Impella® Controller

With Impella® 2.5
Circulatory Support System

INSTRUCTIONS FOR USE

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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® CONTROLLER WITH IMPELLA® 2.5 CIRCULATORY SUPPORT SYSTEM INSTRUCTIONS FOR USE

Rx Only

Abiomed, Inc.
22 Cherry Hill Drive
Danvers, MA 01923
978-777-5410 (voice)
978-777-8411 (fax)
clinical@abiomed.com (email)

Abiomed Europe GmbH
Neuenhofer Weg 3
52074 Aachen, Germany
+49 (241) 8860-0 (voice)
+49 (241) 8860-111 (fax)
europe@abiomed.com (email)

www.abiomed.com

24-Hour Emergency Hotlines:
N. America 1-800-422-8666
Europe +49 (0) 1805 2246633

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INTRODUCTION

PURPOSE OF MANUAL

This Instructions for Use manual is designed for healthcare professionals. It contains clinical and technical considerations to guide healthcare professionals in their use of the Impella® Controller with the Impella® 2.5 Catheter. The Impella® 2.5 and Impella® Controller perform life-sustaining functions. Use of these components requires a thorough understanding of and adherence to these instructions for use. The Impella® Controller with the Impella® 2.5 may only be used for its intended purpose.

MANUAL OVERVIEW

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

- **Section 1: Warnings and Cautions** discusses the warnings and cautions pertaining to the use of the Impella® Controller with the Impella® 2.5.
- **Section 2: Indications, Contraindications, and Potential Adverse Events** discusses indications for use of the Impella® Controller with the Impella® 2.5 and potential adverse events.
- **Section 3: The Impella® 2.5 and Impella® Controller** provides an overview of the blood pump and controller and describes the major components and features of each.
- **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** provides the procedures for using the controller and blood pump.
- **Section 6: Patient Management Topics** provides key information on various topics related to management of patients with the Impella® Controller and Impella® 2.5.
- **Section 7: Cleaning, Storage, Disposal, and Returns** provides instructions on cleaning and storing the components, as well as disposing of components and returning components to Abiomed.
- **Section 8: Terminology, Abbreviations, and Symbols** provides definitions for key terms that appear in the manual as well as descriptions of the abbreviations and symbols that appear on Impella® Controller and Impella® 2.5 components and packaging.
- **Section 9: System Specifications** lists technical information pertaining to the Impella® Controller and Impella® 2.5.
- **Section 10: Impella® Controller Alarms** provides a listing of Impella® Controller alarms and notifications as well as information on what to do to resolve them.
- **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 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. 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.

Do ***NOT*** resterilize or reuse the Impella® 2.5 Catheter. It is a disposable device and is intended for single use only.

Retrograde flow will occur across the aortic valve if the Impella® 2.5 is set at a flow rate of 0 L/min.

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.

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.

If at any time during the course of support with the Impella®, the Impella® Controller alarms "Impella Failure: Sudden Purge Pressure Drop," follow the instructions presented in Section 5 of this manual.

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

During defibrillation, do ***NOT*** touch the pump, 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 the accompanying documents.

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.

CAUTIONS

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*** touch the inlet or outlet areas of the catheter and avoid manual compression of the inlet cannula assembly while placing the device.

Patients with aortic stenosis or other abnormal aortic valve performance may be compromised by the use of the Impella® 2.5. 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 4 minutes. The Impella® 2.5 Catheter may be damaged if replacement takes longer than 4 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 10 hours prior to system operation. 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.

Cautions

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

The use of high-frequency surgical devices may cause temporary interference to the sensor signals. If continuous interference persists, the following warning message appears on the display screen: "Sensor Value not Reliable." Please acknowledge this message. There is no reason to discontinue use of the pump.

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

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

2 INDICATIONS, CONTRAINDICATIONS, AND POTENTIAL ADVERSE EVENTS

INDICATIONS

INDICATIONS FOR USE IN THE UNITED STATES

The Impella® 2.5 Circulatory Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The Impella® 2.5 Circulatory Support System also provides pressure measurements which are useful in determining intravascular pressure.

INTENDED USE IN THE EUROPEAN UNION 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

Investigational Device Exemption (IDE) Clinical Trials

In addition to the indications for use outlined in this IFU, the Impella® 2.5 Circulatory Support system is being evaluated in various FDA approved clinical trials for additional indications and patient populations. Refer to the study protocols for additional indications, contraindications, and inclusion and exclusion criteria if the device is being used under a clinical trial protocol.

