system is operating • Slow scrolling represents normal purge flow rate • Fast scrolling represents bolus flow rate Y connector icon • Appears above the purge system marquee when the Impella® 2.5 System is configured using the Y connector in the set-up configuration Purge flow • Current purge flow displayed in mL/hr below the purge system marquee if the purge flow is known • Not displayed when the purge system is stabilizing, when there is no purge cassette, or when the procedure has not yet started Time remaining in reservoir • Displays the remaining runtime based on the volume of the purge fluid bag at the start of the case and the cumulative time and flow rate of delivery of purge fluid • Not displayed if there is no purge cassette or the procedure has not yet started
Flow area	Information about Impella® 2.5 Catheter flow is displayed in the lower left corner of the display screen. Current flow rate • Mean catheter flow displayed in liters per minute (L/min)—the numbers appear in *white* if the catheter position is correct; *yellow* if the catheter position is incorrect or unknown • If the system is unable to calculate flow, a yellow triangular caution icon is displayed with the message "Flow Calculation Disabled" Catheter operation icon • The circular catheter operation icon rotates when the Impella® 2.5 Catheter is running Low flow alarm limit icon • Indicates whether the alarm is enabled or disabled • Enabled: bell symbol and numeric alarm limit are displayed • Disabled: bell symbol is crossed out (as shown in Figure 4.3)
Central display area	On the home screen, the central display area displays a heart pictogram and Impella® 2.5 Catheter position indicator message. Heart pictogram appears in the center of the home screen display. • Provides a visual representation of the current Impella® 2.5 Catheter position • Overlaid with a translucent yellow "?" when the controller detects an incorrect catheter position or cannot determine catheter position

Purge System Stabilization

The purge system must stabilize after case start, a purge procedure, or resolution of a purge alarm. During this time, it may take up to 3 minutes for purge system information to display on the screen.

Table 4.3 Impella® Controller Display Elements (continued)

Display Element	Description
	Impella® 2.5 Catheter position indicator message displayed to the left of the heart icon. • Displays "Impella Position OK" in green when catheter position is correct • Displays "Impella Position Unknown" in yellow when catheter position is unknown • Displays "Impella Position in Ventricle" in yellow when catheter is in the ventricle • Displays "Impella Position Wrong" in yellow when catheter position is incorrect • Displays "Placement Monitoring Suspended" in yellow when there is a fault in the sensor • Displays "Placement Monitoring Disabled" in yellow when you turn off placement monitoring through the menu

SELECTING PERFORMANCE LEVEL

You can select one of ten performance levels (P0 to P9) for the Impella® 2.5 Catheter (see Table 4.4). Select the lowest performance level that will enable you to achieve the flow rate necessary for patient support.

Table 4.4 Performance Level Flow Rates

Performance Level		*Flow Rate (L/min)	Revolutions Per Minute (rpm)
P0	Impella® 2.5 Catheter motor is stopped	0.0 – 0.0	0
P1	Flow rate increases as the performance level increases	0.0 – 0.5	25,000
P2		0.4 – 1.0	35,000
P3		0.7 – 1.3	38,000
P4		0.9 – 1.5	40,000
P5		1.2 – 1.8	43,000
P6		1.4 – 2.0	45,000
P7		1.6 – 2.2	47,000
P8	Recommended maximum performance level for continuous use	1.9 – 2.5	50,000
P9	Used to confirm stable position after placement; can be used to provide maximum flow for up to 5 minutes. After 5 minutes, the Impella® Controller will automatically default to P8.	2.1 – 2.6	51,000

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

Retrograde Flow

A setting of P0 will result in retrograde flow when the Impella® 2.5 Catheter is placed across the aortic valve. Retrograde flow may also occur at P1.

To select a performance level:

1. Press the **P-LEVEL** soft button to open the performance level icon. (This icon is illustrated in section 5 under "Positioning and Starting the Impella 2.5 Catheter.")
2. Turn the selector knob to increase or decrease the performance level.
3. Press the selector knob to select the new performance level.

IMPELLA® CONTROLLER WAVEFORM SCREEN

The waveform screen (see Figure 4.4) displays real-time operating data for the system. The screen displays the placement signal and motor current waveforms as well as the maximum/ minimum and average values for each waveform in the central display area of the screen.

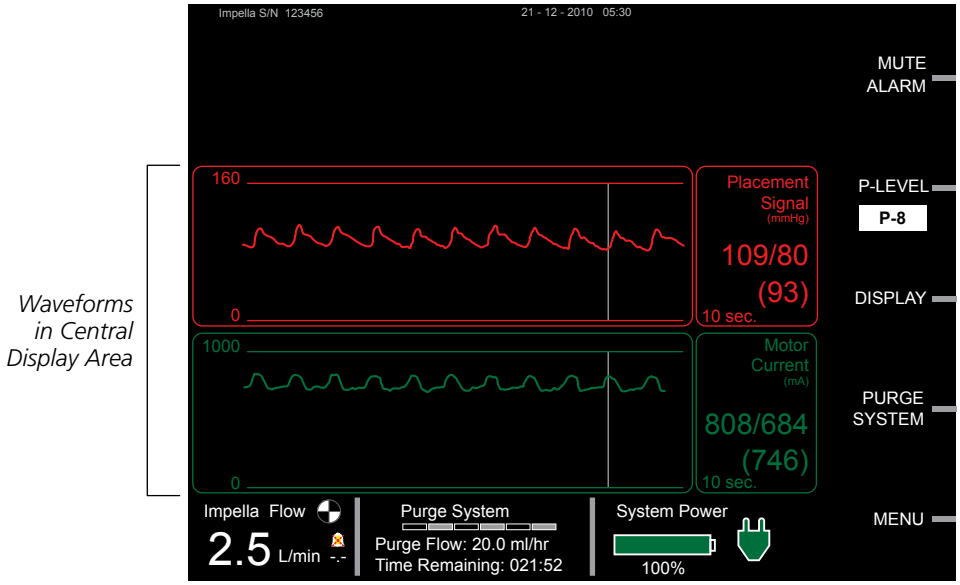


Figure 4.4 Waveform Screen

Figure 4.4 shows two time-based waveform signals from different sources.

- Placement signal waveform
- Motor current waveform

PLACEMENT SIGNAL WAVEFORM

The placement signal waveform displays a pressure measurement that is useful for determining the location of the open pressure area of the catheter with respect to the aortic valve. The placement signal is used to verify the position of the microaxial blood pump by evaluating the current pressure waveform as an aortic or ventricular waveform. The scale for the placement signal waveform is displayed to the left of the waveform. The default scaling is 0–160 mmHg. It can be adjusted in 20 mmHg increments, with a minimum upper limit of 100 mmHg and a maximum upper limit of 240 mmHg for the Impella® 2.5 Catheter.

To the right of the waveform is a display that labels the waveform, provides the units of measurement, and shows the maximum and minimum values and the average value from the samples received. At the bottom of that window is the time scale, which you can set by pressing the **DISPLAY** soft button.

MOTOR CURRENT WAVEFORM

Motor current is a measure of the energy intake of the Impella® 2.5 Catheter motor. The energy intake varies with motor speed and the pressure difference between the inlet and outlet areas of the cannula. Motor current (see Figure 4.4) provides information about the catheter position relative to the aortic valve. When the Impella® 2.5 Catheter is positioned correctly, with the inlet area in the ventricle and the outlet area in the aorta, the motor current is pulsatile because the pressure difference between the inlet and outlet areas changes with the cardiac cycle. When the inlet and outlet areas are on the same side of the aortic valve, the motor current will be dampened or flat because there is little or no pressure difference between the inlet and outlet areas.

The scale for the motor current waveform is displayed to the left of the waveform. The default scaling is 0–1000 mA. It is adjustable in 100 mA increments for the Impella® 2.5 Catheter, with a minimum difference between upper and lower limits of 200 mA and a maximum difference of 1000 mA.

To the right of the waveform is a display that labels the waveform, provides the units of measurement, and shows the maximum and minimum values and the average value from the samples received. You can set the time scale at the bottom of that window by pressing the **DISPLAY** soft button.

IMPELLA® CONTROLLER INFUSION SCREEN

The infusion screen (see Figure 4.5) displays purge system data. In the central display area of the screen, the purge flow rate and purge pressure are plotted as a function of time. To the right of the plots, the current purge flow rate and purge pressure are displayed.

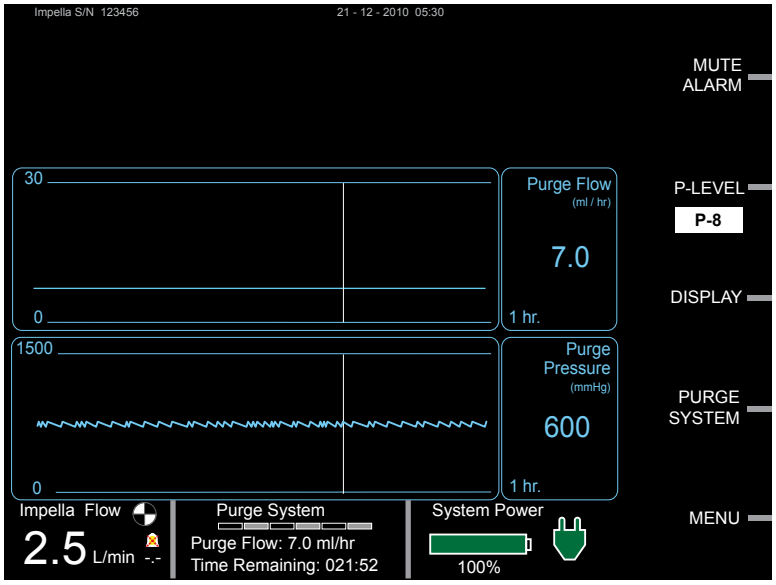


Figure 4.5 Infusion Screen

Purge Flow

In the initial set-up configuration of the Impella® 2.5 System, purge flow is regulated to keep the purge pressure at 600 mmHg, although it may not reach 600 mmHg in low resistance catheters in this configuration.

In the standard configuration, purge flow can range from 2 to 30 mL/hr and purge pressure can range from 300 to 1100 mmHg.

PURGE FLOW

The purge flow rate delivered by the purge cassette is displayed in mL/hr. The standard scale for the purge flow (0–30 mL/hr) is displayed to the left of the purge flow plot. The maximum value on this scale can be adjusted from 20 mL/hr to 200 mL/hr in increments of 10 mL/hr.

To the right of the plot is a display that labels the plot and shows the most recent value update. You can set the time scale at the bottom of the window by pressing the **DISPLAY** soft button.

An advisory alarm will be displayed in the alarm window when the purge flow rate increases or decreases by 2.5 mL/h. The message is intended to aid patient management by alerting the clinician to changes in the rates of dextrose and heparin infusion through the purge fluid. The alarm clears when you press the **MUTE ALARM** button.

PURGE PRESSURE

The Impella® Controller regulates purge pressure, the pressure of the purge fluid delivered through the catheter to the motor. The purge pressure generated by the purge cassette is displayed in mmHg. The standard scale for the purge pressure (0–1500 mmHg) is displayed to the left of the purge pressure plot. The maximum value on this scale can be adjusted from 100 mmHg to 2000 mmHg in increments of 100 mmHg. A warning appears if purge pressure falls below 300 mmHg or exceeds 1100 mmHg.

To the right of the plot is a display that labels the plot and shows the most recent value update. You can set the time scale at the bottom of the window by pressing the **DISPLAY** soft button.

Purge Pressure Depends on System Configuration

When in the initial set-up configuration, the purge pressure is set to 600 mmHg with flows between 2 and 30 mL/hr. After switching to the standard configuration, the purge pressure is set to an ideal pressure and flow for the particular catheter. The pressure can be between 300 and 1100 mmHg and flows between 2 and 30 mL/hr.

MOBILE OPERATION

The Li-Ion batteries must be charged for 5 hours prior to system operation in order to meet the runtime requirement of 1 hour. Failure to do so will yield a shorter runtime. After being unplugged, the Impella® Controller will operate for at least 60 minutes after the batteries have been fully charged.

The Impella® Controller can be operated on internal battery power when it is not connected to AC power.

1. Disconnect the Impella® Controller from AC power.
2. The Impella® Controller beeps once every 5 minutes to alert you that it is running on battery power and a white advisory notification appears in the alarms area on the screen. The AC power icon turns gray with an X through it.
3. When the Impella® Controller is connected back to AC power, the white advisory notification turns gray and the AC power icon turns green.

5 USING THE IMPELLA® CONTROLLER WITH THE IMPELLA® 2.5 CATHETER

STARTUP

	Do ***NOT*** use an Impella® 2.5 System if any part of the system is damaged.
	The sterile components of the Impella® 2.5 System can be used only if the sterilization indicators show that the contents have been sterilized, the packaging is not damaged, and the expiration date has not elapsed.
	Do ***NOT*** resterilize or reuse the Impella® 2.5 Catheter. It is a disposable device and is intended for single use only.
	To prevent malfunction of the Impella® Controller, avoid long-term exposure to direct sunlight and excessive heat (40°C).
	To prevent overheating and improper operation, do ***NOT*** block the cooling vents of the Impella® Controller while it is operating.
	The Li-Ion batteries must be charged for 5 hours prior to system operation in order to meet the runtime requirement of 1 hour. Failure to do so will yield a shorter runtime. After being unplugged, the Impella® Controller will operate for at least 60 minutes after the batteries have been fully charged.
	Have a backup Impella® Controller available in the unlikely event of controller failure.

SUPPLIES NEEDED

- Impella® Controller
- Impella® 2.5 Catheter Set-up and Insertion kit
- Diagnostic catheter (AL1 or MP without side holes)
- 500 cc bag of dextrose solution for purge solution (20% recommended; 5% to 40% acceptable) with 50 IU heparin/mL

TURNING ON THE IMPELLA® CONTROLLER

Battery Switch

Before operating the Impella® Controller for the first time, turn on the switch on the underside of the controller to turn on the batteries.

To turn the controller on:

1. Press and hold the power switch on the right side of the Impella® Controller for 3 seconds (see Figure 5.1).

Figure 5.1 Impella® Controller Power Switch

The Impella® Controller automatically performs a system test when turned on.

A display bar shows the progress of the system test. If the system test passes, the system displays the startup screen (see Figure 5.2).

If the system test fails, the controller displays a system self check failure message:

SYSTEM SELF CHECK FAILED.
CHANGE CONSOLE IMMEDIATELY.

The controller displays the reason for the system test failure at the bottom of the screen.

THE STARTUP SCREEN

The startup screen (see Figure 5.2) appears when you successfully turn on the Impella® Controller.

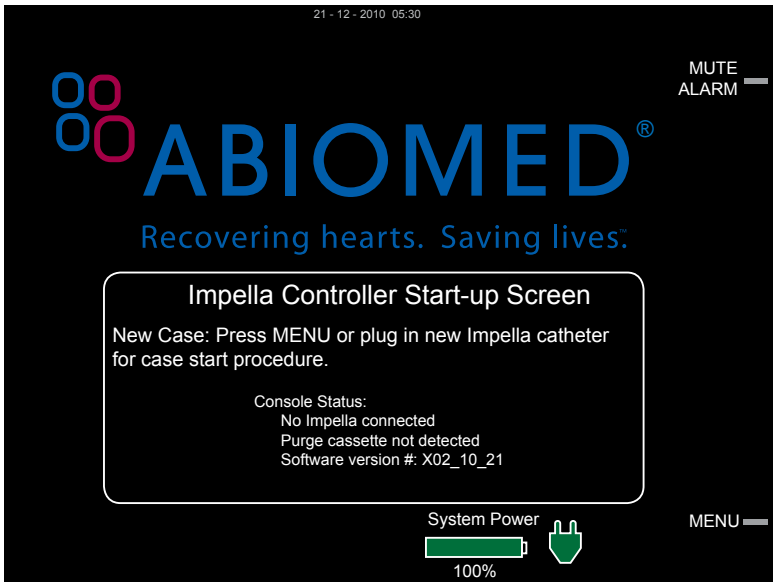


Figure 5.2 Impella® Controller Startup Screen

Check Date and Time

The current date and time appear at the top of the startup screen. Confirm that these are correct.

The startup screen displays:

- The current status of the Impella® 2.5 Catheter (currently not connected to the Impella® Controller in Figure 5.2).
- The current status of the purge cassette (no purge cassette detected in Figure 5.2).
- The current version of the software that the Impella® Controller is running.

The startup screen also displays system power information along the bottom of the screen and two active soft buttons—**MUTE ALARM** and **MENU**—along the right side of the screen.

CASE START

Sensitive Medical Device

The Impella® 2.5 Catheter is a sensitive medical device with extremely fine tolerances. In particular, the inlet and outlet areas of the catheter assembly may be damaged if subjected to strong external forces.

⚠	Fluoroscopy is required to guide placement of the Impella® 2.5 Catheter. The small placement guidewire must be reliably observed at all times.
⚠	The sterile components of the Impella® 2.5 System can be used only if the sterilization indicators show that the contents have been sterilized, the packaging is not damaged, and the expiration date has not elapsed.
⚠	Avoid manual compression of the inlet and outlet areas of the cannula assembly.
⚠	Do ***NOT*** remove the Impella® 2.5 Catheter over the length of the guidewire.
⚠	Handle with care. The Impella® 2.5 Catheter can be damaged during removal from packaging, preparation, insertion, and removal. Do ***NOT*** bend, pull, or place excess pressure on the catheter or mechanical components at any time.
⚠	Do ***NOT*** kink or clamp the Impella® 2.5 Catheter or the 13 Fr peel-away introducer.

Two Ways to Start the Setup Procedure

*You can start the setup procedure from the **MENU** on the startup screen (as described on this page) or when a new Impella® 2.5 Catheter is plugged into the controller.*

CASE START

1. Press the **MENU** soft button from the startup screen. "Case Start" is the default selection on the pop-up menu that appears on the screen.
2. Press the selector knob to select "Case Start." The controller displays the screen shown in Figure 5.3.

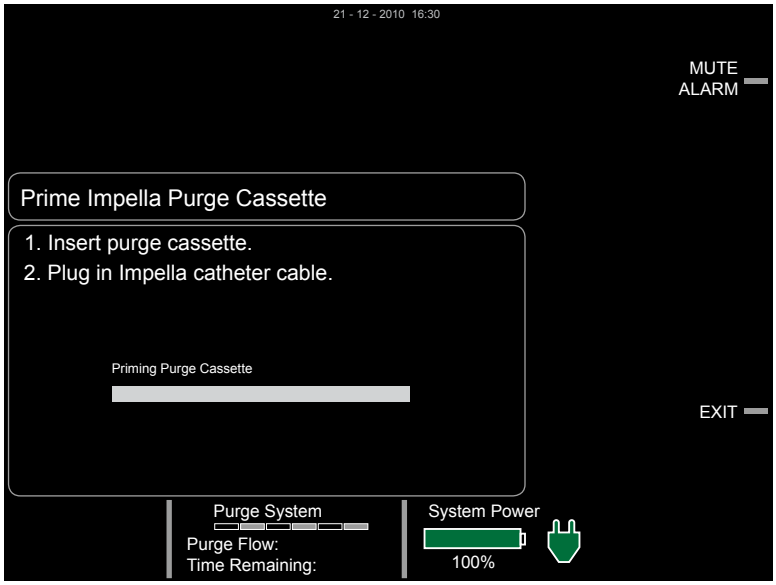


Figure 5.3 Initial Case Start Screen

INSERT PURGE CASSETTE

1. Open the purge cassette package.
2. Spike the fluid bag/bottle and open the pinch clamp.
3. Open the purge cassette door by pressing the release on the left side of the controller. Insert the purge cassette into the Impella® Controller (as shown in Figure 5.4 and described in the steps that follow).

Figure 5.4 Inserting Purge Cassette into Impella® Controller

4. The purge cassette snaps into a molded compartment on the front of the controller. Follow the diagram on the inside of the purge cassette door for proper placement.
5. Slide the purge pressure transmitter into the slot to the right of the purge cassette until it snaps into place. The controller will automatically begin priming the purge cassette.
6. Extend the purge tubing and close the purge cassette door. There is sufficient room around the edges of the purge cassette door so that it will not pinch the purge tubing as it exits.
7. The Impella® Controller automatically begins priming the purge cassette after it is inserted. The progress bar shown in Figure 5.3 marks the progress of the purge cassette priming.

Purge Solution Bottles

If the purge solution is supplied in bottles, open the vent on the purge fluid spike and follow the same procedure as if supplied in bags.

Connect Purge Pressure Transmitter Within 10 Seconds

An alarm will appear if the purge pressure transmitter is not snapped into place within 10 seconds of inserting the purge cassette.

Close Purge Cassette Door

Once the purge cassette is installed, be sure to close the purge cassette door to prevent the purge cassette from being dislodged accidentally.

CONNECT THE IMPELLA® 2.5 CATHETER

Shaded Steps

All shaded steps require sterile technique.

1. Remove the Impella® 2.5 Catheter from its package using sterile technique and inspect the catheter, including its connector, for damage.
2. Remove the white connector cable from its package using sterile technique.
3. Inspect the cable for damage, including damage to the connector pins at the controller end.
4. Secure the black end of the cable to the sterile field.
5. Insert the catheter plug into the connector cable socket (black end). The tab and the slot must be aligned during connection (see Figure 5.5).

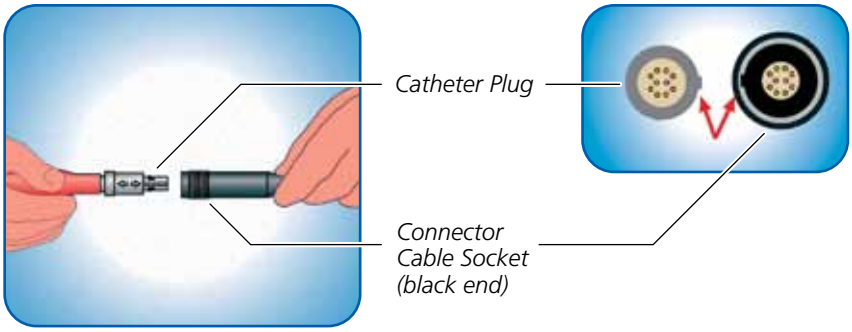


Figure 5.5 Inserting the Catheter Plug into the Connector Cable

6. Pull back on the connection to make sure that the plug has snapped into place.
7. Snap the plastic clip (located on the pressure reservoir of the clear sidearm) to the connector cable as shown in Figure 5.6.

Important Step

Snapping the plastic clip on the pressure reservoir to the connector cable is important to prevent the tube from kinking.

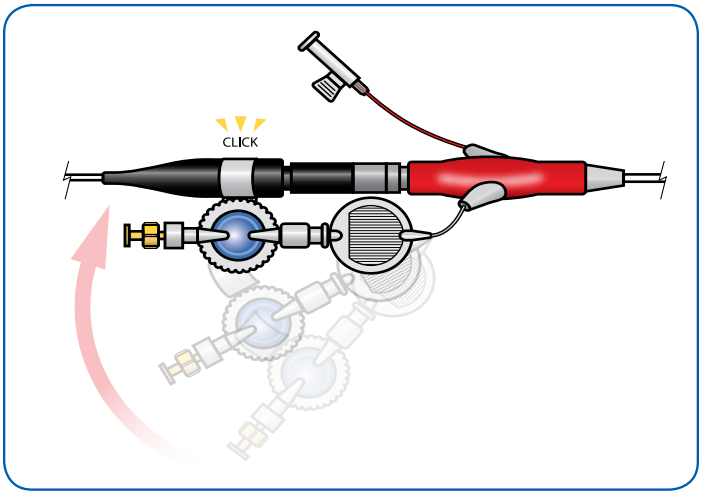


Figure 5.6 Snapping Plastic Clip to Connector Cable

8. Pass the sterile connector cable from the Impella® 2.5 Catheter off the sterile field.

9. Line up the notch on the connector cable with the notch in the blue catheter plug on the front of the Impella® Controller and plug the cable into the controller.

10. Once the purge cassette is primed and the controller detects that the connector cable is plugged in, it prompts you to connect the luer(s) to the Impella® 2.5 Catheter. (See Figure 5.7)

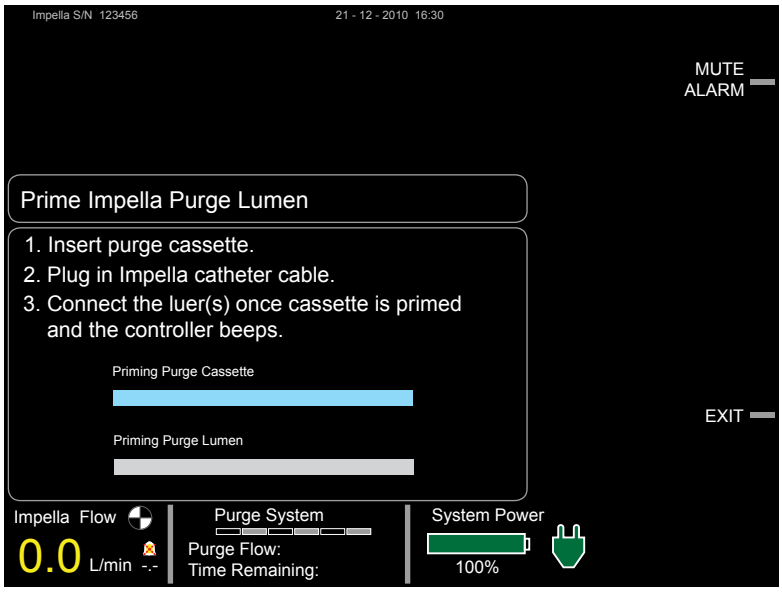


Figure 5.7 Priming the Impella Purge Lumen

11. Connect the luer(s) on the purge tubing to the Impella® 2.5 Catheter as shown in Figure 5.8

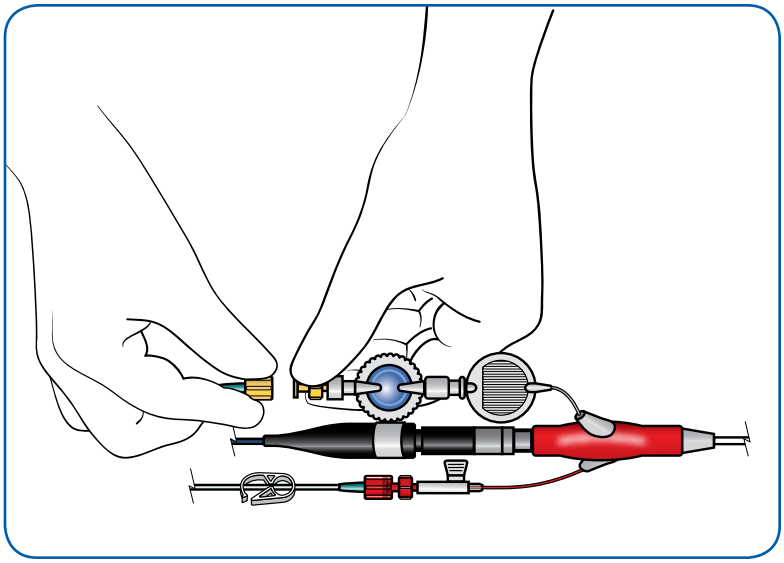


Figure 5.8 Connecting the Luer(s) to the Impella® 2.5 Catheter

12. When the controller detects that the luer(s) are connected, it automatically begins priming the purge lumen at a bolus rate of greater than 250 mL/h and tracking the progress on the second progress bar.

Error Screens

If you miss a step in the process of setting up the Impella® 2.5 Catheter, or if you exceed the amount of time allowed to complete a step, the Impella® Controller will display an error screen with instructions for continuing the setup process.

13. Once the purge lumen is primed, the controller automatically advances to the next screen (Figure 5.9).

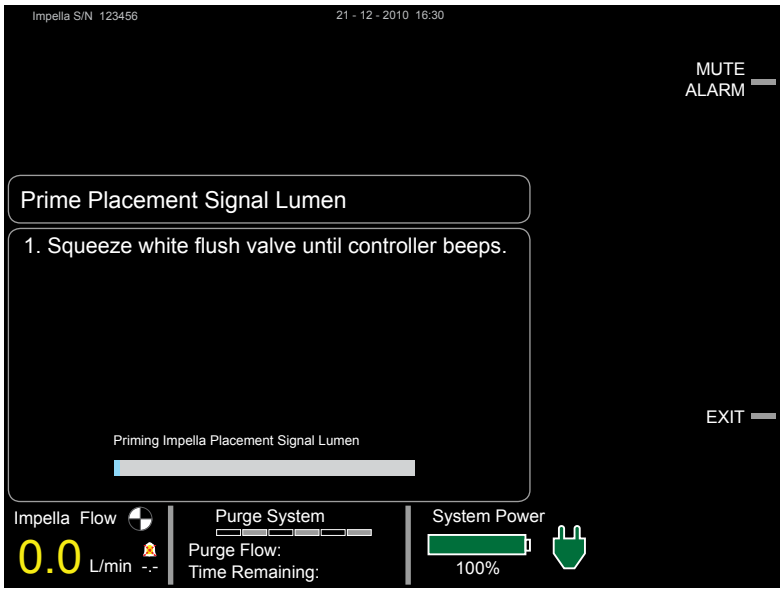


Figure 5.9 Priming the Placement Signal Lumen

14. Prime the Impella® 2.5 Catheter placement signal lumen by squeezing the white flush valve (see Figure 5.10) until the Impella® Controller beeps. The progress bar shows the progress of the priming.

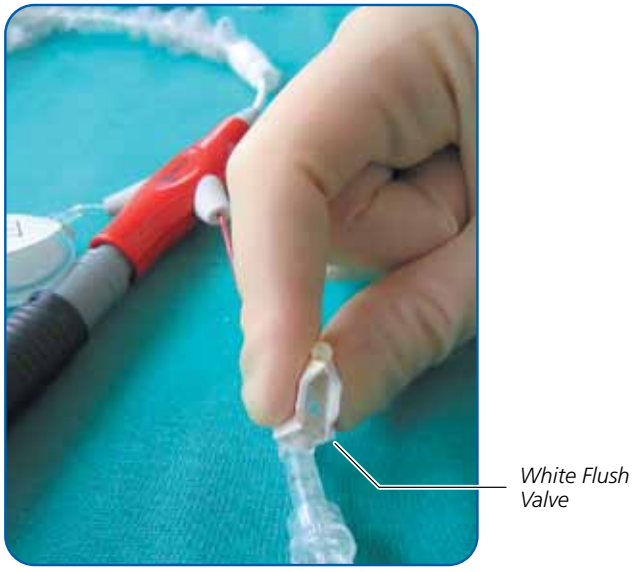


Figure 5.10 Squeezing the White Flush Valve to Prime the Placement Signal Lumen

15. When the system detects that the flush solution has reached the target pressure within the required amount of time, the system will advance to the next screen automatically.

16. The first step on the next screen prompts you to confirm that fluid is exiting the Impella® 2.5 Catheter (see Figure 5.11).

ENTER PURGE FLUID DATA

1. After confirming that fluid is exiting the Impella® 2.5 Catheter, enter the purge fluid information. The screen in Figure 5.11 shows a table of recommended default values for the purge fluid.

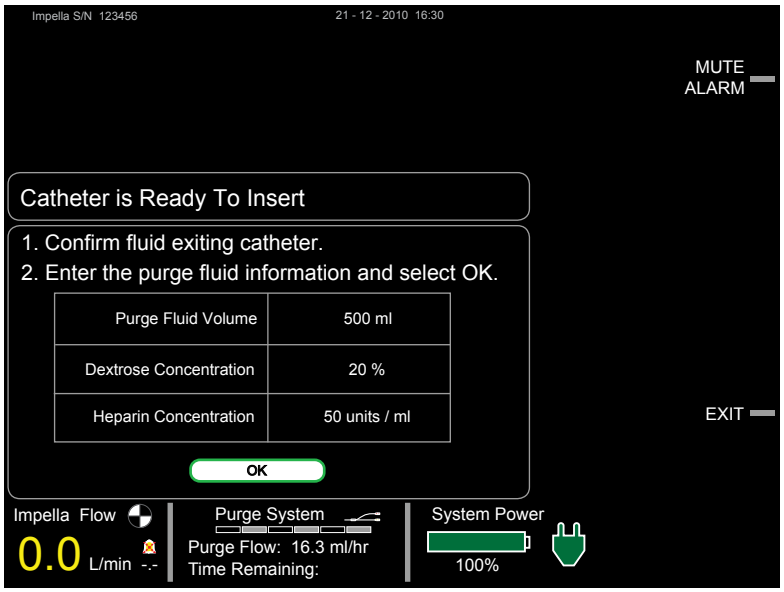


Figure 5.11 Entering Purge Fluid Information

2. To select the default values displayed on the screen, scroll to **OK** below the table and press the selector knob. This will select those values and automatically advance to the next screen.
3. To change the purge fluid information, scroll to the appropriate item and push the selector knob to select it. Then scroll through the values and push the selector knob to make a new selection. The controller will use the default values if no other selections are made.
   - Purge fluid can be set to 50 mL, 100 mL, 250 mL, 500 mL (default), or 1000 mL.
   - Dextrose concentration can be set to 5%, 10%, 20% (default), 30%, or 40%.
   - Heparin concentration can be set to 0, 5, 10, 12.5, 15, 20, 25, or 50 units/mL (default).

SECURE THE PURGE TUBING

1. To complete the setup, connect the purge tubing to the white connector cable by pushing the purge tubing into the clips attached to the white connector cable as shown in Figure 5.12.

Figure 5.12 Connecting the Purge Tubing to the Connector Cable

IMPELLA® 2.5 SYSTEM SET-UP CONFIGURATION

Figure 5.13 illustrates the correct set-up configuration of the Impella® 2.5 System.

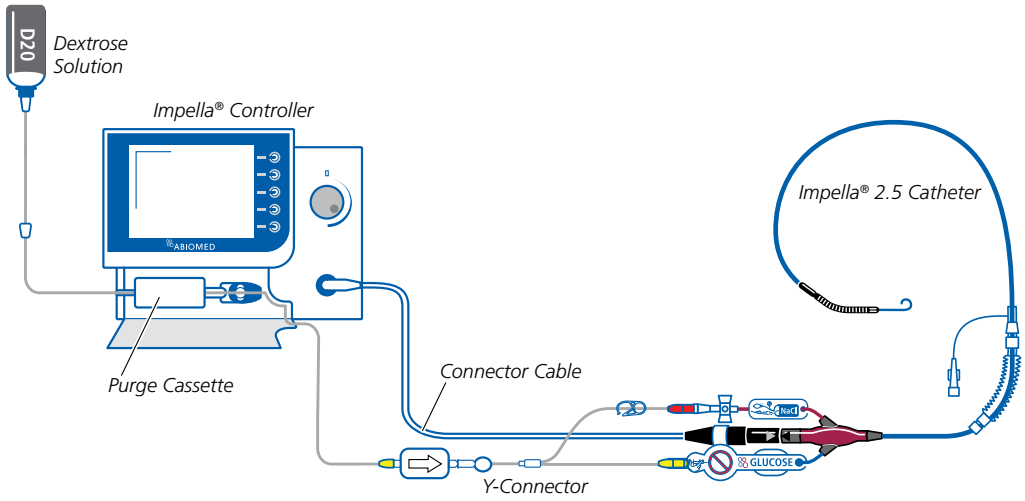


Figure 5.13 Set-up Configuration of the Impella® 2.5 System

INSERTING THE IMPELLA® 2.5 CATHETER

NOTE – Proper surgical procedures and techniques are the responsibility of the medical professional. The described procedure is furnished for information purposes only. Each physician must evaluate the appropriateness of the procedure based on his or her medical training and experience, the type of procedure, and the type of systems used.

⚠	Fluoroscopy is required to guide placement of the Impella® 2.5 Catheter. The small placement guidewire must be reliably observed at all times.
⚠	Avoid manual compression of the inlet and outlet areas of the cannula assembly.
⚠	To prevent malfunction of the locking mechanism of the 13 Fr peel-away introducer, do ***NOT*** hold the hemostatic valve while inserting into the artery.
⚠	Do ***NOT*** kink or clamp the Impella® 2.5 Catheter or the 13 Fr peel-away introducer.
⚠	Handle with care. The Impella® 2.5 Catheter can be damaged during removal from packaging, preparation, insertion, and removal. Do ***NOT*** bend, pull, or place excess pressure on the catheter or mechanical components at any time.

1. Obtain access to the femoral artery.
2. Insert a 5–8 Fr introducer over the 0.035 guidewire (provided) to pre-dilate the vessel.
3. Remove the 5–8 Fr introducer over the 0.035 guidewire. Insert a 10 Fr dilator and then remove it and insert the 13 Fr peel-away introducer with dilator (see Figure 5.14). While inserting the 13 Fr introducer, hold the shaft of the introducer to slide it into the artery.

Figure 5.14 Inserting the 13 Fr Peel-Away Introducer

Use Fluoroscopy for Placement

Impella® 2.5 Catheter performance will be compromised if correct placement cannot be confirmed. While other imaging techniques, such as transesophageal echocardiography (TEE), portable C-Arm fluoroscopy, or chest x-ray can help confirm the position of the Impella® 2.5 Catheter after placement, these methods do not allow visualization of the entire catheter assembly and are inadequate for reliably placing the Impella® 2.5 Catheter across the aortic valve.

GP IIb-IIIa Inhibitors

If the patient is receiving a GP IIb-IIIa inhibitor, the dilator can be removed and the Impella® 2.5 Catheter inserted when ACT is 200 or above.

4. Administer heparin. When the ACT is 250 or above, remove the 13 Fr dilator.

5. Insert a 6 Fr diagnostic catheter with diagnostic guidewire with no side holes (AL1 or Multipurpose recommended; see Figure 5.15) into the 13 Fr introducer and advance it over a diagnostic guidewire into the left ventricle.

Figure 5.15 Inserting the 6 Fr Diagnostic Catheter

Impella® 2.5 Catheter Use in Open Heart Surgery

If the Impella® 2.5 Catheter is used in the OR as part of open heart surgery, manipulation may be performed only through the 9 Fr steering catheter. Direct manipulation of the catheter assembly through the aorta or ventricle may result in serious damage to the Impella® 2.5 Catheter and serious injury to the patient.

6. Remove the 0.035 inch diagnostic guidewire, leaving the diagnostic catheter in the ventricle. Form a curve or bend on the end of the 0.018 inch, 260 cm placement guidewire and then insert it.

7. Advance the placement guidewire into the left ventricle to the apex.

8. Remove the 6 Fr diagnostic catheter.

9. Wet the cannula with sterile water and backload the catheter onto the placement guidewire. One or two people can load the catheter on the guidewire.

Avoid Damaging Inflow Area

During placement of the Impella® 2.5 Catheter, take care to avoid damage to the inlet area while holding the catheter and loading the placement guidewire.

One-person technique

a. Advance the guidewire into the Impella® 2.5 Catheter and stabilize the cannula between the fingers as shown in Figure 5.16. This prevents pinching of the inlet area. The guidewire must exit the outlet area on the inner radius of the cannula and align with the straight black line on the catheter, as shown in Figure 5.17. The cannula can be hyperextended as necessary to ensure the guidewire exits on the inner radius of the cannula.

Two-person technique

b. The scrub assistant can help stabilize the catheter by holding the catheter proximal to the motor. This will allow the implanting physician to visualize the inner radius. The guidewire must exit the outlet area on the inner radius of the cannula and align with the straight black line on the catheter, as shown in Figure 5.17. The physician can focus on advancing the guidewire and, if the cannula needs to be hyperextended, the scrub assistant is available to assist.

Figure 5.16 Loading the Catheter on the Guidewire

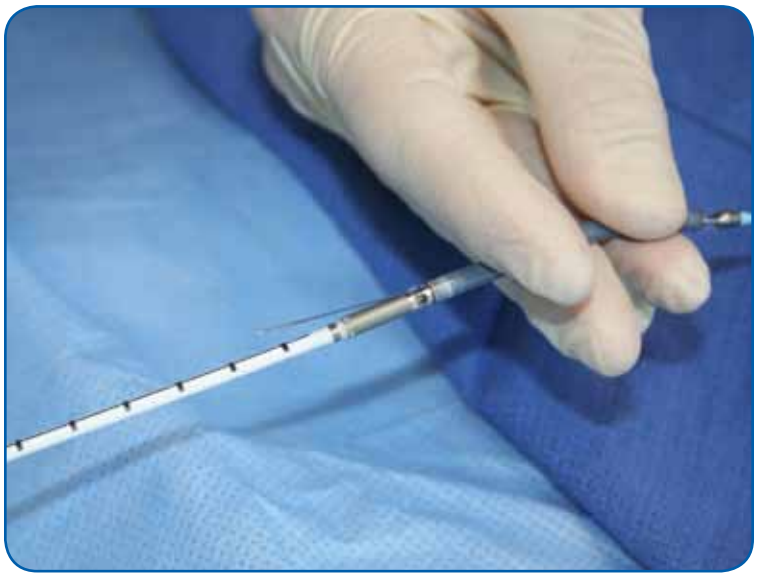


Figure 5.17 Aligning the Placement Guidewire

10. Advance the catheter through the hemostatic valve into the femoral artery (see Figure 5.18) and along the placement guidewire and across the aortic valve using a fixed-wire technique. Follow the catheter under fluoroscopy as it is advanced across the aortic valve, positioning the inlet area of the catheter approximately 4 cm below the aortic valve annulus and in the middle of the ventricular chamber, free from the mitral valve chordae. Be careful not to coil the guidewire in the left ventricle.

Take "Small Bites" During Insertion

While inserting the Impella® 2.5 Catheter, push the catheter from only a few centimeters behind the hub of the peel-away introducer. This prevents the catheter from buckling during insertion.

Do NOT Touch Inlet or Outlet Areas

While feeding the Impella® 2.5 Catheter through the 13 Fr introducer, hold the catheter at the cannula or motor housing. Do NOT touch the inlet area or the outlet areas.

Figure 5.18 Inserting the Impella® 2.5 Catheter

To prevent device failure, do ***NOT*** start the Impella® 2.5 Catheter until the guidewire has been removed.

Do ***NOT*** remove the Impella® 2.5 Catheter over the length of the guidewire.

11. Remove the placement guidewire.
12. Confirm position with fluoroscopy and confirm that an aortic waveform (see Figure 5.19) is displayed on the Impella® Controller.