CONTRAINDICATIONS

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

CONTRAINDICATIONS IN THE UNITED STATES

- Mechanical aortic valve or heart constrictive device.
- Aortic valve stenosis/calcification (graded as ≥ +2 equivalent to an orifice area of 1.5 cm^2 or less).
- Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as ≥ +2).
- Severe peripheral arterial obstructive disease that would preclude Impella® 2.5 device placement.

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)

POTENTIAL ADVERSE EVENTS

POTENTIAL ADVERSE EVENTS (US)

- Death
- Aortic insufficiency
- Arrhythmia
- Bleeding
- Cardiogenic shock
- Hemolysis
- Insertion site infection
- Perforation
- Respiratory dysfunction
- Thrombocytopenia
- Transient ischemic attack (TIA)
- Ventricular fibrillation
- Cerebral vascular accident (CVA) / Stroke
- Aortic valve injury
- Atrial fibrillation
- Cardiac tamponade
- Device malfunction
- Hepatic failure
- Myocardial infarction
- Renal failure
- Sepsis
- Thrombotic vascular (non-CNS) complication
- Vascular injury
- Ventricular tachycardia

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 AND IMPELLA® CONTROLLER

OVERVIEW

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

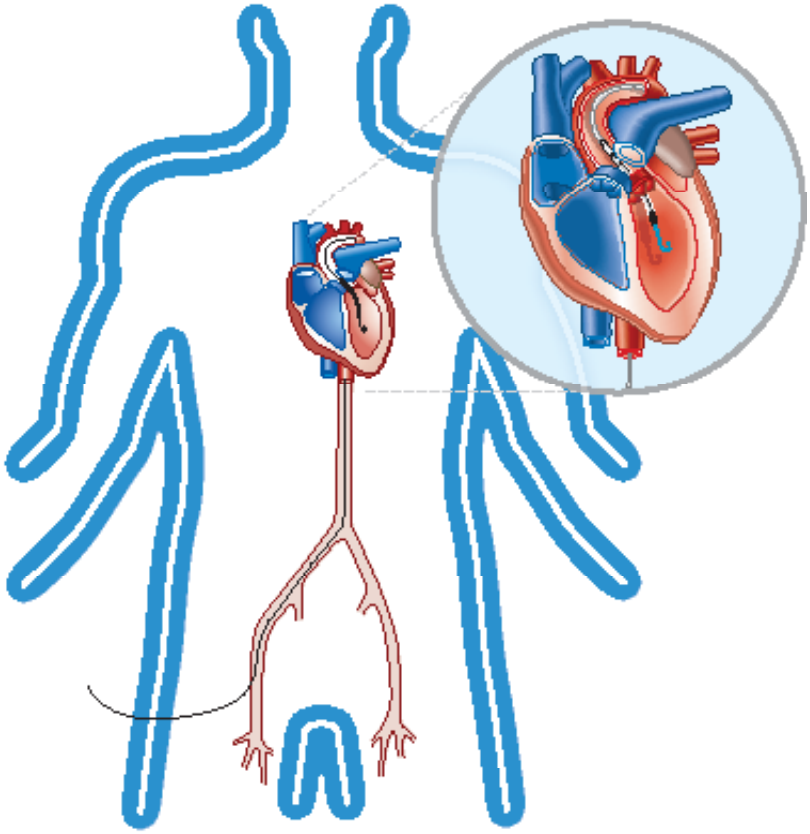


Figure 3.1 Impella® 2.5

When properly positioned, the pump 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 pump on the display screen of the Impella® Controller.

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

Figure 3.2 illustrates how the Impella® Controller connects to the Impella® 2.5 and accessory components.