Maintaining ACT

After insertion of the catheter (and until explant), ACT should be maintained at 160 to 180 seconds.

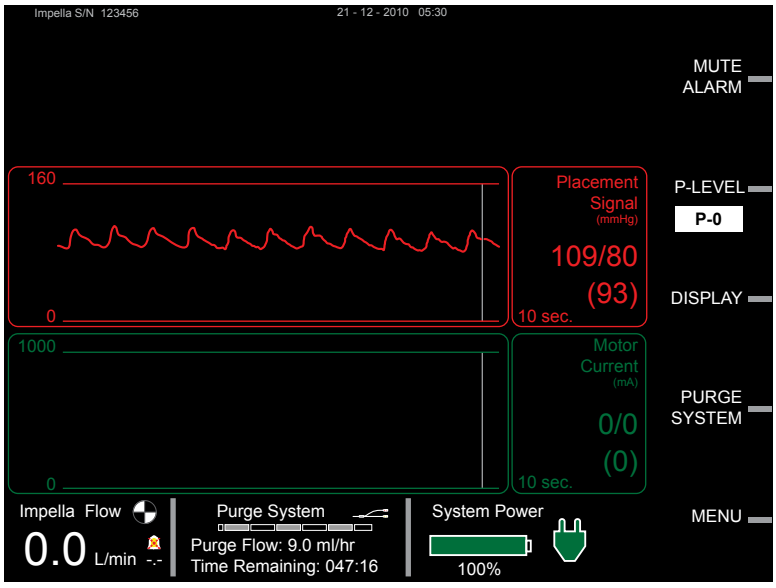


Figure 5.19 Aortic Waveform on Placement Signal Screen

POSITIONING AND STARTING THE IMPELLA® 2.5 CATHETER

> Retrograde flow will occur across the aortic valve if the Impella® 2.5 Catheter is set at performance level P0.

1. Place the catheter plug at the same level as the patient's heart.
2. Reconfirm that the placement guidewire has been removed. Also reconfirm that the controller displays an aortic waveform (refer back to Figure 5.19) and the inlet area of the catheter is approximately 4 cm below the aortic valve. (See step 9 if the controller displays a ventricular waveform.)
3. Press the **P-LEVEL** soft button to open the performance level icon (see Figure 5.20).

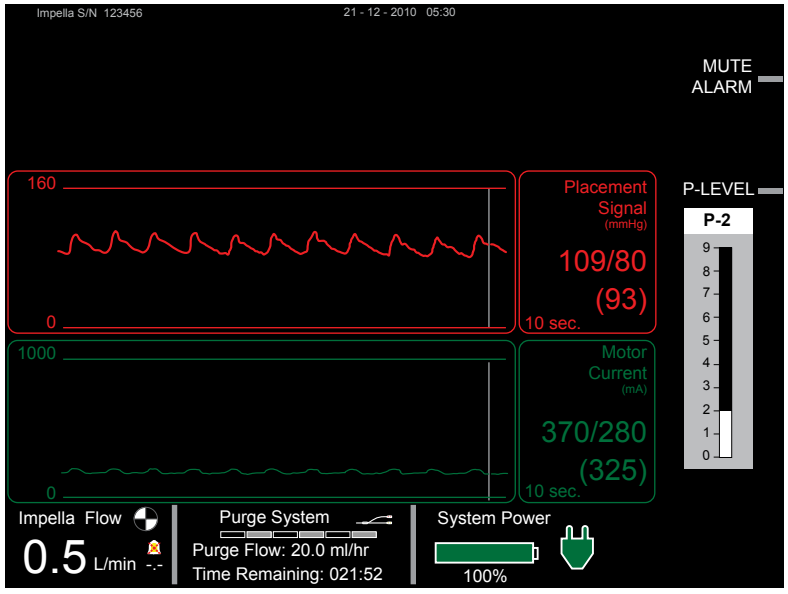


Figure 5.20 Selecting P-Level

4. Turn the selector knob to increase the performance level from P0 to P2.
5. Press the selector knob to select the new performance level.
6. The catheter operation icon in the lower left corner of the screen begins rotating when the Impella® 2.5 Catheter begins to operate.
7. Increase the performance level to P9 to confirm correct and stable placement. Evaluate the catheter position in the aortic arch and remove any excess slack. The catheter should align against the lesser curvature of the aorta rather than the greater curvature. Verify placement with fluoroscopy and with the placement signal screen (see Figure 5.21).

Check Positioning at P9

When the performance level is increased to P9, the Impella® 2.5 Catheter has a tendency to be drawn into the ventricle. Check positioning at P9 to ensure proper placement throughout the performance level setting range.

Importance of Proper Impella® 2.5 Catheter Placement

When the Impella® 2.5 Catheter is not correctly placed, there is no effective unloading of the ventricle (hydraulic short circuit). The patient may not be profiting from the flow rate shown on the controller.

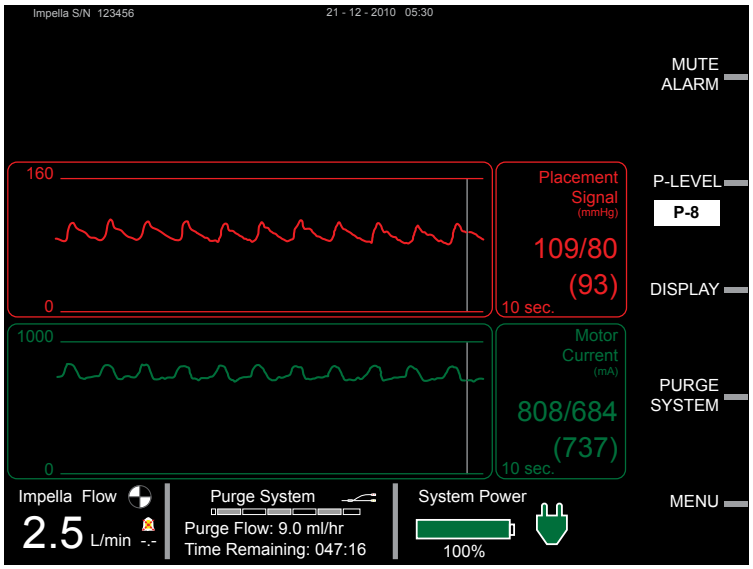


Figure 5.21 Confirming Placement on the Placement Signal Screen

Automatic Performance Level Reduction

*Performance level P9 is useful for confirming stable positioning of the Impella® 2.5 Catheter after placement. However, after 5 minutes of operation at P9, the Impella® Controller will automatically reduce the performance level to P8. The background color for the performance level beneath the **P-LEVEL** soft button label will change to yellow to indicate that the controller has made this change.*

8. Reposition the catheter as necessary.
9. If the Impella® 2.5 Catheter advances too far into the left ventricle and the controller displays a ventricular waveform (see Figure 5.22) rather than an aortic waveform, follow these steps to reposition the catheter.
   a. Pull the catheter back until an aortic waveform is present on the placement signal screen.
   b. When the aortic waveform is present, pull the catheter back an additional 4 cm. (The distance between adjacent markings on the catheter is 1 cm.) The catheter should now be positioned correctly.

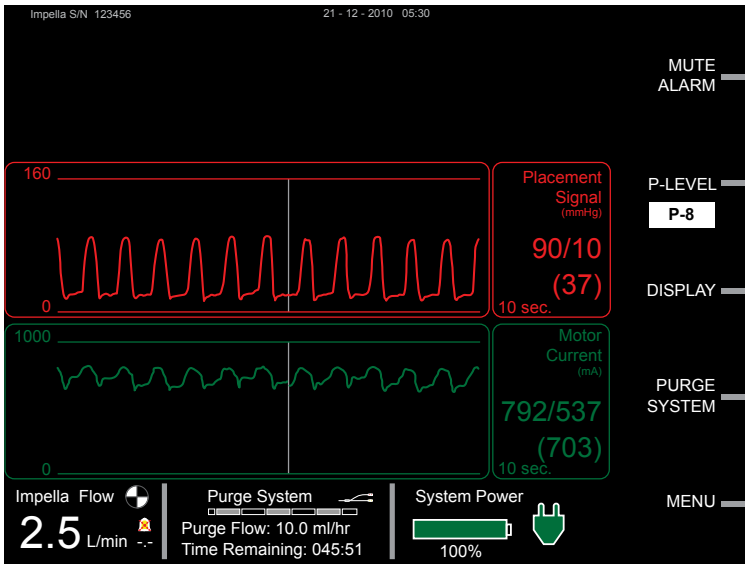


Figure 5.22 Ventricular Waveform on Placement Signal Screen

10. After achieving correct placement, adjust the performance level to the desired level for support.

USE OF THE REPOSITIONING SHEATH AND THE 13 Fr PEEL-AWAY INTRODUCER

To prevent failure of the 13 Fr peel-away introducer, remove the 13 Fr peel-away introducer prior to transport when activated clotting time (ACT) is less than 150 seconds.

Be sure that the stopcock on the peel-away introducer or repositioning sheath is always kept in the closed position. Significant bleed back can result if the stopcock is open.

1. Flush the sidearm of the repositioning sheath located on the catheter shaft.
2. Attach a stopcock and flush the repositioning sheath prior to advancing the sheath.
3. Apply manual pressure above the puncture site and remove the 13 Fr peel-away introducer completely from the artery over the catheter shaft.
4. Grasp the two "wings" and bend back until the valve assembly comes apart. Continue to peel the two wings until the introducer is completely separated from the catheter shaft (see Figure 5.23).

Figure 5.23 Removing the 13 Fr Peel-Away Introducer

5. Place two deadend caps on the stopcock to prevent further usage. The sideport should not be used to give medication or draw blood because the blood could potentially clot. Pressure bags should not be connected to the sideport of the repositioning sheath. If a pressure bag is connected, the sideport must have an infusion pump or flow limiting valve in place to control the amount of fluid administered to the patient.
6. Slide the repositioning sheath over the catheter shaft and advance it into the artery to the yellow eyelet.

Alternative to Waiting Until ACT < 150

If you do not want to wait until ACT is below 150 seconds before removing the Impella® 2.5 Catheter, you can remove it and exchange the peel-away introducer for a non peel-away sheath and dilator over the wire. Then you can wait until ACT is below 150 seconds and remove the sheath without risk of bleeding.

Addition of Heparin to the Purge Solution

As soon as practical after catheter placement, change the purge fluid to include heparin. The recommended heparin concentration is 50 IU/mL in 20% dextrose solution. (Follow the Change Purge Fluid procedure described later in this section to change the purge fluid.)

Vascular Closure

When securing the repositioning sheath, vascular closure may be difficult in obese patients with extensive adipose tissue.

7. Secure the yellow section of the repositioning sheath by suturing it to the skin using the provided eyelet.
8. Attach the anticontamination sleeve to the yellow section of the repositioning sheath. Lock the anchoring ring in place by turning it clockwise. Secure the catheter shaft in place by tightening the connected anchoring ring.
9. Carefully extend the anticontamination sleeve to maximum length and secure the end closest to the red Impella® plug by tightening the anchoring ring.

TRANSFER TO STANDARD CONFIGURATION

Purge Flow

When you transfer to the standard configuration, the purge pressure is no longer regulated at 600 mmHg. In the standard configuration, purge flow can range from 2 to 30 mL/hr and purge pressure can range from 300 to 1100 mmHg.

Abiomed recommends transitioning from the initial set-up configuration to the standard configuration as soon as practical. After 2 hours of operation, if the system is still in the set-up configuration, a white, advisory alarm notification appears on the screen, instructing operators to transfer from the set-up configuration to the standard configuration. Either follow the instructions for completing the transfer or press Mute Alarm to mute the alarm for 30 minutes.

To transfer to the standard configuration, follow these steps.

1. Press **PURGE SYSTEM** and select "Transfer to Standard Configuration" from the menu.
2. Set up the sodium chloride (0.9% NaCl) infusion bag with pressure bag and 96 inch straight IV tubing.
3. Disconnect the red luer on the Y connector from the red pressure sidearm on the red Impella® plug. Clamp and cap the red luer on the Y connector.
4. Create a slow drip from the NaCl pressure bag to flood the luer connector of the red pressure sidearm to displace any air; then make the connection to the red sidearm. Fully open the roller clamp. The controller may alarm during this step.
5. Select **OK** to confirm the transfer. You will no longer see the set-up icon on the bottom of the screen. The advisory alarm message will be gray.

Figure 5-24 illustrates the correct configuration of the Impella® 2.5 System components after transitioning to the standard configuration from the set-up configuration.

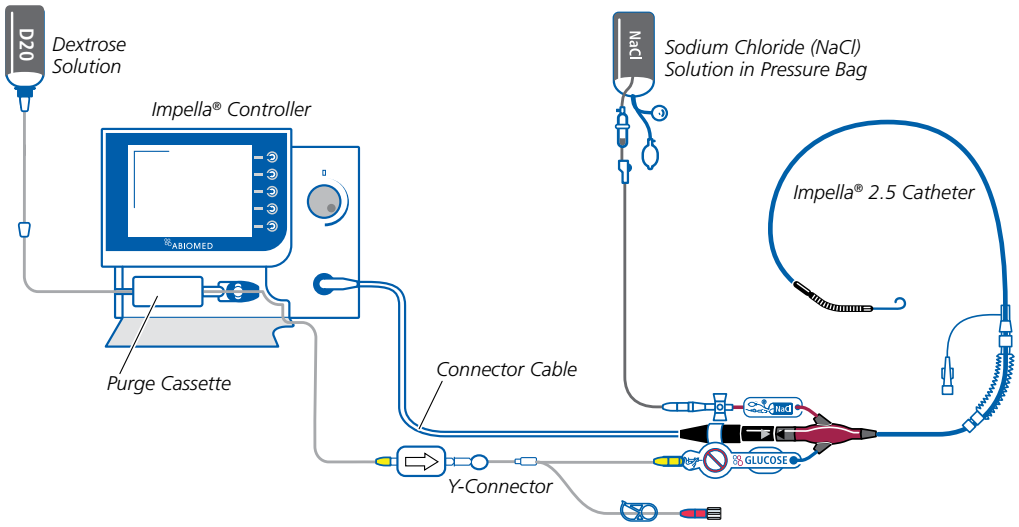


Figure 5.24 Standard Configuration for Impella® 2.5 System after Transfer from the Set-up Configuration

Disconnecting the Y Connector

When you switch to the standard configuration, you can simply disconnect, cap, and clamp the red luer on the Y connector (as shown in Figure 5.24) or you can disconnect the Y connector entirely and connect the yellow luer on the purge tubing directly to the yellow check valve on the Impella® 2.5 Catheter.

PURGE CASSETTE PROCEDURES

When replacing the purge cassette, the replacement process must be completed within 2 minutes. The Impella® 2.5 Catheter may be damaged if replacement takes longer than 2 minutes.

Replacement Time

If the purge flow is more than 7 mL/hr or the dextrose concentration is less than 20%, replacement time will be less than 2 minutes. Replacement should always be performed as quickly as possible.

There are five procedures for maintaining the Impella® 2.5 Catheter purge system:

- Change purge system (changing cassette and purge fluid)
- Change purge fluid
- Change purge cassette
- De-air purge system
- Transfer to standard configuration

Each procedure can be accessed using the **PURGE SYSTEM** soft button. Transferring to the standard configuration was discussed above. The other four purge cassette procedures are discussed below.

CHANGE PURGE SYSTEM

Follow these steps to change both the purge cassette and purge fluid:

1. Press **PURGE SYSTEM** and select "Change Purge System" from the menu.
2. Open the purge cassette package. If the system is in the standard configuration, disconnect the Y connector from the purge cassette tubing as shown in Figure 5.25.

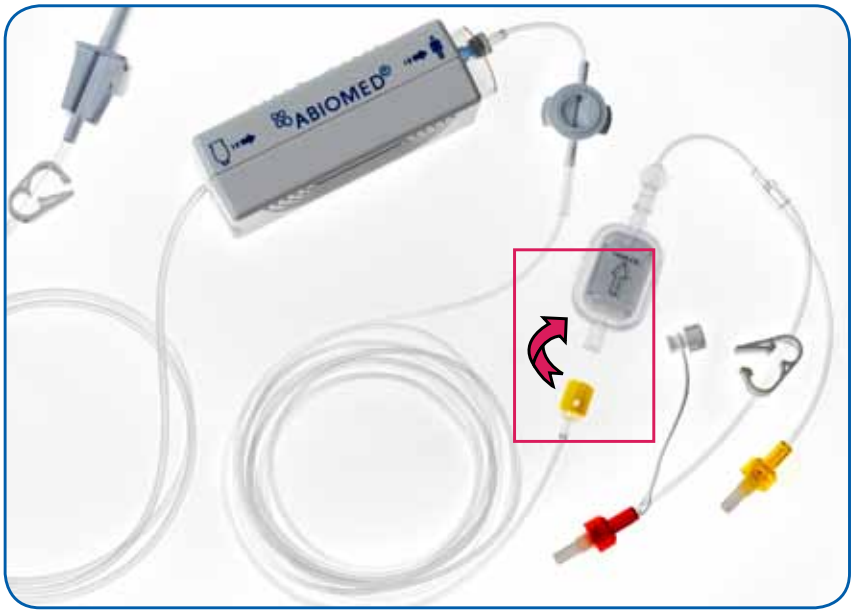


Figure 5.25 Disconnecting the Y Connector from the Purge Cassette Tubing

Connecting the Purge Tubing to the Catheter

If you have NOT switched to the standard configuration, be sure to connect both the red and yellow luers on the Y connector to the Impella® 2.5 Catheter.

If you have switched to the standard configuration, connect the yellow luer on the purge tubing directly to the yellow check valve on the Impella® 2.5 Catheter.

3. Spike the fluid bag/bottle and open the pinch clamp.
4. Select **OK** to deliver a bolus to the pressure reservoir so that the reservoir can maintain purge pressure during the change. A progress bar shows the progress of the bolus. After the bolus is delivered, the controller automatically proceeds to the next screen.
5. Disconnect the luer(s) from the Impella® 2.5 Catheter and remove the used purge cassette.
6. Insert the new purge cassette into the controller. Be sure to slide the purge pressure transmitter into place and extend the purge tubing through the gap in the purge cassette door when you close the door.
7. The system automatically primes the purge cassette. A progress bar shows the progress of the priming. Once the priming is complete, you are prompted to connect the purge tubing to the Impella® 2.5 Catheter.
8. Connect the luer(s) on the end of the purge tubing to the luer(s) on the Impella® 2.5 Catheter.

9. Purge system change is complete. Enter the purge fluid information and select **OK**.
   a. To select the default purge fluid values displayed on the screen, scroll to and select **OK**. This will select those values and automatically advance to the next screen.
   b. To change the purge fluid information, scroll to the appropriate item and push the selector knob to select it. Then scroll through the values and push the selector knob to make a new selection. (Refer to "Entering Purge Fluid Data" in the Case Start discussion at the beginning of this section for a listing of purge fluid, dextrose concentration, and heparin concentration options.) The controller will use the default values if no other selections are made.

CHANGE PURGE FLUID

These are the steps you will follow to change only the purge fluid.

1. Press **PURGE SYSTEM** and select "Change Purge Fluid."
2. Select **OK** to deliver a bolus to the pressure reservoir so that the reservoir can maintain purge pressure during the change. A progress bar shows the progress of the bolus. After the bolus is delivered, the controller automatically proceeds to the next screen.
3. Clamp the supply line before removing the purge fluid bag.
4. Replace the purge fluid bag and unclamp the supply line.
5. Select **OK** to complete bag change and start purge system again.
6. Enter the purge fluid information and select **OK**.
   a. To select the default purge fluid values displayed on the screen, scroll to and select **OK**. This will select those values and automatically advance to the next screen.
   b. To change the purge fluid information, scroll to the appropriate item and push the selector knob to select it. Then scroll through the values and push the selector knob to make a new selection. (Refer to "Entering Purge Fluid Data" in the Case Start discussion at the beginning of this section for a listing of purge fluid, dextrose concentration, and heparin concentration options.) The controller will use the default values if no other selections are made.
7. The next screen asks whether you want to flush the fluid from the purge cassette.
   a. To proceed with the flush, scroll to and select **OK**.
   b. To skip the flush, press **EXIT** to complete the Change Purge Fluid procedure.
8. If you are proceeding to flush the purge fluid from the cassette, select **OK** to deliver a bolus to the system. A progress bar shows the progress of the bolus. After the bolus is delivered, the controller automatically proceeds to the next screen.
9. Disconnect the luer(s) from the Impella® 2.5 Catheter and select **OK** to flush the purge cassette. A progress bar shows the progress of the flush. When complete, the controller proceeds to the next screen.
10. When the purge cassette flush is complete you can connect the luer(s) to the Impella 2.5 Catheter to complete the procedure or press **BACK** to repeat the flush.

Purge Solution Bottles

If the purge solution is supplied in bottles, open the vent on the purge fluid spike and follow the same procedure as if supplied in bags.

Flushing Purge Cassette Fluid

It may be helpful to flush the fluid from the purge cassette when you are changing dextrose concentration.

Changing the Purge Cassette

The Change Purge Cassette procedure will only be available if the Impella® Controller detects that the cassette is defective.

CHANGE PURGE CASSETTE

These are the steps you will follow to replace only the purge cassette.