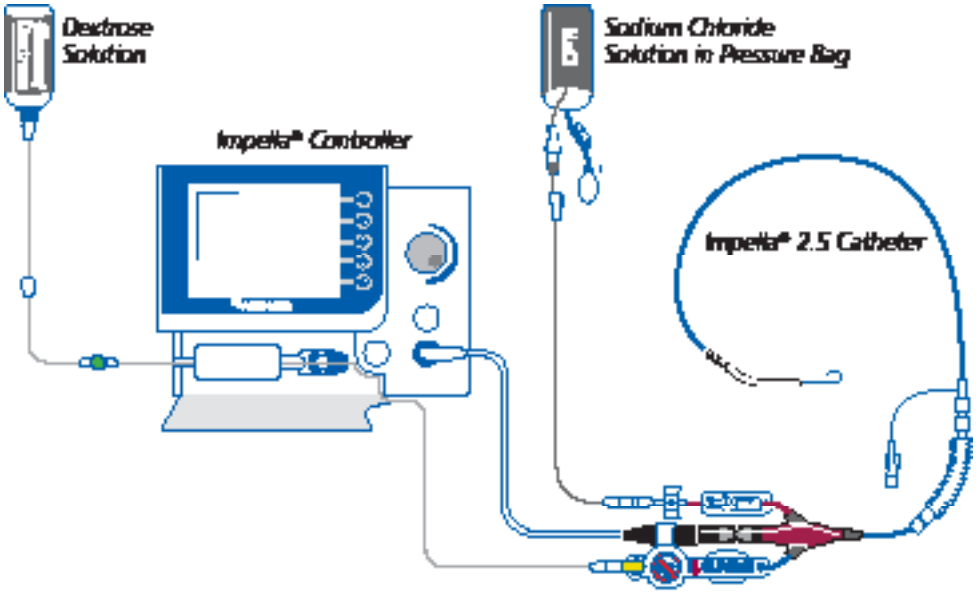


Figure 3.2 Impella® Controller, Impella 2.5, and Accessories

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 3.3 illustrates the Impella® 2.5 Catheter. Table 3.1 describes each component from the pigtail at one end to the check valve on the other end.

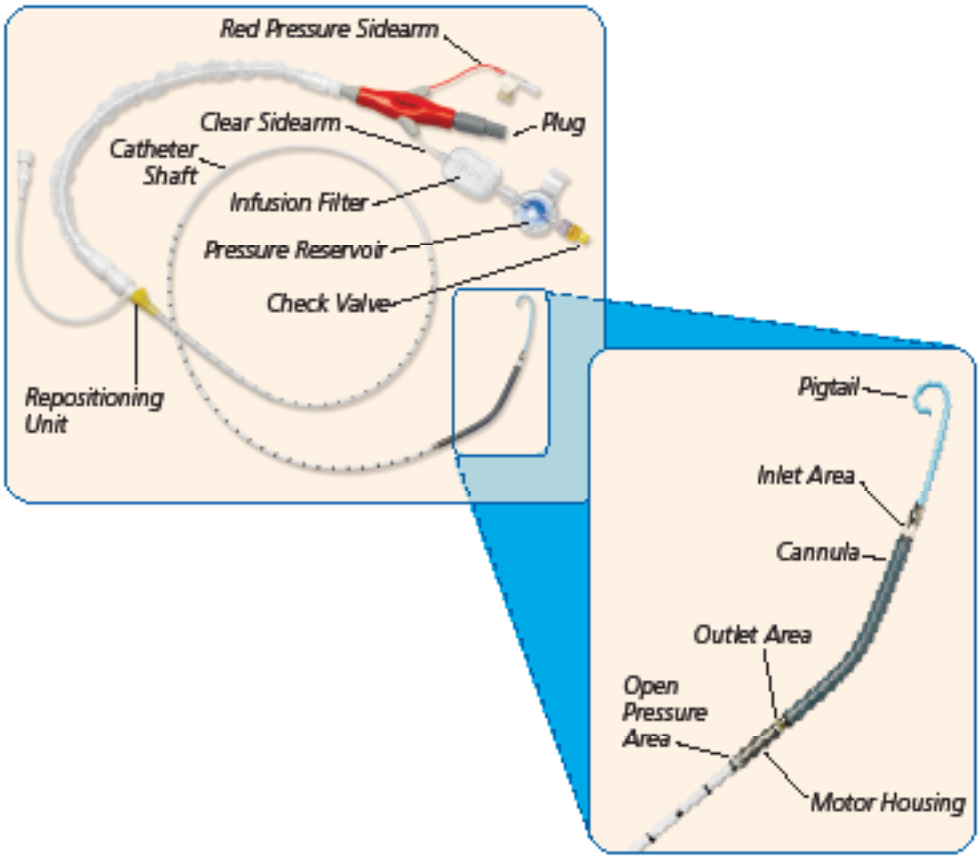


Figure 3.3 Impella® 2.5 Catheter

Table 3.1 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.
Cannula	The 12 Fr cannula has a spiral-shaped reinforced body that is shaped in a 45-degree angle.
Inlet area	The inlet area, where the blood enters the cannula, is located at the distal tip of the cannula.
Outlet area	The proximal end of the cannula is attached to the outlet area where the blood exits the cannula.

Table 3.1 Impella® 2.5 Catheter Components (cont'd)

Component	Description
Motor housing	The motor housing is 12 Fr in diameter and consists of a completely 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 plug. The lumen of the catheter shaft contains a purge lumen, a pressure measurement lumen, and a pump monitoring cable. The catheter shaft has longitudinal and transversal marks: • The longitudinal marks along the inner radius of the cannula show the position of the curved, flexible cannula. • The transversal marks at 1 cm intervals aid in proper positioning.
Repositioning unit	The repositioning unit consists of an introducer and an anticontamination sleeve with an anchoring ring. • The introducer (with hemostatic valve) is graduated from 11 Fr to 15 Fr. It is located on the catheter shaft and allows repositioning of the catheter. • The anchoring ring of the anticontamination sleeve secures the catheter sheath to the introducer.
Plug	The plug at the proximal end of the catheter connects the catheter to the Impella® Controller through a connector cable. 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 purge line. It leads to the infusion filter, the pressure reservoir, and the check valve.
Infusion filter	The infusion filter prevents bacterial contamination and prevents air from entering the catheter.
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.

IMPELLA® CONTROLLER

The Impella® Controller (see Figure 3.4) provides three vital functions to the operation of the Impella® 2.5:

- The controller provides an interface for monitoring and controlling the function of the Impella 2.5
- The controller provides a fluid purge to the Impella 2.5 motor
- The controller provides backup power when the controller 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.

Impella® Controller Battery Power

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

Figure 3.4 Impella® Controller – Front View

PURGE CASSETTE

Do not use saline in the purge system.

The purge cassette delivers rinsing fluid to the Impella® pump. The purge fluid (typically 20% dextrose solution plus heparin 50 IU/mL) flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the pump motor. Figure 3.5 illustrates the purge cassette and related components. Table 3.2 describes each component.