1. Press **PURGE SYSTEM** and select "Change Purge Cassette."
2. Open the purge cassette package.
3. Disconnect the luer(s) from the Impella® 2.5 Catheter and remove the used purge cassette.
4. Spike the fluid bag and open the pinch clamp.
5. Insert a new purge cassette into the controller. Be sure to slide the purge pressure transmitter into place and extend the purge tubing through the gap in the purge cassette door when you close the door.
6. The system automatically primes the purge cassette. A progress bar shows the progress of the priming. Once the priming is complete, you are prompted to connect the purge cassette to the Impella® 2.5 Catheter.
7. Connect the luer(s) on the end of the purge tubing to the luer(s) on the Impella® 2.5 Catheter.
8. When the purge cassette change is complete, press **OK** to exit.

DE-AIR PURGE SYSTEM

These are the steps you will follow to de-air the purge system.

1. Press **PURGE SYSTEM** and select "De-air Purge System."
2. Make sure that the purge fluid bag is NOT empty or inverted and that the tubing is NOT clamped.
3. Disconnect the purge tubing from the Impella® 2.5 Catheter.
4. Press **OK** to initiate the de-air function. A progress bar shows the progress of the de-air procedure. Once complete, the system advances to the next screen.
5. Confirm that no air remains in the purge tubing. If air remains, press **BACK** to repeat the air removal process.
6. Connect the purge tubing to the luer(s) on the Impella® 2.5 Catheter to complete the de-air procedure.

TROUBLESHOOTING THE PURGE SYSTEM

LOW PURGE PRESSURE

If at any time during the course of support with the Impella® 2.5 Catheter, the Impella® Controller alarms "Purge Pressure Low," follow the instructions below.

1. Inspect the purge system for leaks.
2. If there are no leaks, change to a purge fluid with a higher dextrose concentration. To do this, open the **PURGE SYSTEM** menu and select "Change Purge Fluid." Follow the instructions on the screen. (Refer to "Purge Cassette Procedures" earlier in this section of the manual.)
3. If the pressure stabilizes, no other action is required.
   If the purge pressure is not stable, proceed to Step 4.
4. If the low purge pressure alarm remains unresolved for more than 20 minutes, there may be a problem with the purge cassette. Replace the purge cassette. (Refer to "Purge Cassette Replacement" instructions earlier in this section.)
5. If the low purge pressure alarm still remains unresolved for more than 20 minutes, this may be a sign of Impella® 2.5 Catheter damage. Complete the following steps immediately:
   a. Open the performance level icon and reduce the performance level to P1.
   b. Slowly pull back on the Impella® 2.5 Catheter until it is in the descending aorta (approximately 20 cm for an average size patient; 1 cm marks are available on the catheter).
   c. Turn off the Impella® 2.5 Catheter by opening the performance level icon and reducing the P-level to P0.
   d. Disconnect the catheter from the Impella® Controller.
   e. Remove the Impella® 2.5 Catheter with the use of fluoroscopic imaging. If no fluoroscopy is available, leave the catheter in the descending aorta until fluoroscopy is available for visual assistance during removal of the Impella® 2.5 Catheter.

Purge Pressure

In the initial set-up configuration, the purge pressure is set to 600 mmHg, although it may not reach 600 mmHg in low resistance catheters in this configuration.

In the standard configuration, optimal purge pressure is different for every Impella® 2.5 Catheter. Purge pressure can range from 300 mmHg to 1100 mmHg. While purge pressure varies during operation, the Impella® Controller automatically maintains purge pressure within an acceptable range for each Impella® 2.5 Catheter.

PURGE SYSTEM OPEN

If at any time during the course of support with the Impella® 2.5 Catheter, the Impella® Controller alarms "Purge System Open," follow the instructions below.

1. Inspect the purge system for leaks.
2. If no leaks are visible, there may be a problem with the purge cassette. Replace the purge cassette. (Refer to instructions earlier in this section of the manual.)
3. If the Purge System Open alarm remains unresolved, this may be a sign of Impella® 2.5 Catheter damage. Complete the following steps immediately:
   a. Open the performance level icon and reduce the performance level to P1.
   b. Slowly pull back on the Impella® 2.5 Catheter until it is in the descending aorta (approximately 20 cm for an average size patient; 1 cm marks are available on the catheter).
   c. Turn off the Impella® 2.5 Catheter by opening the performance level icon and reducing the P-level to P0.
   d. Disconnect the catheter from the Impella® Controller.
   e. Remove the Impella® 2.5 Catheter with the use of fluoroscopic imaging. If no fluoroscopy is available, leave the catheter in the descending aorta until fluoroscopy is available for visual assistance during removal of the Impella® 2.5 Catheter.

Purge System Open Alarm

This alarm may occur if purge pressure is less than 100 mmHg.

Unresolved High Purge Pressure / Purge Flow Low Alarm

If not resolved by the recommendations provided, high purge pressure—which triggers the "Purge Flow Low" alarm message—could be an indication of a kink in the Impella® 2.5 Catheter. In this case, the motor is no longer being purged and may eventually stop. Clinicians should monitor motor current and consider replacing the Impella® 2.5 Catheter whenever a rise in motor current is seen.

HIGH PURGE PRESSURE

If the purge pressure exceeds 1100 mmHg, the Impella® Controller displays the "Purge Flow Low" alarm message.

1. Inspect the purge system and check the Impella® 2.5 Catheter for kinks in the tubing.
2. If pressure remains high, decrease the concentration of dextrose in the purge solution (eg, change from 20% dextrose to 10% dextrose).

De-air Procedure

You may run the de-air procedure (described earlier in this section) after changing the dextrose concentration to decrease the amount of time it takes for a change to occur.

PURGE SYSTEM BLOCKED

If a "Purge System Blocked" alarm occurs, the purge fluid flow stops.

1. Check the purge system tubing and the Impella® 2.5 Catheter for kinks or blockages.
2. Decrease the concentration of dextrose in the purge solution.
3. Replace the purge cassette.

PATIENT WEANING

Weaning the patient from the Impella® 2.5 Catheter is at the discretion of the physician.
The following weaning protocols are provided as guidance only.

RAPID WEANING

1. Initiate rapid weaning by decreasing catheter performance level in 2-level steps at intervals of several minutes (for example, P6 to P4 to P2). Do ***NOT*** decrease performance level to below P2 until just before removing the catheter from the ventricle.
2. When the performance level has been reduced to P2, maintain the patient on P2 support for *at least 10 minutes* before discontinuing circulatory support.
3. If the patient's hemodynamics remain stable, decrease the performance level to P1, pull the catheter into the aorta, and stop the motor by decreasing the performance level to P0.
4. Explant the catheter.
5. Follow institutional guidelines for arterial closure.
6. Disconnect the connector cable from the Impella® Controller and turn the controller off by pressing the power switch on the side of the controller for 3 seconds.

SLOW WEANING

1. Initiate slow weaning by decreasing catheter performance level in 2-level steps over time as cardiac function allows (for example, P6 to P4 to P2). Do ***NOT*** decrease performance level to below P2 until just before removing the catheter from the ventricle.
2. When the performance level has been reduced to P2, maintain the patient on P2 support until the patient's hemodynamics remain stable before discontinuing circulatory support.
3. If the patient's hemodynamics remain stable, decrease the performance level to P1, pull the catheter into the aorta, and stop the motor by decreasing the performance level to P0.
4. Explant the catheter.
5. Follow institutional guidelines for arterial closure.
6. Disconnect the connector cable from the Impella® Controller and turn the controller off by pressing the power switch on the side of the controller for 3 seconds.

Remove the Impella® 2.5 Catheter With Care

Removal of the Impella® 2.5 Catheter must be completed with care to avoid damage to the catheter assembly.

6 PATIENT MANAGEMENT TOPICS

PATIENT MANAGEMENT OVERVIEW

The information and instructions in this section of the manual are not intended to supersede established medical procedures concerning patient care. Best practice, as determined by the medical community, should always be observed. In each case, the clinician must determine whether the application of information provided is appropriate for the particular clinical setting.

GENERAL PATIENT CARE 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® 2.5 Catheter when transferring a patient from one bed to another.
- To prevent the purge tubing from kinking, do not allow the red Impella® plug to hang freely from the catheter and do not bend the catheter near the red Impella® plug. Consider attaching the red Impella® plug and catheter to a short armboard to prevent the catheter from kinking near the plug.
- Use care when moving or turning a patient; the Impella® 2.5 Catheter may move out of position and cause a positioning alarm.
- Monitor pedal pulses.

TRANSPORT WITHIN THE HOSPITAL

Patients supported with the Impella® 2.5 System may require transport within the hospital for various reasons. Transport can be safe and simple for patients supported with Impella® 2.5 Catheter.

Considerations for transport within the hospital:

- The Impella® Controller and Impella® 2.5 Catheter are designed to operate on battery power for at least 1 hour.
- Confirm that the battery capacity displayed on the controller is 100%.
- If transport time might be longer than 1 hour, bring an extension cord or confirm that you will be able to connect the controller to AC power once you arrive at your destination.
- Use care when rolling the Impella® Controller cart, and pay close attention when going over thresholds and through elevator doors.
- Do not stress the connector cable from the controller to the Impella® 2.5 Catheter.

Battery Power Note

If the Impella® Controller is allowed to discharge completely and the system shuts down due to low battery, the controller will need to charge for an extended period of time before it will turn on again.

TRANSPORT BETWEEN HOSPITALS

During transport, the Impella® Controller may be exposed to stronger electromagnetic disturbance than during in-hospital use. Strong electromagnetic disturbance may cause the Impella® Controller to display soft button menu selections that were not selected by the user. Operators should be aware that, under these conditions, the operating parameters are not affected. No user intervention is required. Monitor Impella® 2.5 Catheter flow and patient hemodynamics to confirm normal operation. The condition will resolve itself once the Impella® Controller is no longer exposed to the disturbance.

The Impella® Controller and Impella® 2.5 Catheter have been cleared by the FDA for hospital-to-hospital transport via ambulance, helicopter, or fixed-wing aircraft. Specifically, the Impella® Controller is qualified for safe use by healthcare professionals to facilitate the transport of patients supported by the Impella® 2.5 System from one medical facility to another. The Impella® 2.5 System performs life-sustaining functions. To use the system during transport you must understand and follow the instructions in this manual. The transport team should include person(s) fully trained in the use of the Impella® Controller and the Impella® 2.5 Catheter.

If a patient on Impella® Controller circulatory support requires additional resources and specialized teams at another location (eg, a larger facility such as a transplant center), the patient may be transferred safely to such a location using the Impella® Controller.

GUIDELINES FOR PATIENT TRANSPORT

Maintaining optimal patient hemodynamic status and correct Impella® 2.5 Catheter position are two key factors in managing patients supported with the Impella® 2.5 System during transport. Steps should be taken to eliminate or minimize any aspect of the transport that might adversely affect these factors.

The Impella® Controller is designed to operate for 60 minutes on battery power. Transport teams should take this into consideration when planning the transport. If the total transport time is expected to include more than 60 minutes during which the system will be disconnected from AC power, arrangements should be made to use a vehicle with a built-in DC to AC power inverter.

IMPORTANT TRANSPORT CONSIDERATIONS

1. Planning is critical to success. Abiomed representatives can help with planning for transport. They can be contacted 24 hours a day at 1-800-422-8666.
2. The Impella® Controller should be fully charged prior to transport. Keep the Impella® Controller connected to AC power (or an AC inverter) whenever possible.
3. Do not stress the connector cable from the controller to the Impella® 2.5 Catheter. Such tension could move the catheter out of correct position and compromise patient circulatory support.
4. Carefully monitor purge pressures during changes in altitude.

5. The Impella® Controller should be positioned to allow easy access to the display screen and soft buttons to view alarms and make any necessary changes.
6. Maintain ACTs between 160 and 180 or at the level recommended by the physician responsible for the patient.

RIGHT HEART FAILURE

The Impella® 2.5 Catheter is a left-side support device only. Patients being supported by the Impella® 2.5 Catheter should be monitored for signs of right heart failure.

Caregivers should monitor the patient closely for the following potential signs of right heart failure:

- Reduced output from the Impella® 2.5 Catheter
- Suction alarms
- Elevated filling pressures (CVP)
- Signs of liver failure
- Elevated pulmonary pressures

If the patient is exhibiting signs of right heart failure, the clinical team should assess the need for biventricular support.

CARDIOPULMONARY RESUSCITATION (CPR)

Cardiopulmonary resuscitation (CPR) should be initiated immediately if indicated for any patient being supported by the Impella® 2.5 Catheter.

If CPR is indicated, the following actions are recommended:

1. Initiate CPR per hospital protocol.
2. Reduce the Impella® 2.5 Catheter flow rate to 1 L/min.
3. When cardiac function has been restored:
   a. Return the flow rate to previous level.
   b. Assess placement signals on the controller.

Note:

- During CPR, placement monitoring and flow calculations will not be accurate.
- If flows do not return to pre-CPR values, verify proper placement of catheter and sufficient filling of left ventricle. If placement and filling are not satisfactory, it may be an indication that the catheter has been damaged.

Cardiac Arrest

*The Impella® 2.5 Catheter will **NOT** provide hemodynamic support during cardiac arrest.*

DEFIBRILLATION

During defibrillation, do ***NOT*** touch the Impella® 2.5 Catheter, cables, or Impella® Controller.

If emergency defibrillation is required during support with the Impella® 2.5 System, universal safety precautions should be followed. To avoid the risk of electrical shock, caregivers should use caution during defibrillation to ensure they do not touch the Impella® 2.5 Catheter, cables, or controller.

ECG INTERFERENCE

Operating the Impella® Controller may cause interference with electrocardiogram (ECG) signals. Please check the electrode pads and leads for good fixation and contact. If interference persists, activate the 50/100 Hz band-elimination filter or the 60/120 Hz band-elimination filter (also known as notch filter) on your ECG device. The filter frequency will be based on the AC power frequency for the country in which you are operating the equipment. If your ECG device does not have the appropriate filters, disconnect the Impella® Controller temporarily from AC power to obtain an undisturbed signal. Please observe the battery status while running the Impella® Controller on battery power.

LATEX

The Impella® Controller, Impella® 2.5 Catheter, and all accessories approved by Abiomed, are 100% latex free.

USE OF ECHOCARDIOGRAPHY FOR POSITIONING OF THE IMPELLA® 2.5 CATHETER

BACKGROUND

Echocardiography is a commonly used tool for evaluating the position of the Impella® 2.5 Catheter relative to the aortic valve and other intraventricular structures post-placement. The best echocardiographic views for positioning the Impella® 2.5 Catheter in the left ventricle are a long axis transesophageal echocardiogram (TEE) or a parasternal long axis transthoracic echocardiogram (TTE). These long axis views allow you to see both the aortic valve and Impella® 2.5 Catheter inlet area.

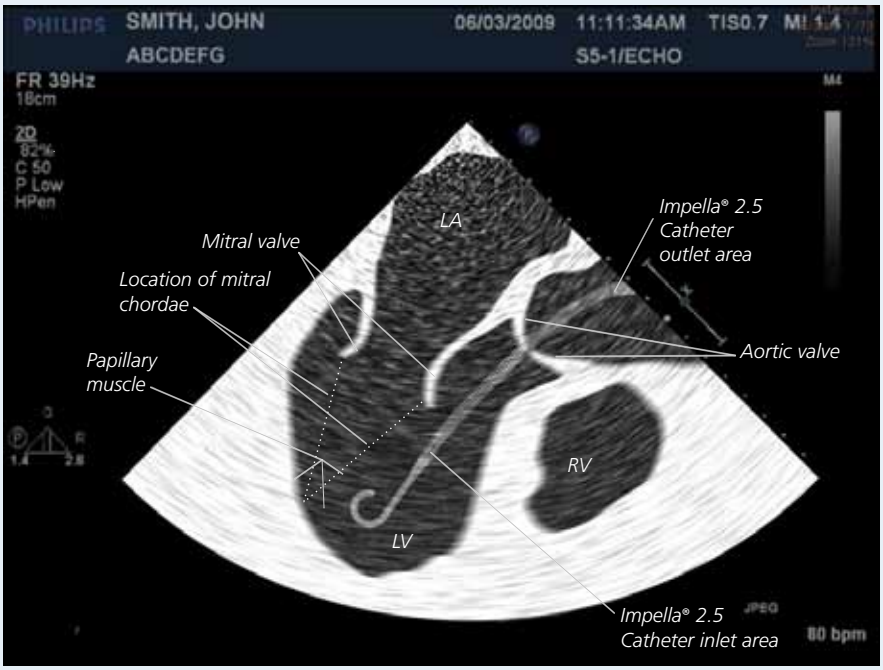
Evaluate the position of the Impella® 2.5 Catheter if the Impella® Controller displays position alarms or if you observe lower than expected flows or signs of hemolysis. If the catheter does not appear to be correctly positioned, initiate steps to reposition it.

Positioning and Placement

Impella® 2.5 Catheter performance will be compromised if correct placement cannot be confirmed. While other imaging techniques, such as transesophageal echocardiography (TEE), portable C-Arm fluoroscopy, or chest x-ray, can help confirm the position of the Impella® 2.5 Catheter after placement, these methods do not allow visualization of the entire catheter assembly and are inadequate for reliably placing the Impella® 2.5 Catheter across the aortic valve.

The illustrations below identify the structures you would expect to see in transesophageal echocardiography (top) and transthoracic echocardiography (bottom). In these illustrations, the Impella® 2.5 Catheter is positioned correctly; however, these depictions are stylized and in actual echocardiograms the pigtail and inlet and outlet areas may not be seen as distinctly.

Transesophageal Echocardiogram (TEE) of Impella® 2.5 Catheter



Transthoracic Echocardiogram (TTE) of Impella® 2.5 Catheter

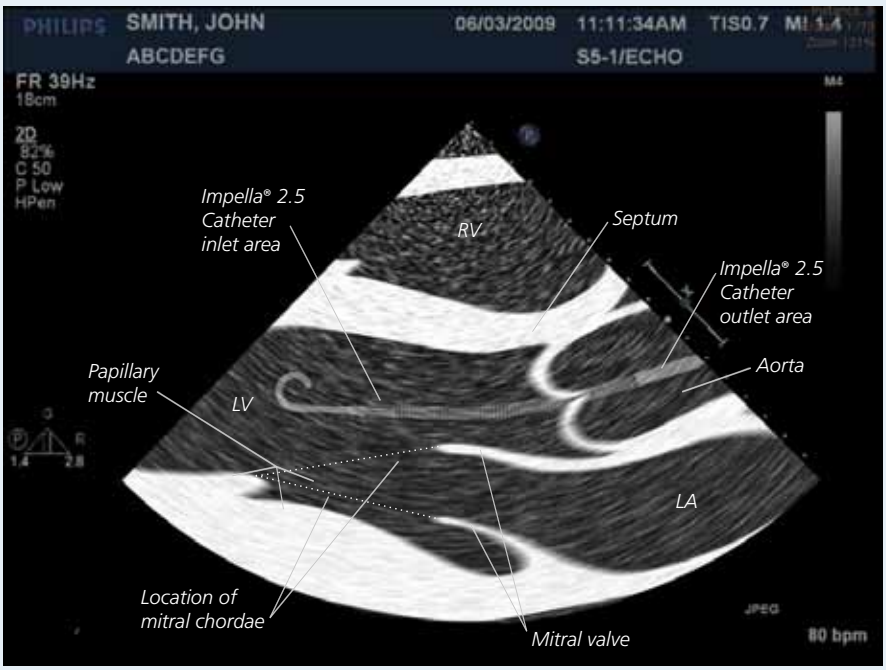


Figure 6.1 Labeled TEE and TTE Images of the Impella® 2.5 Catheter Position

Four Impella® 2.5 Catheter positions you are likely to encounter when examining echocardiograms from patients supported with the Impella® 2.5 Catheter include:

- Correct Impella® 2.5 Catheter position
- Impella® 2.5 Catheter too far into the left ventricle
- Impella® 2.5 Catheter inlet in the aorta
- Impella® 2.5 Catheter in papillary muscle

The following pages describe each situation. Figure 6.2 illustrates a transesophageal echocardiogram (TEE) of each situation. Figure 6.3 illustrates a transthoracic echocardiogram (TTE) of each.