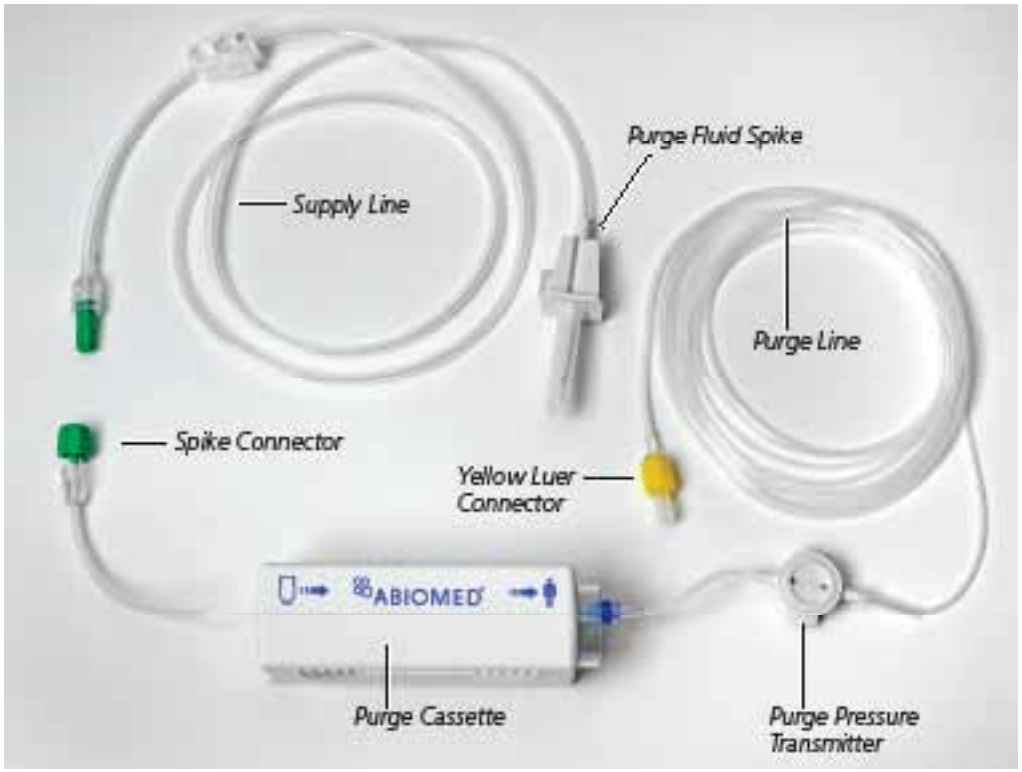


Figure 3.5 Purge Cassette

Table 3.2 Purge Cassette Components

Component	Description
Purge cassette	Contains the components for circulating the purge fluid; maintains the pressure barrier between the blood and the motor at the proper level
Purge pressure transmitter	Contains a membrane that transmits pressure to the controller based on the purge pressure in the purge line; a transducer in the controller measures the pressure so that it can be displayed on the screen
Purge line	Carries purge fluid from the purge cassette to the Impella® pump
Yellow luer connector	Connects the purge line to the pressure reservoir (yellow luer lock) on the Impella® pump
Purge fluid spike	One end spikes the purge fluid bag and the other end connects the bag to the purge cassette supply line
Spike connector	Connects the purge cassette supply line to the purge fluid spike
Supply line	Carries fluid from the purge fluid bag to the purge cassette

ACCESSORIES

Table 3.3 illustrates and describes the accessories used with the Impella® 2.5 and Impella® Controller.

Table 3.3 Impella® 2.5 and Impella® Controller Accessories

Component	Description
 ***Figure 3.6 White Connector Cable***	The white connector cable connects the Impella® 2.5 Catheter to the Impella® Controller. The connector cable is attached to the Impella® pump in the original packaging. • The socket at the black end of the cable connects to the Impella® catheter plug. • The white plug at the opposite end of the cable is inserted into the blue pump plug on the front of the Impella® Controller.
 ***Figure 3.7 Introducer Kit***	The introducer kit is used to position the pump. It contains: • 13 Fr peel-away introducer with hemostatic valve • 13 Fr dilator • 18 G Seldinger needle • 10 cc syringe • 0.035 in stiff guidewire
 ***Figure 3.8 0.018 in/260 cm Placement Guidewire***	The 0.018 in/260 cm placement guidewire is used for the placement of the catheter. The guidewire has a radiopaque, shapable tip.

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
	20% dextrose solution with 50 IU/mL of heparin is used as the purge fluid. The purge cassette infuses the purge fluid through the catheter.

Figure 3.9 20% Dextrose in Water

	The Impella® Controller Cart holds the Impella® Controller. The cart has wheels for easy transport of the controller and a storage basket.

Figure 3.10 Impella® Controller Cart

4 USING THE IMPELLA® CONTROLLER

OVERVIEW

The Impella® Controller is the primary user control interface for the Impella® 2.5. It controls the pump performance, monitors the Impella® 2.5 for alarms, and provides real time catheter position information regarding the location of the pump 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

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

Figure 4.1 Impella® Controller Features – Front and Side Views

Table 4.1 Impella® Controller 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, navigate, 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 4.2) When the pump is running the default soft button labels are as follows: • **MUTE ALARM** • **TARGET FLOW** • **DISPLAY** • **PURGE SYSTEM** • **MENU**
Selector knob	Rotating push button; turn clockwise and counterclockwise to scroll through menu items; push to make a selection. NOTE: In many situations, selector knob function is circular—that is, once you scroll to the end of the list of selections, the system circles through the list again as you continue to turn the knob. On some screens, however, the selector knob function is NOT circular and you must turn the knob in the reverse direction to get to previous items.
Pump plug	Connection point on the controller for the Impella® pump
Purge cassette door	Spring-loaded door that opens to provide access to the purge cassette
Purge cassette	Contains the components for circulating purge fluid; maintains the pressure barrier between the blood and the motor at the proper level. (The purge cassette and its components are described in Section 3 of this manual.)
Purge pressure transmitter	Applies pressure to the transducer in the controller so that purge presure can be measured
Bed mount	Metal bracket on the back of the controller; attaches controller to the bed
Purge cassette door release	Located on the left side of the controller; press to open the purge cassette door
RS-232 service jack	Interface for data transfer to an external device
USB connector	Connection for downloading data
Ethernet jack	Connection for downloading data or software upgrades
Equipotential ground stud	Used to ground the Impella® Controller according to hospital procedures
AC fuses	Electrical safety device in the event of current overload
Power cord retainer mounting holes	For mounting power cord retainer
Power switch	Turns the controller ON or OFF • ON: Press and hold the power switch key for 3 seconds • OFF: (1) Disconnect the Impella® Catheter from the Impella® Controller. (2) Press and hold the power switch for 3 seconds. (3) Press OK 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 hardware switch-off
AC plug	Connection point on the controller for the AC power cord