CORRECT IMPELLA® 2.5 CATHETER POSITION

For optimal positioning of the Impella® 2.5 Catheter, the inlet area of the catheter should be about 4 cm below the aortic valve annulus and well away from papillary muscle and subannular structures. The outlet area should be well above the aortic valve. If the Impella® 2.5 Catheter is correctly positioned, echocardiography will likely show the following, as depicted in Figures 6.2a (TEE) and 6.3a (TTE):

- Catheter inlet area about 4 cm below the aortic valve
- Catheter outlet area well above the aortic valve (frequently not visible on TEE or TTE images)
- Catheter angled toward the left ventricular apex away from the heart wall and not curled up or blocking the mitral valve

IMPELLA® 2.5 CATHETER TOO FAR INTO THE LEFT VENTRICLE

If the Impella® 2.5 Catheter is positioned too far into the left ventricle, the patient will not receive the benefit of Impella® 2.5 Catheter support. Blood will enter the inlet area and exit the outlet area within the ventricle. Obstruction of the Impella® 2.5 Catheter inlet area can lead to increased mechanical forces on blood cell walls and subsequent hemolysis, which often presents as dark or blood-colored urine. If the Impella® 2.5 Catheter is too far into the left ventricle, echocardiography will likely show the following, as depicted in Figures 6.2b (TEE) and 6.3b (TTE):

- Catheter inlet area more than 4 cm below the aortic valve
- Catheter outlet area across or near the aortic valve
- Catheter too close to the heart wall or mitral valve

IMPELLA® 2.5 CATHETER INLET IN THE AORTA

If the inlet area of the Impella® 2.5 Catheter is in the aorta, the patient will not receive the benefit of Impella® 2.5 Catheter support. The catheter will pull blood from the aorta rather than the left ventricle. In addition, suction is possible if the inlet area is against the wall of the aorta or valve sinus. If the inlet area of the Impella® 2.5 Catheter is in the aorta, echocardiography will likely show the following, as depicted in Figures 6.2c (TEE) and 6.3c (TTE):

- Catheter inlet area in aorta or near the aortic valve
- Catheter pigtail too close to the mitral valve

IMPELLA® 2.5 CATHETER IN PAPILLARY MUSCLE

If the inlet area of the Impella® 2.5 Catheter is too close to or entangled in the papillary muscle and/or subannular structures surrounding the mitral valve, it can affect mitral valve function and negatively impact catheter flow. If the inlet area of the catheter is lodged adjacent to the papillary muscle, the inflow may be obstructed, resulting in suction alarms. This positioning is also likely to place the outlet area too close to the aortic valve, which can cause outflow at the level of the aortic valve with blood streaming back into the ventricle, resulting in turbulent flow and hemolysis. If the Impella® 2.5 Catheter is too close to or entangled in the papillary muscle, echocardiography will likely show the following, as depicted in Figures 6.2d (TEE) and 6.3d (TTE):

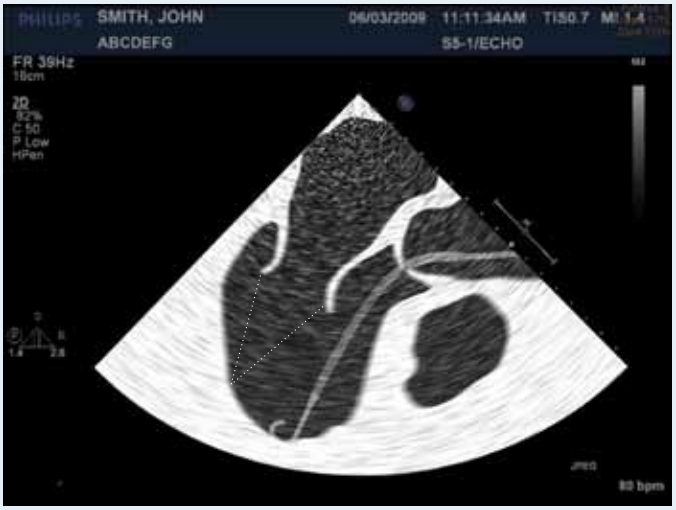
- Catheter pigtail in papillary muscle
- Catheter inlet area more than 4 cm below the aortic valve or lodged between papillary muscle and the myocardial wall
- Catheter outlet area too close to the aortic valve

The following figures depict transesophageal and transthoracic echocardiographic images of these four Impella® 2.5 Catheter positions. Figure 6.2 shows four transesophageal depictions of Impella® 2.5 Catheter position and Figure 6.3 shows four transthoracic depictions of Impella® 2.5 Catheter position.

Correct Impella® 2.5 Catheter Position (TEE) 6.2a

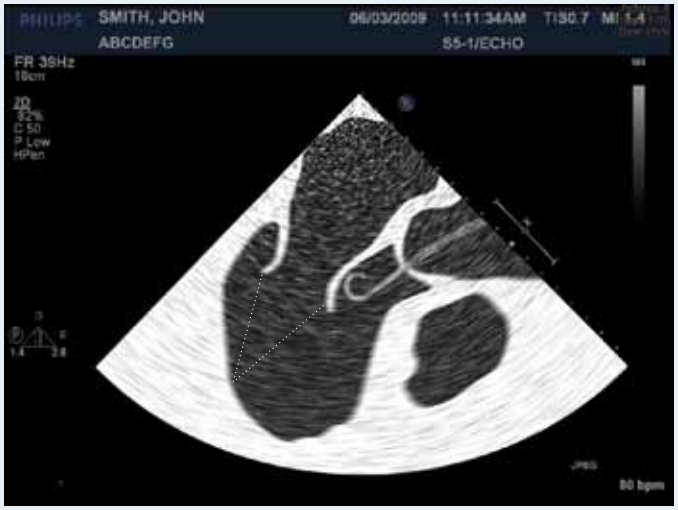
- Catheter inlet area about 4 cm below the aortic valve
- Catheter outlet area well above the aortic valve
- Catheter angled toward the left ventricular apex away from the heart wall and not curled up or blocking the mitral valve

Impella® 2.5 Catheter Too Far into Left Ventricle (TEE) 6.2b



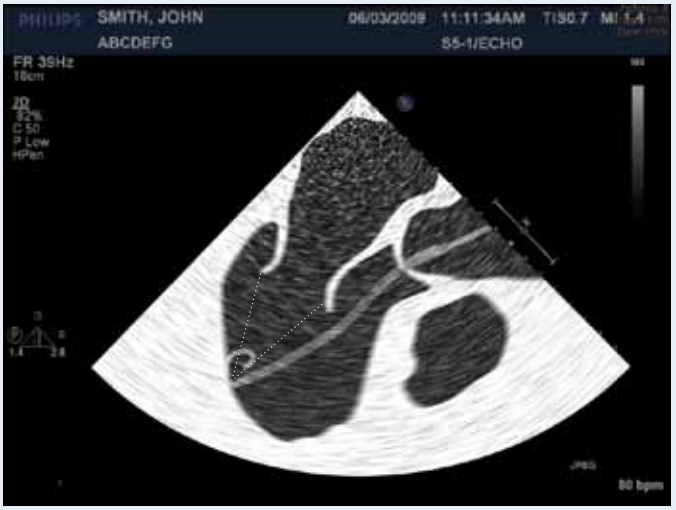
- Catheter inlet area more than 4 cm below the aortic valve
- Catheter outlet area across or near the aortic valve
- Catheter too close to the heart wall or mitral valve

Impella® 2.5 Catheter Inlet in Aorta (TEE) 6.2c



- Catheter inlet area in aorta or near the aortic valve
- Catheter pigtail too close to the mitral valve

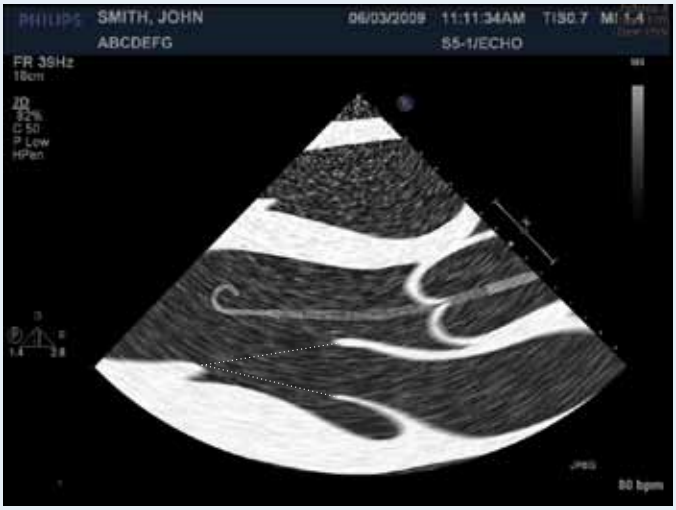
Impella® 2.5 Catheter in Papillary Muscle (TEE) 6.2d



- Catheter pigtail in papillary muscle
- Catheter inlet area more than 4 cm below the aortic valve or lodged between papillary muscle and the myocardial wall
- Catheter outlet area too close to the aortic valve

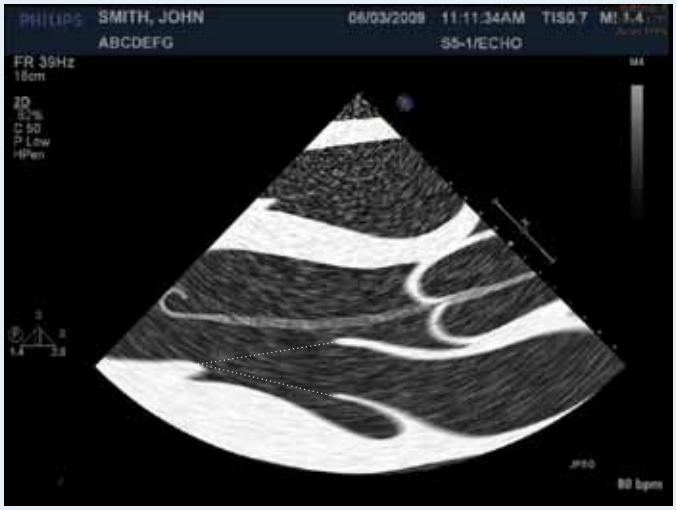
Figure 6.2 Transesophageal Echocardiographic (TEE) Illustrations of Impella® 2.5 Catheter Position

Correct Impella® 2.5 Catheter Position (TTE) 6.3a



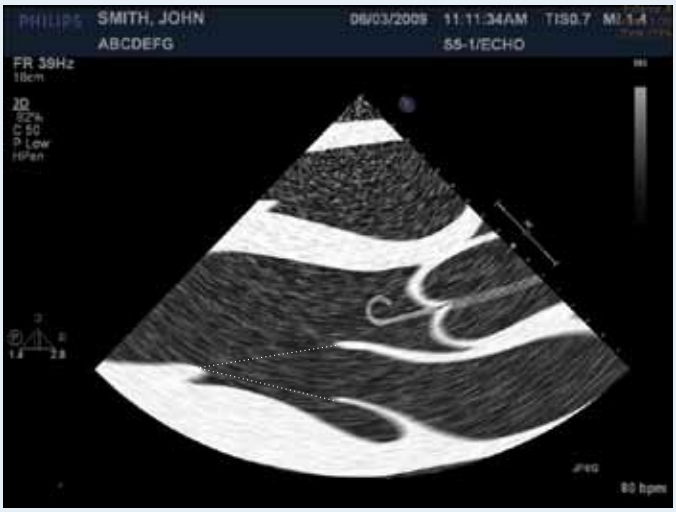
- Catheter inlet area about 4 cm below the aortic valve
- Catheter outlet area well above the aortic valve
- Catheter angled toward the left ventricular apex away from the heart wall and not curled up or blocking the mitral valve

Impella® 2.5 Catheter Too Far into Left Ventricle (TTE) 6.3b



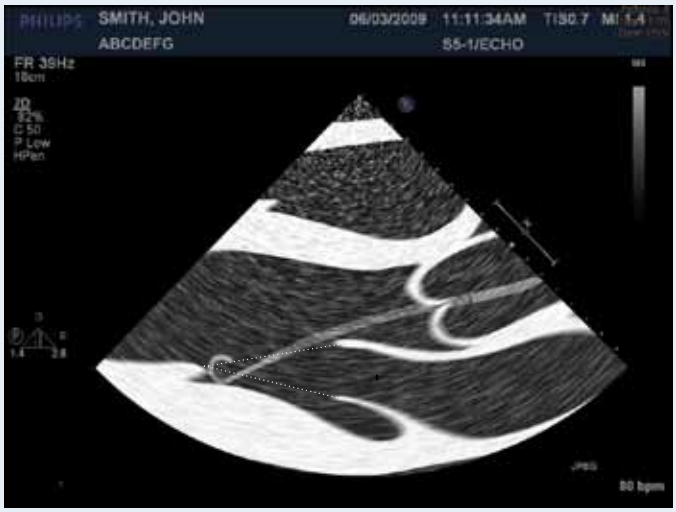
- Catheter inlet area more than 4 cm below the aortic valve
- Catheter outlet area across or near the aortic valve
- Catheter too close to the heart wall or mitral valve

Impella® 2.5 Catheter Inlet in Aorta (TTE) 6.3c



- Catheter inlet area in aorta or near the aortic valve
- Catheter pigtail too close to the mitral valve

Impella® 2.5 Catheter in Papillary Muscle (TTE) 6.3d



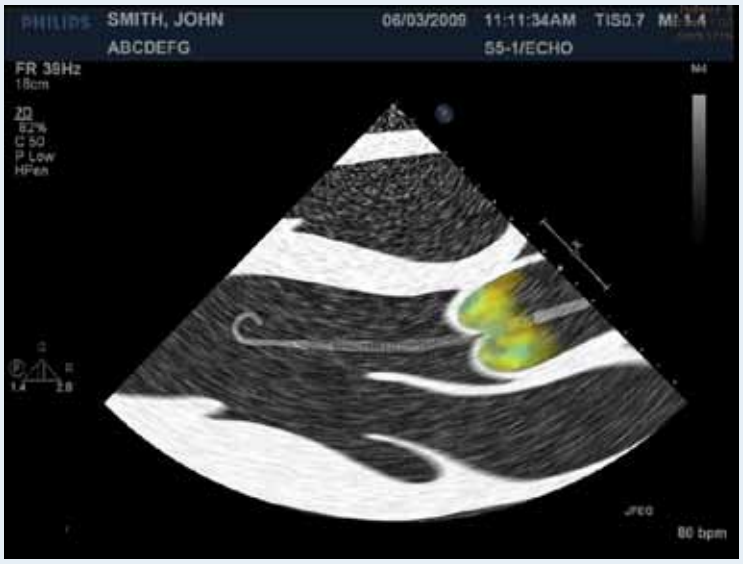
- Catheter pigtail in papillary muscle
- Catheter inlet area more than 4 cm below the aortic valve or lodged between papillary muscle and the myocardial wall
- Catheter outlet area too close to the aortic valve

Figure 6.3 Transthoracic Echocardiographic (TTE) Illustrations of Impella® 2.5 Catheter Position

COLOR DOPPLER ECHOCARDIOGRAPHY

When moving a patient supported with an Impella® 2.5 Catheter, it is important to monitor catheter migration. Adding color Doppler to an echo is another way to verify catheter position. If the Impella® 2.5 Catheter is correctly positioned, a dense mosaic pattern of turbulence will appear *above* the aortic valve near the outlet area of the catheter, as shown in the top image in Figure 6.4. If, however, the echocardiogram reveals a dense mosaic pattern of turbulence *beneath* the aortic valve (bottom image in Figure 6.4), this likely indicates that the outlet area of the catheter is in the wrong position, that is, the catheter is too far into the ventricle or entangled in papillary muscle. (Note: If using transesophageal echocardiography [TEE], look for the mosaic patterns in the same locations relative to the aortic valve and Impella® 2.5 Catheter outlet area.)

Correct Impella® 2.5 Catheter Position (Color Doppler TTE)



Incorrect Impella® 2.5 Catheter Position (Color Doppler TTE)

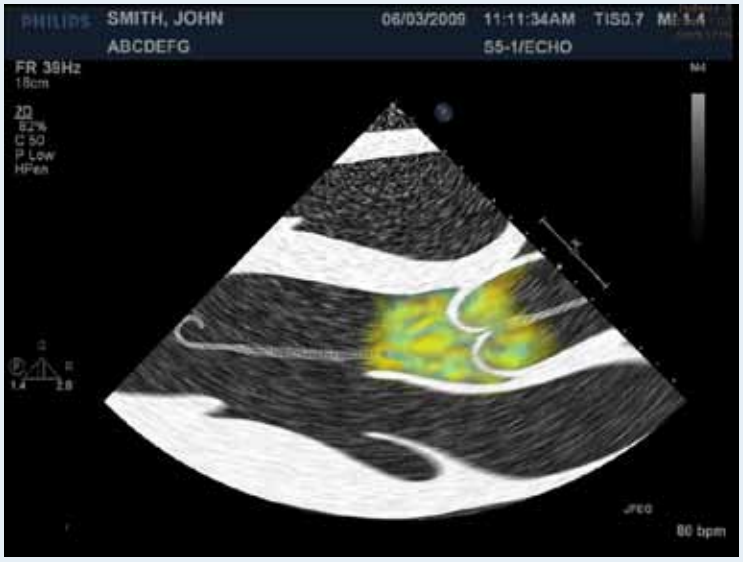


Figure 6.4 Correct and Incorrect Impella® 2.5 Catheter Position (Color Doppler TTE)

POST-INSERTION POSITIONING (PIP) CHECKLIST

Completing the steps shown in the following post-insertion positioning checklist can help to ensure proper position of the Impella® 2.5 Catheter following insertion. Pay particular attention to positioning after the patient is moved from the operating room or catheterization laboratory.

1. Remove slack in the Impella® 2.5 Catheter by increasing performance level to P9 and align the catheter against the lesser curvature of the aorta (rather than the greater curvature).
2. Use fluoroscopy to verify that the slack has been removed.
3. Verify that the Impella® 2.5 Catheter inlet area is optimally positioned about 4 cm below the aortic valve.
4. Return to previous performance level.
5. Secure the Impella® 2.5 Catheter at a firm external fixation point in the groin area.

Handling Repositioning Issues

*To ensure that the Impella® 2.5 Catheter remains positioned properly following insertion, discuss with the care team **who** will resolve repositioning issues that may arise and **how** they will resolve the issues (eg, portable fluoroscopy, echocardiography).*

UNDERSTANDING AND MANAGING IMPELLA® 2.5 CATHETER POSITION ALARMS

The Impella® Controller continuously monitors the catheter based on the placement signal and the motor current.

- Placement signal: *Is the signal characteristic of aortic or ventricular pressure?*
- Motor current: *Is the signal "pulsatile" or "flattened"?*

If the system alarms with one of the positioning alarms described in this section, fluoroscopic imaging is the best method for confirming position. You can also use TEE, TTE, or a standard chest X-ray.

If the Impella® 2.5 Catheter is either partly (just the pigtail) or completely in the ventricle, reposition the catheter under imaging guidance. If guidance is not available, use the repositioning guide to reestablish proper placement. (The repositioning guide is discussed later in this section.)

If the Impella® 2.5 Catheter is completely out of the ventricle, do not attempt to reposition the catheter across the valve without a guidewire.

The following pages describe possible placement conditions and the associated signal characteristics and alarm messages as well as actions to take for each.

CORRECT POSITION

If the Impella® 2.5 Catheter is in the correct position, the waveform screen will appear as shown in Figure 6.5.

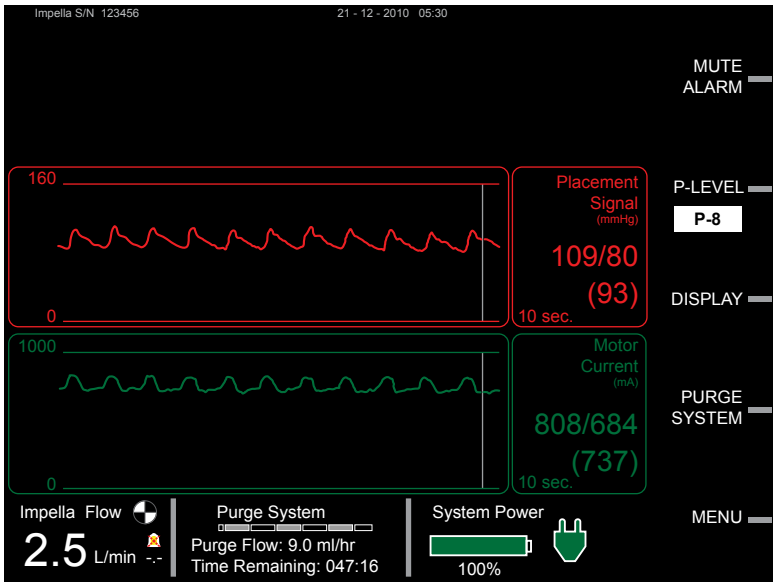


Figure 6.5 Correct Impella® 2.5 Catheter Position

IMPELLA® 2.5 CATHETER FULLY IN VENTRICLE

If the Impella® 2.5 Catheter is fully in the ventricle, the following alarm will appear:

Impella Position Wrong

In this situation, the waveform screen will appear as shown in Figure 6.6.

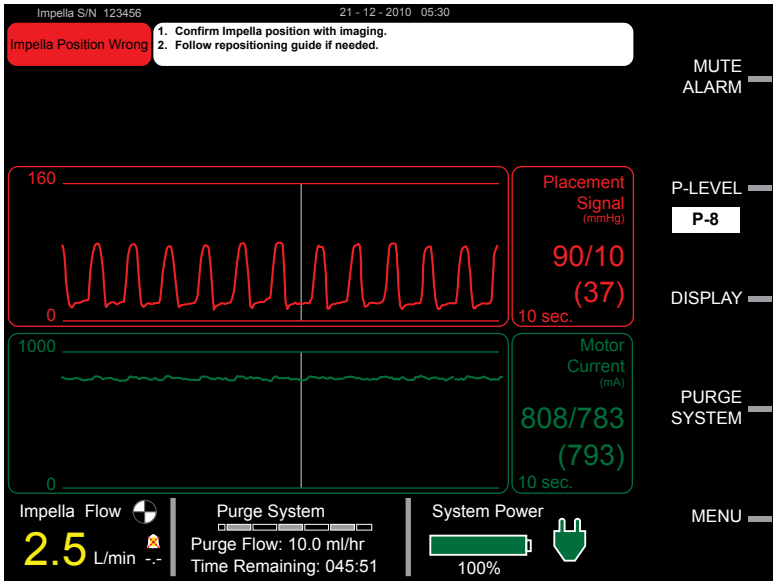


Figure 6.6 Impella® 2.5 Catheter Fully in Ventricle

Actions to take:

1. Under fluoroscopic or echocardiographic guidance, if available, reduce the performance level to P2 and carefully pull back the Impella® 2.5 Catheter until the aortic waveform signal is showing.
2. When you see the aortic waveform signal, pull the catheter back an additional 4 cm.

Repositioning Guide

The repositioning guide can also be used for correcting Impella® 2.5 Catheter positioning.

IMPELLA® 2.5 CATHETER COMPLETELY IN THE AORTA or INLET AND OUTLET AREAS IN VENTRICLE AND OPEN PRESSURE AREA IN AORTA

If the Impella® 2.5 Catheter is completely in the aorta or if the inlet and outlet areas are in the ventricle and the open pressure area is in the aorta, the following alarm will appear:

Impella Position Wrong

In this situation, the waveform screen will appear as shown in Figure 6.7.

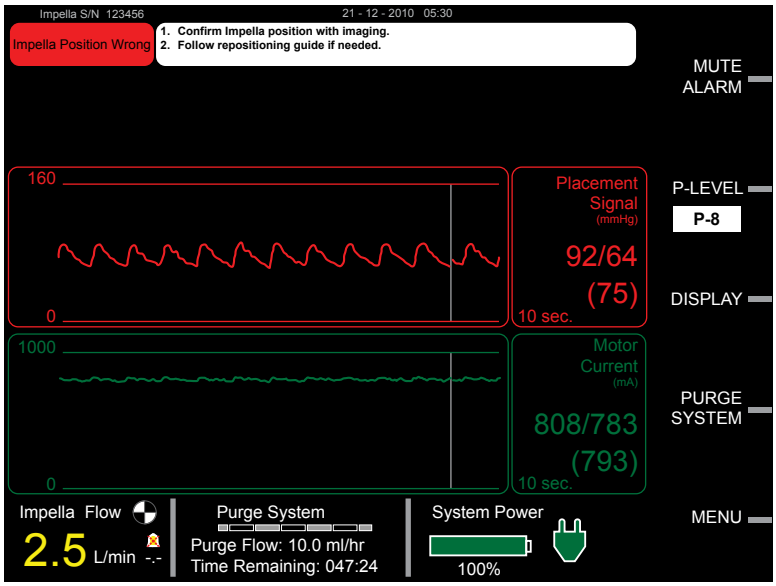


Figure 6.7 Impella® 2.5 Catheter Completely in the Aorta or Inlet and Outlet Areas in Ventricle and Open Pressure Area in Aorta

Actions to take:

1. Under fluoroscopic or echocardiographic guidance, determine the Impella® 2.5 Catheter position.
2. Reduce performance level to P2 and reposition the catheter as necessary.
3. If fluoroscopic or echocardiographic imaging is not available, reposition the catheter according to the repositioning guide.
4. If step 3 does not provide correct positioning, obtain imaging equipment (fluoroscopy, echocardiography, or chest x-ray) to check the catheter position.

LOW NATIVE HEART PULSATILITY

When a patient has poor native ventricular function, the placement signal may remain pulsatile; however, the amplitude will be dampened and both the minimum and maximum values will be greater than zero because the aortic valve does not open and the Impella® 2.5 Catheter raises the aortic blood pressure above the ventricular pressure during systole.

In a situation of low native heart pulsatility, the Impella® Controller may not be able to determine the catheter position. You may see the following indication on the home screen:

Impella Position Unknown

In this situation, the screen will appear as shown in Figure 6.8.

Figure 6.8 Impella® 2.5 Catheter Position Unknown

Actions to take:

1. Assess cardiac function.

IMPELLA® 2.5 CATHETER OUTLET AREA ON OR NEAR AORTIC VALVE

If the Impella® 2.5 Catheter outlet area is on or near the aortic valve, the catheter may be too deep in the ventricle. The following alarm will appear:

Impella Position Wrong

In this situation, the waveform screen will appear as shown in Figure 6.9.

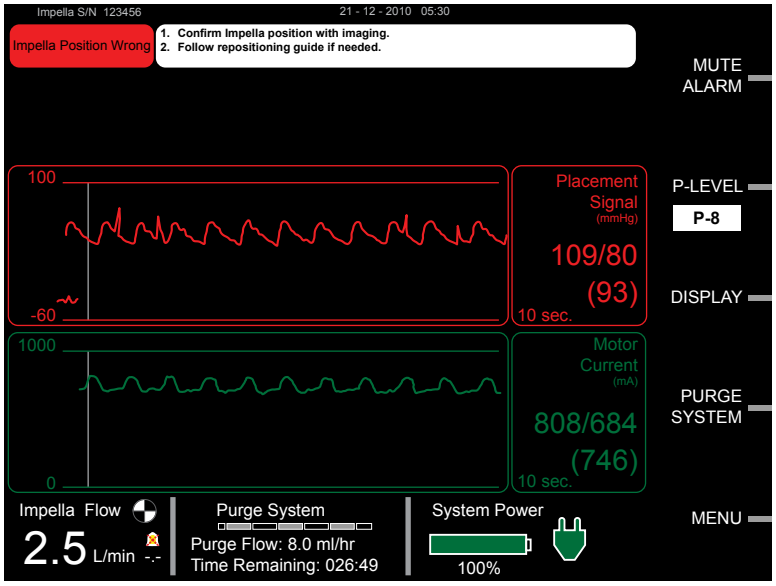


Figure 6.9 Impella® 2.5 Catheter Outlet Area on or near Aortic Valve

Actions to take:

1. Assess and adjust Impella® 2.5 Catheter position under fluoroscopic or echocardiographic guidance, if available.
2. If fluoroscopic or echocardiographic guidance is not available, reduce the performance level to P2 and gently pull the catheter back 2 cm to see if the condition resolves.

SUCTION

Suction may occur if the blood volume available for the Impella® 2.5 Catheter is inadequate or restricted. Suction limits the amount of support that the Impella® 2.5 Catheter can provide to the patient and results in a decrease in arterial pressure and cardiac output. It can damage blood cells, leading to hemolysis. It may also be an indicator of right heart failure.

If this alarm occurs, follow the recommended actions:

1. Reduce performance level by 1 or 2 levels to reduce the effects of suction.
2. Check the Impella® 2.5 Catheter for correct positioning using imaging. Reposition the catheter by rotating or moving it into or out of the ventricle slightly. Either or both of these actions could help move the inlet of the Impella® 2.5 Catheter away from the interior ventricular wall.
3. Assess patient's fluid intake and output to confirm adequate volume status.
4. Confirm right ventricular function by assessing CVP or right side function with echocardiography. If CVP is not an option, check the pulmonary artery diastolic pressure to assess the patient volume status.
5. Return the performance level to pre-alarm setting.

HEMOLYSIS

When blood is pumped, it is subjected to mechanical forces. Depending on the strength of the blood cells and the amount of force applied, the cells may be damaged, allowing hemoglobin to enter the plasma. Pumping forces can be generated by a variety of medical procedures including heart lung bypass, hemodialysis, or ventricular assist device (VAD) support. Patient conditions—including catheter position, pre-existing medical conditions, and small left ventricular volumes—may also play a role in patient susceptibility to hemolysis.

Patients who develop high levels of hemolysis may show signs of decreased hemoglobin levels, dark or blood-colored urine, and in some cases, acute renal failure. Plasma-free hemoglobin (PfHgb) is the best indicator to confirm whether a patient is exposed to an unacceptable level of hemolysis. Clinically significant hemolysis is defined as two consecutive PfHgb measurements greater than 40 mg/dL. For surgical patients, the first measurements must be at least 72 hours post implant.

Management technique may differ depending on the underlying cause of hemolysis. Table 6.1 provides guidance for various circumstances.

Table 6.1 Guide for Managing Hemolysis in Various Circumstances

Condition	Controller Indicators	Clinical Indicators	Management
Impella® 2.5 inlet area in close proximity to intraventricular wall	• Suction alarms • Lower than expected flows	Imaging (see note)	• Reposition the catheter by rotating or moving the catheter into or out of the ventricle slightly. Either or both of these actions could help move the inlet of the catheter away from the intraventricular wall. • If repositioning will be delayed, reduce the performance level if tolerated by patient hemodynamics. Return to the target P-level after repositioning. • Reassess position after performance level has returned to desired target value.
Wrong pump position	• Position alarms with higher than expected flows • Suction alarms with lower than expected flows • Pump outlet blocked alarms	Imaging (see note)	• Reposition the catheter by rotating or moving the catheter into or out of the ventricle slightly. Either or both of these actions could help move the inlet of the catheter away from the intraventricular wall. • If repositioning will be delayed, reduce the performance level if tolerated by patient hemodynamics. Return to the target P-level after repositioning. • Reassess position after performance level has returned to desired target value.
Higher than needed flow setting	• There may be no controller indicators • Suction alarms	• Normal hemodynamics • Native recovery	• Reduce performance level until patient pressure starts to drop. • Slowly increase performance level.
Inadequate filling volume	• Position alarms • Suction alarms • Lower than expected flows	• Low CVP • Low PCWP • Low AOP • High PA pressures • Right heart failure • High urine output • Increased bleeding or chest tube drainage	• Reduce the performance level if tolerated by patient hemodynamics. • Correct I and O balance. • Consider giving volume; additional volume will expand the end systolic ventricular volume. • Reduce PA pressure. • Improve right heart function.
Pre-existing patient conditions or other medical procedures	N/A	• Patient past medical history • Current procedures or treatments	

Note on imaging: *All imaging technology represents the anatomy in two dimensions (2D). It is not possible to assess the interactions between the catheter and the intraventricular anatomy that occur in three dimensions (3D). Abiomed strongly recommends that the catheter be repositioned, even if the imaging view shows correct position.*

OPERATING THE IMPELLA® 2.5 CATHETER WITHOUT HEPARIN IN THE PURGE SOLUTION

The Impella® 2.5 Catheter is designed to be operated with a purge solution that contains heparin. Operation of the system without heparin in the purge solution has not been tested. In the event that a patient is intolerant to heparin, due to heparin-induced thrombocytopenia (HIT) or bleeding, physicians should use their clinical judgment to assess the risks versus benefits of operating the Impella® System without heparin.

If it is in the best interest of the patient to operate the system without heparin, the dextrose solution is still required, and physicians should consider *systemic delivery* of an alternative anticoagulant. DO NOT add any alternative anticoagulant (such as a direct thrombin inhibitor) to the purge fluid. The Impella® 2.5 Catheter has not been tested with any alternative anticoagulants in the purge solution.

REPOSITIONING GUIDE

Abiomed strongly recommends using fluoroscopy to guide placement and positioning of the Impella® 2.5 Catheter. However, if fluoroscopy or other imaging guidance is not available, you can use the repositioning guide to correct the position of the catheter across the aortic valve. The repositioning guide provides information about the current position of the catheter and the actions required to reposition it.

To use the repositioning guide:

1. Press **MENU** and scroll to "Start Repositioning Guide." Press the selector knob to initiate the repositioning guide algorithm. Follow the instructions in the instructional display area under the headline "Reposition Guide Active."

Start Repositioning Guide

*The repositioning guide is an option on the **MENU** only if the controller has triggered wrong or unknown Impella® 2.5 Catheter position or a catheter overflow blocked alarm.*

Wait for New Flow Level

*After you press **OK** to decrease the performance level, the system displays a message instructing you to wait until the new performance level is reached before advancing the catheter.*

2. Press **OK** to decrease performance level as directed on the first screen of the repositioning guide (Figure 6.10). The system reduces performance level to P2.

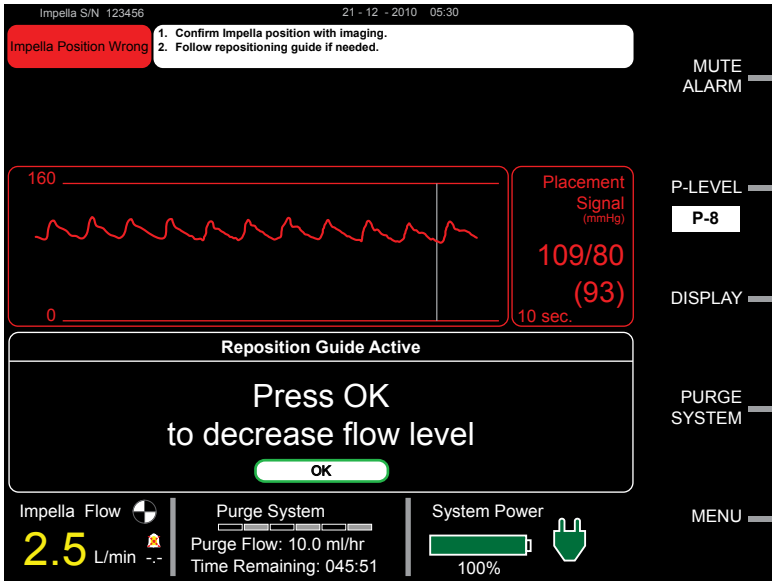


Figure 6.10 First Repositioning Guide Screen

3. Push the Impella® 2.5 Catheter forward as directed in the screen shown in Figure 6.11 until the placement signal shows ventricular pressure.

Yellow Background for Performance Level

If the Impella® Controller reduces the performance level without any user interaction, the background color changes to yellow (as shown in Figure 6.11).

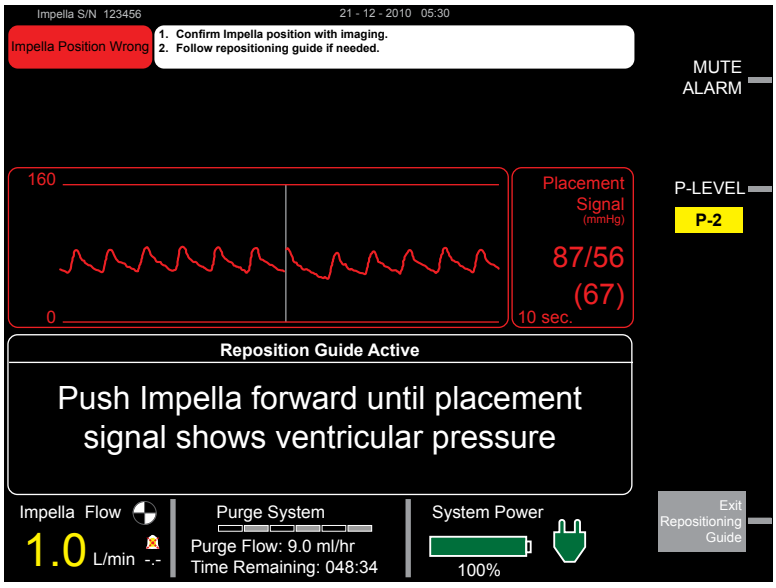


Figure 6.11 Second Repositioning Guide Screen

4. Pull the Impella® 2.5 Catheter back as directed in the screen shown in Figure 6.12 until the placement signal shows aortic pressure.

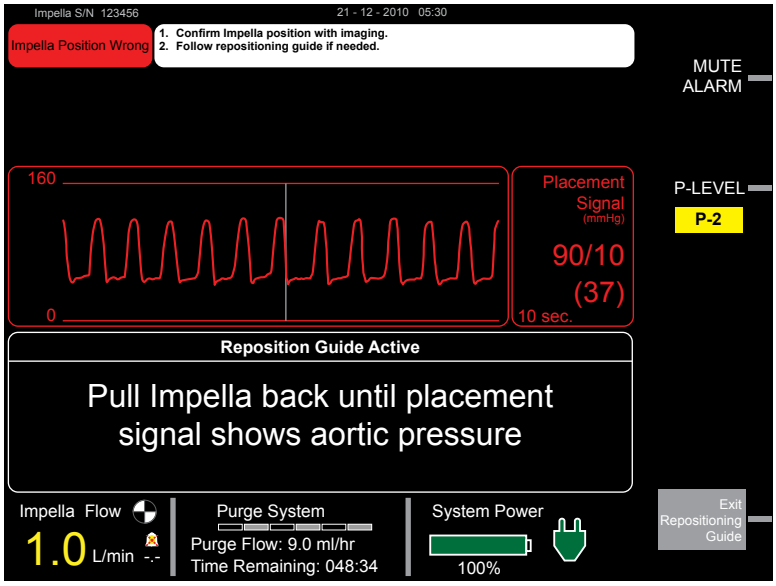


Figure 6.12 Third Repositioning Guide Screen

5. Pull the Impella® 2.5 Catheter back 4 centimeters as directed in the screen shown in Figure 6.13. Each mark on the catheter equals 1 centimeter.

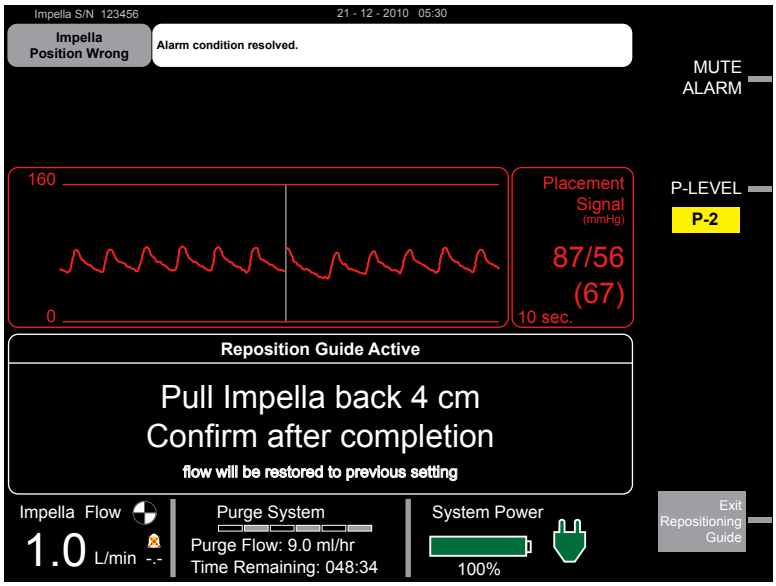


Figure 6.13 Exit Repositioning Guide Screen

6. Exit the Repositioning Guide using the **Exit Repositioning Guide** soft button shown in Figure 6.13. When you exit, the controller returns to the original performance level.

PLACEMENT SIGNAL LUMEN

BACKGROUND

The Impella® 2.5 Catheter uses a fluid-filled pressure lumen with an inlet at the proximal end of the motor housing and the pressure sensor located in the red Impella® plug. The Impella® Controller software monitors both the pressure waveform characteristics and motor current to determine the placement of the Impella® 2.5 Catheter inlet and outlet areas relative to the aortic valve.

Table 6.2 provides recommended standards for maintaining the placement signal.

Table 6.2 Recommended Standards for Maintenance of the Placement Signal

Heparin in the flush solution	Abiomed suggests that the hospital follow its own established protocol for using heparin in the flush solution.
Frequency of line and flush solution change out	Abiomed suggests that the hospital follow its own established protocol for time interval for change of the flush solution.
Periodic flushing of the placement signal lumen. Note: Either of these actions may result in sensor or position alarms.	*Slight dampening* If you observe a dampened placement signal, pinch the white flush valve located on the red sidearm for a few seconds to restore the placement signal quality. *Severe or lost pressure* 1. Close the roller clamp and disconnect the IV tubing connected to the red pressure sidearm. 2. Connect a syringe of saline to the port and squeeze the white flow valve as you draw negative pressure. 3. Continue aspiration of the port until blood is visualized in the syringe. 4. Disconnect the syringe and open the roller clamp until slow drips of saline exit the tubing. 5. Flood the open port of the red pressure sidearm and then reconnect. 6. Squeeze the white wings of the flow valve for 15 to 20 seconds to flush the pressure lumen to remove all blood from the pressure lumen.
Pressure bag inflation pressure	Between 300 mmHg and 350 mmHg; check and maintain the pressure level by checking it every 1 to 3 hours.

Restoring Placement Signal Quality

You may get a sensor or position alarm if you pinch the white flush valve to restore placement signal quality.

FLUSH SOLUTION CHANGE OUT PROCEDURE

1. Prime the new NaCl flush solution setup and close the roller clamp.
2. Place the NaCl bag in a pressure bag and inflate to between 300 mmHg and 350 mmHg.
3. Close the roller clamp and disconnect the old flush solution connected at the red sidearm port.

4. Open the roller clamp on the new flush solution setup until you get a slow drip.
5. Position the male luer connector over the female luer connector and fill to overflow, displacing any air, as shown in Figure 6.14.

Figure 6.14 Displacing Air During Flush Solution Change Out Procedure

6. Connect and secure luer fittings.
7. Fully open the roller clamp and squeeze the white wings for approximately 5 to 10 seconds to complete the internal prime. This final prime should eliminate any risk of lost or dampened pressure caused by blood tracking into the pressure lumen during the pressure tubing change.