IMPELLA® CONTROLLER HOME SCREEN DISPLAY

The home screen displays operating parameters and information for the entire system. Figure 4.2 illustrates the Impella® Controller home screen display. Each element of the display is described in Table 4.2.

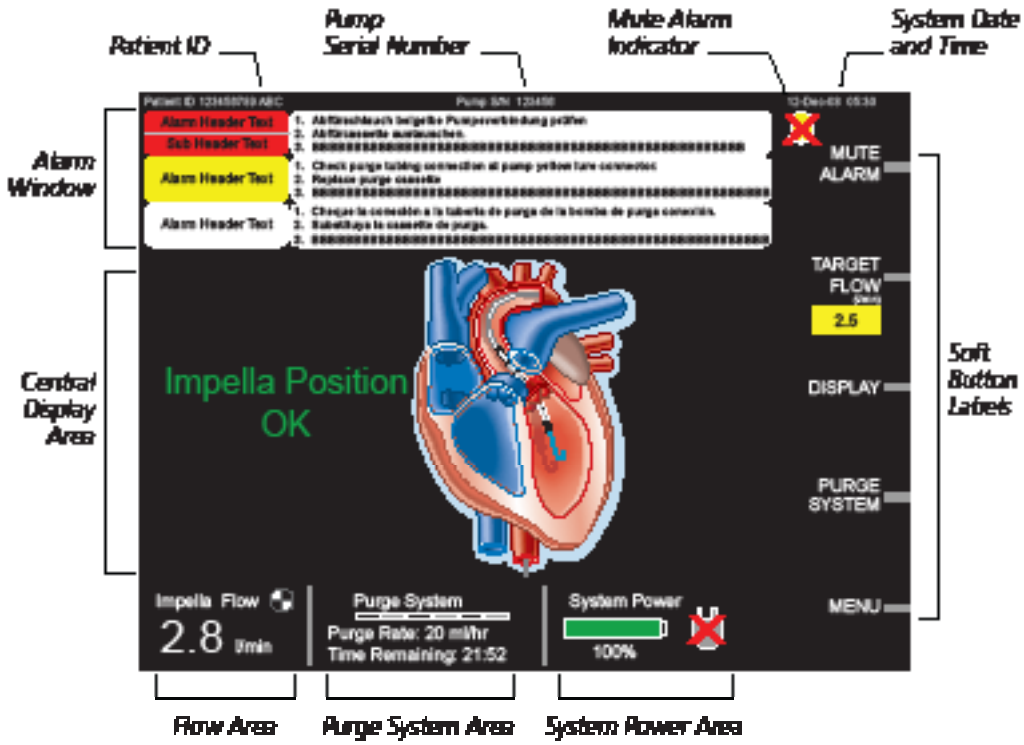


Figure 4.2 Impella® Controller Home Screen Display

Table 4.2 Impella® Controller Display Elements

Display Element	Description
Patient identification (ID)	Displayed in the upper left corner of the display screen if the information has been entered. The Patient ID can be up to 31 characters in length.
Pump serial number	Displayed in the upper center of the display screen if a blood pump is connected to the controller.
System date and time	The current date and time (24-hour format) are displayed in the upper right corner of the screen display.
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 warning 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 10 of this manual for further discussion of Alarms.)