DATA SNAP SHOT RECORDING

The Impella® Controller can hold up to 24 hours of real-time data. Once memory is full, the controller starts overwriting the old data. The Data Snap Shot feature allows you to permanently save real-time operating data for later analysis. Data Snap Shot is automatically turned on during certain alarm conditions to capture data for analysis. You can also manually turn on the feature at any time to capture data for later analysis.

To manually access the Data Snap Shot feature:

1. Press **MENU** and scroll to "Data Snap Shot." Press the selector knob.
2. The controller records data for a predefined period of 10 minutes.

INFUSION HISTORY

The Impella® Controller has an Infusion History screen that displays the infusion volume as well as the amount of heparin and dextrose infused each hour. The current time period is displayed at the top of the list. The calculations begin when the case start procedure is completed and Impella® 2.5 Catheter performance level is greater than P0.

Figure 6.15 shows a sample Infusion History screen.

Figure 6.15 Infusion History Screen

HOW TO CHANGE TO A BACKUP CONTROLLER

A backup Impella® Controller should be available at all times when a patient is on support. In the event that the controller fails, follow the steps below to transition the Impella® 2.5 Catheter to the backup controller.

1. Confirm that the backup controller is powered on and ready.
2. Disconnect the yellow luer connector from the Impella® 2.5 Catheter to release the pressure and then immediately reconnect it.
3. Transfer the purge cassette and purge solution from the original controller to the backup controller.
4. Remove the white connector cable from the original controller and plug it into the catheter plug on the front of the backup controller.
5. Once the Impella® 2.5 Catheter is connected to the backup controller, a message will appear on the screen asking you to confirm re-starting the Impella® 2.5 Catheter at the previously set performance level.
6. Press **OK** within 10 seconds to confirm restarting the Impella® 2.5 Catheter at the previously set performance level.

Change Purge Fluid to Obtain Accurate Purge Values

To get accurate purge values after changing to a backup controller, perform the Change Purge Fluid procedure (described in section 5 of this manual) and replace the purge fluid bag.

EMERGENCY SHUTDOWN PROCEDURE

In the unlikely event that the Impella® Controller software stops responding, follow the procedure below to restart the controller without stopping the Impella® 2.5 Catheter.

1. Press and hold the power switch for 30 seconds.
2. An "Emergency Shutdown Imminent" alarm will sound at 15 seconds.
3. The controller will shut down after 30 seconds.
4. Restart the controller.

7 IMPELLA® CONTROLLER ALARMS

ALARMS OVERVIEW

The Impella® Controller monitors various functions to determine whether specific operational parameters are within expected limits. When a parameter goes outside of its specified limits, the Impella® Controller sounds an alarm tone and displays an alarm message that can be viewed on the display screen on the front of the controller. The alarm tone indicates the severity of the alarm. The alarm message on the display screen is color-coded for severity and provides details on the cause of the alarm and how to resolve the alarm.

ALARM LEVELS

Alarms are divided into three levels of severity:

- Advisory (white)
- Serious (yellow)
- Critical (red)

Table 7.1 Alarm Levels

Category	Description	Audible Indicator*	Visual Indicator
Advisory	Notification	1 beep every 5 minutes	Alarm header on white background
Serious	May become harmful or life-threatening if not addressed immediately	3 beeps every 15 seconds	Alarm header on yellow background
Critical	Immediately harmful or life-threatening	10 beeps every 6.7 seconds	Alarm header on red background

* Sound pressure of audible alarm indicators is >80 dBA

For some alarms, there is a short delay between the triggered event and the audible annunciation and visual display of the alarm. (For more information, refer to the "Alarm Delay Information" discussion in section 8 of this manual.)

ALARM DISPLAY

The alarm window is located in the upper left region of the display screen on the front of the Impella® Controller (see Figure 7.1). Alarms are listed in order of priority, with the highest priority alarm at the top. Up to three alarms may be displayed at one time. The colored background behind the highest priority alarm will alternate between two shades of that color. The white panel displayed to the right of the alarm header contains instructions for resolving the alarm condition. The instructions should be followed in the order given.

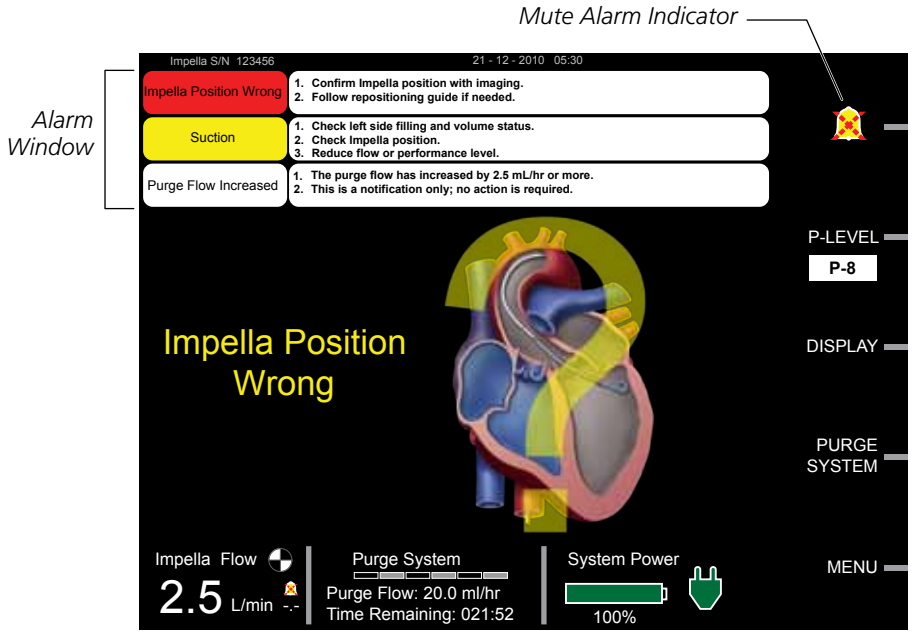


Figure 7.1 Alarm Window

Alarms That Resolve On Their Own

*The audible indicator will shut off if an alarm condition is resolved before you press **MUTE ALARM**. The visual message, however, will continue to be displayed, with the alarm header on a gray background, for 20 minutes or until you press **MUTE ALARM**. This allows you to identify the alarm that occurred.*

MUTE ALARM FUNCTION

Pressing the **MUTE ALARM** button on the upper right of the Impella® Controller display screen will silence the audible alarm indicator for 2 minutes (for red or yellow alarms) or 5 minutes (for white advisory alarms). When an alarm is silenced, the words "MUTE ALARM" next to the button are replaced by the mute alarm indicator, a crossed-out bell icon (as shown in Figure 7.1).

ALARM HISTORY SCREEN

The alarm history screen may be accessed through the **MENU**. This screen contains a log of the alarms that occurred during the case. This log is not maintained when the Impella® Controller is powered down or after a power failure. The controller does, however, maintain a long-term log that is saved after the Impella® Controller is powered down or after a power failure and this information may be downloaded by Abiomed personnel.

ALARM MESSAGE SUMMARY

Table 7.2 briefly describes all of the alarm messages that may appear on the Impella® Controller when used with the Impella® 2.5 Catheter.

Table 7.2 Impella® Controller Alarm Messages

Severity	Alarm Header	Action	Cause
Critical Alarms	**Impella Stopped** **Controller Failure**	1. Replace controller. 2. Restart Impella.	There is a problem with the controller electronics.
	Controller Failure	Switch to backup controller.	There is a problem with the controller electronics.
	Impella Stopped	1. Restart Impella. 2. Replace Impella after 3rd unsuccessful restart attempt.	There may be a mechanical or electrical problem in the Impella® 2.5 Catheter.
	Impella Disconnected	1. Check cable connection to console. 2. Check Impella connection to cable.	Running Impella® 2.5 Catheter disconnected.
	Emergency Shutdown Imminent	Release ON/OFF push button.	Power switch pressed for 15 seconds while Impella® 2.5 Catheter still connected.
	Battery Failure	1. Plug controller into AC power. 2. Press switch located on the underside of the controller. 3. Switch to backup controller.	A battery switch is turned off or there is a malfunction of the switch.
	Battery Temperature High	Switch to backup controller.	Battery temperature is greater than 60°C.
	Battery Critically Low	Plug controller into AC power.	Battery power has 15% remaining capacity.
	Battery Failure	Plug controller into AC power.	One of the batteries has failed.
	Air in Purge System	The purge system has stopped. Follow the instructions in the De-air Tool to remove the air from the system.	There is air in the purge tubing.
	Purge System Failure	Switch to backup controller and replace purge cassette.	There is a problem with the purger unit driver.

Table 7.2 Impella® Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Critical Alarms	**Impella Stopped** **Reverse Flow**	Restart Impella, or remove Impella from ventricle.	Impella® 2.5 Catheter is not running; possible reverse flow through Impella® 2.5 Catheter.
	Impella Position Wrong	1. Confirm Impella position with imaging. 2. Follow repositioning guide if needed.	Controller has detected that Impella® 2.5 Catheter is in the wrong position.
	Impella Failure	Replace Impella.	There is a problem with the Impella® 2.5 Catheter motor.
	Impella Motor Current High	Replace Impella.	There is a problem with the Impella® 2.5 Catheter motor.
	Purge System Open	1. Check the purge system tubing for open connections or leaks. 2. Replace purge cassette.	Purge pressure has dropped below 100 mmHg for 20 seconds or longer.
	Purge Pressure Low	1. Check purge system tubing for leaks. 2. Increase concentration of dextrose in the purge solution. 3. Replace purge cassette.	Purge pressure has dropped below 300 mmHg with the purge flow ≥30 mL/hr for 30 seconds or longer.
	Purge System Blocked	1. Check all purge system tubing for kinks or blockages. 2. Decrease concentration of dextrose in the purge solution.	Purge flow has dropped below 1 mL/hr. Kinked or blocked purge connecting tube. Kinked or blocked purge lumen in Impella® 2.5 Catheter.
	Purge Flow Low	1. Check purge system tubing for kinks. 2. Decrease concentration of dextrose in the purge solution.	Purge pressure is ≥1100 mmHg with the purge flow <2 mL/hr.
	Purge Line Click-On Not Detected	Check the purge line click-on and make sure it is fully inserted.	The controller is not detecting that the purge pressure transmitter is clicked into the front of the controller.

Table 7.2 Impella® Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Serious Alarms	**Controller Error**	Switch to backup controller.	There is a problem with the controller electronics.
	Impella Defective	Do not use Impella. Replace Impella.	There is a problem with the Impella® 2.5 Catheter electronics.
	Impella Position Wrong	1. Confirm Impella position with imaging. 2. Pull Impella back 2 cm. 3. Follow repositioning guide if needed.	Controller has detected that the Impella® 2.5 Catheter is in the wrong position, with the outlet area too close to the aortic valve.
	Suction	1. Check left side filling and volume status. 2. Check Impella position. 3. Reduce flow or performance level.	Suction is detected.
	Battery Temperature High	1. Check controller for blocked air vents. 2. Switch to backup controller.	Battery temperature is greater than 50°C and less than or equal to 60°C.
	Impella Flow Low	1. Adjust low flow limit value. 2. Check for suction. 3. Check for high afterload pressure.	Actual flow is below the target P-level.
	Impella Sensor Failure	Placement monitoring is suspended. 1. Monitor patient hemodynamics. 2. Monitor Impella position with imaging.	There is a problem with the Impella® 2.5 Catheter sensor signal.
	Battery Level Low	Plug controller into AC power.	Battery power has 50% remaining capacity.
	Battery Comm. Failure	Plug controller into AC power.	Loss of communication to the battery.
	Purge Cassette Failure	Replace purge cassette.	There is a problem with the purge cassette software.
	Purge Volume Critically Low	1. Open the **PURGE SYSTEM** menu and select Change Purge Fluid. 2. Follow the instructions to change the purge fluid.	There are 15 mL (in addition to 5% of the starting bag volume) or fewer remaining in the purge fluid bag.

Table 7.2 Impella® Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Advisory Alarms	**Purge Volume Low**	1. Open **PURGE SYSTEM** menu and select Change Purge Fluid. 2. Follow the instructions to change the purge fluid.	There are 30 mL (in addition to 5% of the starting bag volume) or fewer remaining in the purge fluid bag.
	Purge Flow Increased	The purge flow has increased by 2.5 mL/hr or more. This is a notification only; no action is required.	Purge flow has increased by ≥2.5 mL/hr.
	Purge Flow Decreased	The purge flow has decreased by 2.5 mL/hr or more. This is a notification only; no action is required.	Purge flow has decreased by ≥2.5 mL/hr.
	Impella Position Unknown	Impella 2.5 Catheter position unknown due to low pulsatility. Assess cardiac function.	Impella 2.5 Catheter position unknown due to low pulsatility; or catheter position unknown detected by algorithm.
	AC Power Disconnected	Controller is running on battery power.	AC power was disconnected.
	Transfer to Standard Configuration	Follow instructions under Purge System to transfer to Standard Configuration.	Follow instructions or press **MUTE ALARM** to clear the alarm for 30 minutes.
	Complete Procedure	1. Follow the steps on the screen, or 2. Exit the procedure.	User has not responded to a particular screen for more than 1 minute (in de-air and purger procedures) or 5 minutes (in transfer to standard configuration procedure).

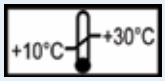
8 GENERAL SYSTEM INFORMATION

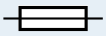
TERMINOLOGY, ABBREVIATIONS, AND SYMBOLS

TERMINOLOGY AND ABBREVIATIONS

Catheter serial number	Identification number of the Impella® 2.5 Catheter; stated on the package label, on the red Impella® plug, and the Impella® Controller display screen
Dextrose and **Glucose**	The terms "dextrose" and "glucose" are used interchangeably to refer to the solution used as purge fluid for the Impella® 2.5 System
Hz	Hertz
Motor housing (or pump housing)	Enclosure of the Impella® 2.5 Catheter motor
Pump	Central delivery unit of the Impella® 2.5 Catheter, consisting of the motor, motor housing, cannula with inlet and outlet, and pigtail at the tip
Purge pressure	Pressure present in the Impella® 2.5 Catheter and in the infusion line
Purge system	Impella® purge cassette used for rinsing the Impella® 2.5 Catheter
Retrograde flow	Reverse flow through the cannula when the Impella® 2.5 Catheter is at a standstill (eg, regurgitation)
V	Volt
VA	Volt ampere (Watt)

SYMBOLS

	Caution; consult instructions for use
	Defibrillator-proof type CF equipment
	Keep dry
	Storage temperature (eg, 10°C to 30°C)
CE	Declares conformity with directive 93/42/EEC for medical devices
 **2009-02**	Date of manufacture (eg, February 2009)

	Caution; consult instructions for use
LOT	Symbol for lot designation; the manufacturer's lot designation must be stated after the LOT symbol
REF 123456	Abiomed part number (eg, part number 123456)
SN 123456	Manufacturer's serial number (eg, serial number 123456)
Non Sterile!	The product is not sterile
 **2012-06**	Use-by date (eg, use before June 2012)
	Do not reuse
STERILE EO	Sterilized using ethylene oxide
	Electric scrap; must be disposed of separately. Must not be disposed of as domestic waste.
	Protective Earth
	ON / OFF
	Alternating current (AC) only
	Equipotentiality
	Fuse
	Non-ionizing electromagnetic radiation
	USB port
	CAT 5 Port (Ethernet)

IMPELLA® CONTROLLER MECHANICAL SPECIFICATIONS

Parameter	Specification	
Temperature	Operating:	10°C to 40°C (50°F to 104°F)
	Storage:	–15°C to 50°C (5°F to 122°F)
Relative Humidity	Operating:	95%
	Storage:	95%
Atmospheric Pressure	Operating:	8000 ft (750 hPa) to –1000 ft (1050 hPa)
	Storage:	18,000 ft (500 hPa) to –1000 ft (1050 hPa)
Dimensions	Height:	351 mm (13.8 in)
	Width:	443 mm (17.4 in)
	Depth:	236 mm (9.3 in)
Dimensions – Packaged	Height:	508 mm (20.0 in)
	Width:	559 mm (22.0 in)
	Depth:	406 mm (15.0 in)
Weight	Maximum:	11.8 kg (26.1 lbs)
Weight – Packaged	Maximum:	13.6 kg (30 lbs)
Maintenance and repair interval	12 months (Work must be performed by technicians authorized by Abiomed)	

IMPELLA® CONTROLLER ELECTRICAL SPECIFICATIONS

AC operation	100-230 V AC (nominal); 47-63 Hz; 1.1 A
Internal battery operation	14.4 V DC (nominal); lithium ion
Characteristic values	
Max. power consumption under load	120 VA
9.7 fuses	2 Amp. 250 V. 5 mm x 20 mm, slow-blow fuses
Running time without AC power with fully charged batteries	At least 60 minutes (charging duration of at least 5 hours)
Electrical system	Installation in accordance with pertinent regulations is required for use in medical facilities (eg, VDE 0100, VDE 0107, or ICE stipulations). Observe country-specific regulations and national deviations.

EQUIPMENT DESIGN

The Impella® Controller conforms to the applicable requirements of the following standards:

- UL 60601-1 (2003), 1st Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- CAN/CSA C22.2 No 601.1-M90 (1990; Reaffirmed 2005), 2nd Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- EN 60601-1 (1990), 2nd Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety + A1(93) + A2(95) + A1.3(96)*
- IEC 60601-1 (1988), 2nd Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety + A1(91) + A2(95)*
- IEC 60601-1-2 (2001), *Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*
- IEC 60601-1-4 (2000), Edition 1.1 Consolidated Edition *Medical Electrical Equipment, Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems*
- IEC 60601-1-1, (2000/12/01), 2nd Edition *Medical Electrical Equipment, Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems*
- IEC 60601-1-8, (2003/08/01), Edition 1 *Medical Electrical Equipment, Part 1-8: General Requirements for Safety – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems*
- IEC 60601-1-6, (2004/06/01), Edition 1 *Medical Electrical Equipment, Part 1-6: General Requirements for Safety – Collateral Standard: Usability*

EQUIPMENT CLASSIFICATIONS

Type of protection against electric shock	IEC 60601-1: Class I degree of protection: CF defibrillation-proof and internally powered. Relies not only on basic insulation against shock but also includes additional protection. Accomplished by providing means for connecting the equipment to the protective earth conductor of the fixed wiring of the installation in a way that prevents accessible metal parts from becoming live if basic insulation fails.
Degree of protection against electric shock for Impella® Controller	Class I Equipment
Mode of operation	Continuous
Degree of protection against explosion hazard	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Also not suitable for use in an oxygen-enriched atmosphere.
Degree of protection against harmful ingress of water	IEC 60529: IPX1 protected against dripping water.

FEDERAL COMMUNICATIONS COMMISSION (FCC) NOTICE

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by Abiomed, Inc. could void the user's authority to operate this device.

ELECTROMAGNETIC COMPATIBILITY

	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the electromagnetic compatibility (EMC) information provided in this document.
	Portable and mobile RF communications equipment can affect medical electrical equipment.
	The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
	Use of cables, other than those sold by Abiomed, may result in increased emissions or decreased immunity of the Impella® Controller.
	The Impella® Controller uses RFID (radio frequency identification) to identify and communicate with the purge cassette. Other equipment may interfere with the Impella® Controller even if that other equipment complies with CISPR emission requirements.
	During transport, the Impella® Controller may be exposed to stronger electromagnetic disturbance than during in-hospital use. Strong electromagnetic disturbance may cause the Impella® Controller to display soft button menu selections that were not selected by the user. Operators should be aware that, under these conditions, the operating parameters are not affected. No user intervention is required. Monitor Impella® 2.5 Catheter flow and patient hemodynamics to confirm normal operation. The condition will resolve itself once the Impella® Controller is no longer exposed to the disturbance.

NOTE: The EMC tables and other guidelines that are included in this manual provide information to the customer or user that is essential in determining the suitability of the equipment or system for the electromagnetic environment of use, and in managing the electromagnetic environment of use permit the equipment or system to perform to its intended use without disturbing other equipment and systems or non-medical electrical equipment.

TABLE 201
Guidance and Manufacturer's Declaration – Emissions, All Equipment and Systems

The Impella® Controller is intended for use in the electromagnetic environment specified below. The customer or user of the Impella® Controller should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Enforcement – Guidance
RF Emissions CISPR 11	Group 1 Class A	The Impella® Controller uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonics IEC 61000-3-2	Class A	The Impella® Controller is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	Complies	

TABLE 202
Guidance and Manufacturer's Declaration – Immunity

The Impella® Controller is intended for use in the electromagnetic environment specified below. The customer or user of the Impella® Controller should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	±2 kV Mains ±1 kV for input/ output lines	±2 kV Mains ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	> 95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles > 95% dip for 5 seconds	> 95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles > 95% dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Impella® Controller requires continued operation during power mains interruptions, it is recommended that the Impella® Controller be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.

TABLE 203
Guidance and Manufacturer's Declaration – Emissions, Equipment and Systems that are Life-Supporting

The Impella® Controller is intended for use in the electromagnetic environment specified below. The customer or user of the Impella® Controller should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be separated from the Impella® Controller by no less than the recommended separation distances calculated/listed below:
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	$d = 0.6\sqrt{P}$ 80 to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum power rating in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Impella® Controller is used exceeds the applicable RF compliance level above, the Impella® Controller should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Impella® Controller.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m

TABLE 205
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Impella® Controller, Equipment and Systems that are Life-Supporting

The Impella® Controller is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Impella® Controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Impella® Controller as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output	Recommended Separation Distances for the Impella® Controller (m)		
Output Power of Transmitter (Watts)	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0.01	0.12	0.06	0.12
0.1	0.38	0.19	0.38
1	1.2	0.6	1.2
10	3.8	1.9	3.8
100	12	6.0	12

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

RFID Transmitter / Receiver Specifications

Frequency	13.56 MHz
Receiver bandwidth	14 kHz
Effective radiated power	30 nW
Modulation	ASK

ALARM DELAY INFORMATION

For some Impella® Controller alarms, there is a short delay between the triggered event and the audible annunciation and visual display of the alarm.

Impella Defective	8 second delay
Impella Position Wrong	11±5 second delay
Controller Error	12±3 second delay
Emergency Shutdown Imminent	15±1 second delay
Battery Failure	28±8 second delay
Controller Failure	38±8 second delay
Battery Comm. Failure	40±10 second delay
Purge System Blocked	75±45 second delay

PATIENT ENVIRONMENT

The Impella® Controller and the components of the Impella® 2.5 System are approved for use within the patient environment defined in IEC 60601-1-1 and in the figure below.

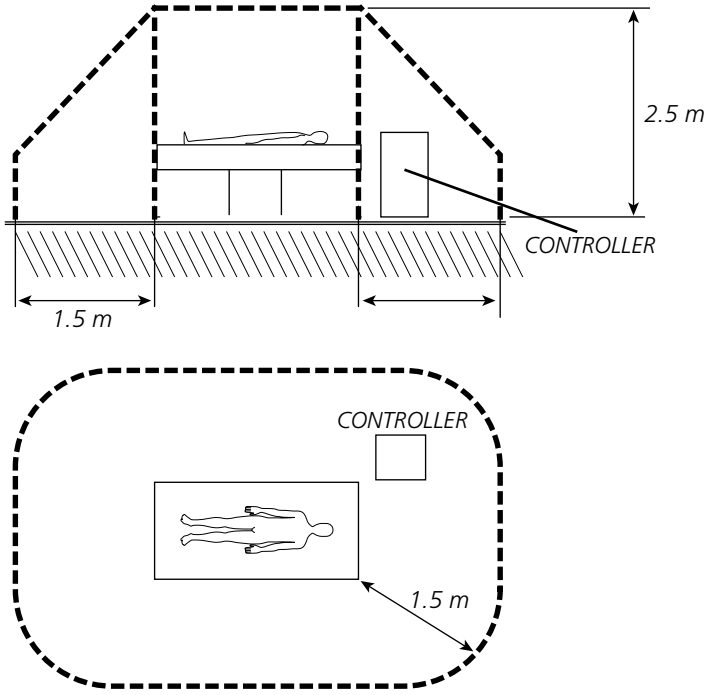


Figure 8.1 Impella® Controller Patient Environment

WHITE CONNECTOR CABLE

Length	2.5 m
Service life	Single use only

IMPELLA® 2.5 CATHETER PARAMETERS

Speed range	0 to 51,000 rpm
Power consumption	Less than 0.99 A
Voltage	Max. 20 V DC
Flow-Maximum	2.5 L/min
Purging the Impella® 2.5 Catheter	
Recommended purge fluid	20% dextrose solution with heparin concentration of 50 IU per mL
Dextrose concentration	5% to 40%
Purge pressure	300 to 1100 mmHg
Infusion rate	2 to 30 mL/h
Maximum duration of use	
EU and Canada	Up to 5 days
Reliability	87.4% with 80% confidence at 5 days based on chi-squared test
Dimensions of Impella® 2.5 Catheter	
Length of invasive portion (without catheter)	130 ± 3 mm
Diameter	Max. 4.2 mm (nom. 4.0 mm)
Classification per DIN EN 60601-1 European Directive 93/42/EEC	Protection class II, degree of protection: CF (Impella® Controller and Impella® 2.5 Catheter)
Classification per MDD/93/42/EEC	Class III
Latex free	Yes

Latex Free

The Impella® Controller and Impella® 2.5 Catheter, including all accessories, are latex free.

IMPELLA® 2.5 CATHETER DIMENSIONS

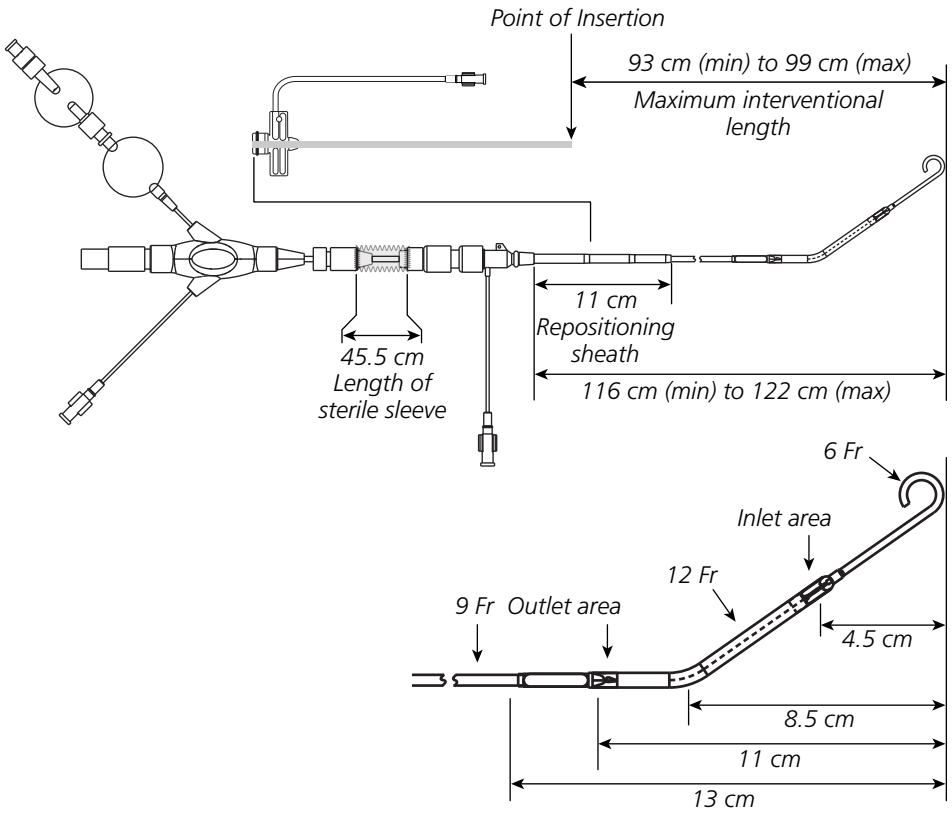


Figure 8.2 Impella® 2.5 Catheter Dimensions

ANATOMIC CONSIDERATIONS

In a small number of cases (about 2 in every 100 patients) the Impella® 2.5 Catheter cannot be successfully placed; or can be placed and the performance is compromised due to patients having anatomic conditions outside of the range for which the Impella® 2.5 Catheter was designed.

The following table describes anatomic conditions that may affect the insertion or operation of the Impella® 2.5 Catheter. Physicians should consider these characteristics when evaluating small or very tall patients for Impella® 2.5 Catheter support.

Condition	Effect
The size and tortuosity of the femoral and iliac arteries	Limits the ability of the Impella® 2.5 Catheter to be advanced from the insertion site into the left ventricle
Distance from the insertion site to the apex of the left ventricle	For very tall patients, the maximum interventional length may not be sufficient to allow correct placement of the Impella® 2.5 Catheter
Systolic left ventricular (LV) long axis < 7 cm	The Impella® 2.5 Catheter may interfere with the mitral valve
Systolic left ventricular (LV) long axis > 11 cm	The Impella® 2.5 Catheter pigtail will not have a surface to push against to help stabilize its position, and may have a tendency to swing or bounce

CLEANING

- Clean the Impella® Controller keypad and display with either 70% isopropyl alcohol or soap and water. (NOTE: Be aware that soft buttons may be activated when you spray or wipe the display.)
- Clean the Impella® Controller housing with mild detergent.
- Do not allow any fluids to enter the connector sockets.
- Clean the connector cable with 70% isopropyl alcohol.

STORING THE IMPELLA® CONTROLLER

The Li-Ion batteries must be charged for 5 hours prior to system operation in order to meet the runtime requirement of 1 hour. Failure to do so will yield a shorter runtime. After being unplugged, the Impella® Controller will operate for at least 60 minutes after the batteries have been fully charged.

- Place the Impella® Controller on a horizontal surface to prevent falling.
- Connect the AC power cord to an AC outlet.
- The battery may be destroyed if the Impella® Controller is stored with a depleted battery.

Storing the Controller

To keep the Impella® Controller battery charged, the controller should be plugged into an AC outlet. When plugged into an AC outlet, the controller battery will charge whether the controller is on or off.

DISPOSING OF THE IMPELLA® 2.5 CATHETER AND ACCESSORIES (EUROPEAN UNION)

The Impella® 2.5 Catheter and connector cable are disposable items that must be disposed of in accordance with hospital regulations for blood contaminated materials.

The Impella® Controller is marked according to Directive 2002/96/EEC. Devices sold within the EEC can be returned to Abiomed Europe GmbH for correct disposal.

RETURNING AN IMPELLA® 2.5 CATHETER TO ABIOMED (UNITED STATES)

To return an Impella® 2.5 Catheter to Abiomed, contact your local Clinical Consultant for an Abiomed-approved return kit.* The kit includes instructions for returning the Impella® 2.5 Catheter to Abiomed.

** Only available in the United States*

APPENDICES

APPENDIX A: IMPELLA® SYSTEM LIMITED SERVICE WARRANTY

IMPELLA® SYSTEM LIMITED SERVICE WARRANTY (UNITED STATES)

Abiomed®, Inc. warrants that, at the time of installation, all Impella® Systems (the "Goods") sold will be free from defects in material and workmanship and remain free from defects under normal use and service for a period of one (1) year from the date of shipment. Extended warranty and service may, at Abiomed's option, be offered for an additional charge, in which event separate or additional terms and conditions may apply. This warranty provides coverage for the Impella® Controller.

This warranty does not cover routine preventative maintenance or replacement parts that are consumed per the controller's periodic maintenance schedule outlined in the Operator's and Service Manuals.

The express warranty set forth on this page is the only warranty given by Abiomed with respect to any goods furnished hereunder. Abiomed makes no other warranty, express, implied or arising by custom or trade usage, and specifically makes no warranty of merchantability or of fitness for any particular purpose. Said express warranty shall not be enlarged or otherwise affected by Abiomed's rendering of technical or other advice or service in connection with the Goods.

Abiomed shall not be liable for incidental or consequential losses, damages or expenses, directly or indirectly arising from the sale, handling or use of the Goods, or from any other cause relating thereto, and Abiomed's sole responsibility under this warranty will be, at its option, to 1) repair or replace the Goods or any components of the Goods found to be defective in workmanship or material during the foregoing warranty period, or 2) to refund the purchase price paid. All replaced components and Goods will become the property of Abiomed. This warranty shall not apply if the Goods have been: (a) repaired or altered in any way by other than Abiomed or Abiomed authorized service personnel; (b) subjected to physical or electrical abuse or misuse; or (c) operated in a manner inconsistent with Abiomed's instructions for use of the Goods. If Abiomed determines that a claim was not caused by Abiomed or Abiomed's authorized service personnel, then Buyer shall pay Abiomed for all related costs incurred by Abiomed. This warranty is not transferable without the express written consent of Abiomed.

Under this warranty, Abiomed will provide at no charge, updates or modifications which directly affect the safe operation of the Goods. Abiomed is not obligated to provide updates or modifications which provide (a) product improvement or enhancement; (b) new product features, or (c) options to the Goods.

Abiomed has no obligation to provide a loaner system during service or maintenance of the Goods. However, at Abiomed's sole discretion, Abiomed may provide such loaner systems.

This warranty applies to the Impella® Controller and not to any disposable or other component of the Impella® System. Specific items excluded from this warranty include, but are not limited to, pumps, external tubing, and accessories.

This warranty may not be amended without the express written consent of an authorized officer of Abiomed.

IMPELLA® SYSTEM LIMITED SERVICE WARRANTY (EUROPE)

Please contact your EU representative for warranty information.

APPENDIX B: TECHNICAL SAFETY INSPECTIONS, MAINTENANCE, AND REPAIR

TECHNICAL SAFETY INSPECTIONS

In accordance with the specification issued by Abiomed as per §6 MPBetreibV (German regulation), the Impella® Controller must be subject to yearly technical safety inspections. Technical safety inspections may only be carried out by authorized technicians in accordance with the technical safety inspection requirements presented below and must be documented in the medical product logbook in accordance with §7 MPBetreibV.

A sticker on the device indicates the date for the next required inspection. Figure B.1 shows a sticker indicating that inspection is required in May 2012. However, the stipulations in the medical product logbook are binding in any case.

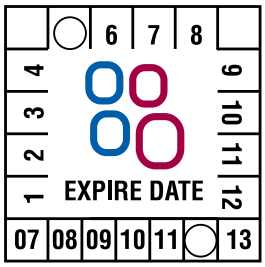


Figure B.1 Inspection Sticker Showing Inspection Required in May 2012

The following technical safety inspections are required for the Impella® Controller:

- Inspection of labeling and instructions for use
- Visual inspection of the device and its accessories for any signs of damage
- Testing for electrical safety as per DIN VDE 751 or DIN EN 60 601
- Leakage current test
- Dielectric strength test
- Functional testing of all switches, keys, rotary knobs, sockets, and control lights on the device
- Checking battery operation

If defects become apparent during the technical safety inspections that could endanger patients, employees, or third parties, then the device must not be operated until the defects have been remedied by proper technical servicing.

MAINTENANCE AND REPAIR

The Impella® Controller is subject to 1 year maintenance and repair intervals. The corresponding work must be performed by technicians authorized by Abiomed, and must be documented in the medical product logbook in accordance with §7 MPBetreibV (German regulation).

APPENDIX C: ABIOMED-APPROVED GUIDEWIRES AND INTRODUCERS

ABIOMED-APPROVED GUIDEWIRES

Use only Abiomed-tested and supplied guidewires with the Impella® 2.5 Catheter. Guidewires are specifically designed with unique characteristics to optimize performance of the Impella® 2.5 System. Guidewires and catheters should always be used in accordance with Abiomed's instructions.

Table C.1 lists the alternative guidewires that have been tested and approved for use with the Impella® 2.5 System.

Table C.1 Alternative Guidewires

Guidewire	Catalog number
Boston Scientific Platinum Plus™ ST 0.018 in	46-605, model ST/0.018/260
Boston Scientific Platinum Plus™ ST 0.014 in	1752 (H74917520), model ST/.014/300
Boston Scientific V-18 Control Wire™ ST 0.018 in	46-854, model V18/18/300
Abbott SteelCore™ 18	1003282

ALTERNATIVE QUALIFIED INTRODUCER SHEATHS

Abiomed has developed and qualified a 13 Fr introducer kit for use with the Impella® 2.5 Catheter. This kit was specifically designed for use with the Impella® 2.5 Catheter and takes into account several technical parameters, such as:

- Size of the sheath (internal diameter and length)
- Blood leakage through the hemostatic valve
- Force required to pass the device through the hemostatic valve
- The ability to replace the introducer with a longer-term sheath

Testing and qualification, based on the above criteria, has been completed.

Table C.2 describes alternative introducer sheaths. Use this information to evaluate the performance of these alternative introducer sheaths relative to each other and to the Abiomed-provided introducer.

Table C.2 Alternative Introducer Sheaths

Manufacture	Model	Fr	Length
Cook Incorporated	Check-Flo® II	14	13 cm
Cook Incorporated	Check-Flo® Performance Introducer	14	30 cm
St. Jude Medical	FastCath™ Hemostasis Introducer	13, 14	12 cm, 30 cm

APPENDIX D: IMPELLA® CONTROLLER MENU STRUCTURE

OVERVIEW

The soft buttons on the Impella® Controller provide access to the controller menu structure. The menu structure has 5 main elements:

- **MUTE ALARM**
- **P-LEVEL**
- **DISPLAY**
- **PURGE SYSTEM**
- **MENU**

This Appendix provides an overview of the Impella® Controller menu structure. Many of the functions accessed through this menu structure are also discussed elsewhere in this manual.

MUTE ALARM

The **MUTE ALARM** soft button mutes (silences) active alarms. It does not open another menu.

When you press **MUTE ALARM**, a bell icon with an X through it replaces the words "MUTE ALARM" in the upper right of the display screen. If no alarms are active, no bell icon is displayed. When you press **MUTE ALARM** it acknowledges all active alarms and silences the audible alarm indicator for 2 minutes (for red or yellow alarms) or 5 minutes (for white alarms). (Refer to section 7 of this manual for more information about Impella® Controller Alarms.)

P-LEVEL

The **P-LEVEL** soft button opens the performance level icon enabling you to select the desired performance level. The performance level icon is shown in Figure 5.20 in section 5 of this manual and the procedure for setting performance level is described in "Positioning and Starting the Impella® 2.5 Catheter" in section 5.

DISPLAY

The **DISPLAY** soft button opens a menu that includes the following options for viewing waveforms and navigating to other screen displays:

- **Y-axis Scale** – opens a menu from which you can select a waveform and change its appearance by adjusting the scale of the y-axis.

  Once the waveform is selected, turn the selector knob clockwise to increase the y-axis scale and counterclockwise to decrease the y-axis scale.

  Select **OK** to accept the new y-axis scale.

  Select **Restore** to return to the default y-axis scale.

  Select **Initial** to set the y-axis to the previously set scale.

  Select **Center Signal** to center the waveform.

  Select **Cancel** to exit the tool.

- **Time Scale** – allows you to apply different time scales to the currently displayed waveforms.
- **Center** – automatically centers the motor current waveform and adjusts the range accordingly.
- **Infusion** – opens the Infusion History screen. The Infusion History screen, which is discussed in "Infusion History" in section 6 of this manual, shows the volume and amount of heparin and dextrose delivered. The top entry in the table shows the volume and amount of heparin and dextrose infused from the top of the hour through the current time.
- **Purge** – displays the purge system waveforms and pressure and flow values.
- **Placement** – opens the placement signal / motor current waveform screen (described in section 4 under "Impella® Controller Waveform Screen").
- **Home** – opens the home screen (described in section 4 under "Impella® Controller Waveform Home Screen").

PURGE SYSTEM

The **PURGE SYSTEM** soft button opens a menu that includes the following purge system procedure options:

- **Change Purge Fluid** – starts the procedure to change the purge fluid
- **Change Purge Cassette** – starts the procedure to replace the purge cassette
- **Change Purge System** – starts the procedure to change both the purge fluid and purge cassette
- **De-air Purge System** – starts the de-air procedure
- **Transfer to Standard Configuration** – starts the procedure for transferring from the set-up configuration of the Impella® 2.5 System to the standard configuration.

These procedures are described in section 5 of this manual.

MENU

The **MENU** soft button opens a menu of options related to controller settings, alarm history, repositioning, and starting a procedure. The menu includes the following options:

- **Settings / Service** – allows you to set screen brightness, select the language for the system displays, display system information, or adjust the low flow limit.

  Screen Brightness. Opens the Screen Brightness selection box. The brightness of the screen display can be set from 50% to 100%. Select **OK** to confirm selection. Select **Cancel** to cancel selection.

  Language. Opens the Language selection box. Use the selector knob to select German, English, French, Italian, Spanish, or Dutch. The system will immediately change the language on the controller for all displayed text. This language will be used after system restart unless another language is selected.

  System Information. Opens the System Information table. This provides information about the software version, IP addresses, current type of Impella Catheter, and current catheter runtime.

  Low Flow Limit. Opens the Low Flow Limit box. Use the selector knob to adjust the low flow limit from 0.5 to 9.9 L/min in increments of 0.1 L/min. Select "Set Default" to set the low flow limit to the currently measured average flow rate minus 0.3 L/min. (The minimum low flow limit is 0.5 L/min.) Select "OFF" to turn off low flow limit monitoring. Press the selector knob to confirm your selection. NOTE: If the current limit is off, the default low flow limit value will be the initial value.

- **Alarm History** – opens the Alarm History table. This provides a visual display of the chronology of stored alarm messages. The most recently occurring alarm message is displayed at the top of the list. For each message, the date and time it occurred and the alarm message heading is displayed. You can use the selector knob to select individual alarm messages and an explanation for the selected alarm message will be displayed in the failure description box. Press **EXIT** to exit the alarm history analysis.
- **Data Snap Shot** – starts the Data Snap Shot function to save real-time operating data for later analysis. Data Snap Shot is described under "Data Snap Shot" in section 6 of this manual.
- **Start Repositioning Guide** – opens the repositioning guide, which provides information about the current position of the Impella® 2.5 Catheter and the actions required to reposition the catheter. The repositioning guide is described under "Repositioning Guide" in section 6 of this manual.
- **Case Start** – begins the case procedure. Case Start is described in section 5 of this manual under "Case Start."

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Impella® 2.5 Catheter, 0.018 inch Guidewire
Manufactured by Abiomed Europe GmbH
CE 0482

Impella® Controller, Impella® Purge Cassette
Manufactured by Abiomed, Inc.
CE 0086