Table 4.2 Impella® Controller Display Elements (cont'd)

Display Element	Description
Supply line	Carries fluid from the purge fluid bag to the purge cassette
Mute Alarm indicator	Displayed below the system date and time in the upper right of the display screen. (See Section 10 of this manual for more information about the Mute Alarm function.) • 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. **MUTE ALARM** • Mutes (silences) active alarms **TARGET FLOW** (or **NEXT**) • **TARGET FLOW** – Brings up the target flow icon, which enables users to set the current flow rate for the Impella 2.5 • **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 making changes in purge fluid, purge cassette, or the purge system, or de-airing the purge system • **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 procedure • **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 25% and 50% charged • Partial red bar for battery that is less than 25% charged • Moving gray bar indicates battery is in charging mode • Numeric percentage of battery power remaining displayed below the battery icon AC plug indicator • Green plug symbol indicates that the controller is running on AC power • Gray plug icon with a red X indicates no AC power detected and the controller is running on battery power

Table 4.2 Impella® Controller Display Elements (cont'd)

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 • Strobes from left to right when the purge system is operating • Slow strobing represents normal purge flow rate • Fast strobing represents bolus flow rate Purge rate • Current purge rate displayed in mL/hr below the purge system marquee if the purge rate is known • Not displayed if there is no purge cassette or 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® flow is displayed in the lower left corner of the display screen Current flow rate • Mean pump flow displayed in liters per minute (L/min)—the numbers appear in *white* if the pump position is correct; *yellow* if the pump 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" Pump icon • The circular pump icon rotates when the blood pump is running
Central display area	On the home screen, the central display area displays a heart pictogram and Impella® position indicator message. Heart pictogram appears in the center of the home screen display • Provides a visual representation of the current Impella® pump position • Overlaid with a translucent yellow "?" when the controller detects an incorrect pump position or cannot detect pump position Impella® position indicator message displayed to the left of the heart image • Displays "Impella® Position OK" in green when pump position is correct • Displays "Impella® Position Unknown" in yellow when pump position is unknown • Displays specific message in yellow when pump position is incorrect

IMPELLA® CONTROLLER WAVEFORM SCREEN DISPLAY

The waveform screen (see Figure 4.3) displays operating data for the system. The screen displays up to two waveforms and current pump data in the central display area of the screen.

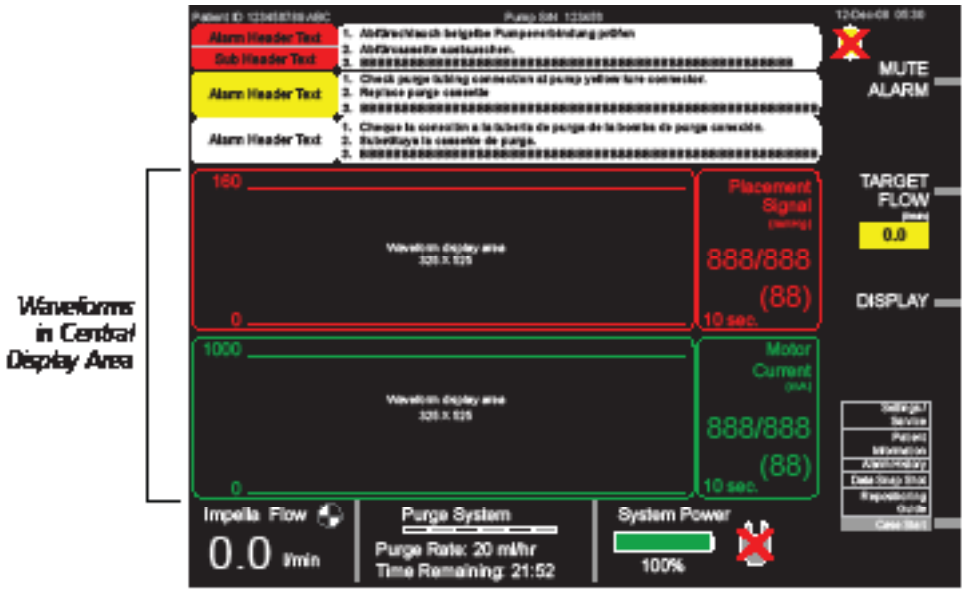


Figure 4.3 Waveform Screen Display (Waveform TBD)

Figure 4.3 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 corresponds to the location of the open pressure area of the catheter. 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 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.

To the left of the waveform is a display that labels the waveform, provides the units of measurement, shows the upper and lower range values, and the average value from the samples received from the last value update. At the bottom of that window is the time scale, which can be set to 10 seconds, 5 minutes, or 5 hours using the **DISPLAY** soft button. The default time scale is 10 seconds.

Motor Current

Motor current is the measurement of electricity through the Impella® motor required to rotate the Impella® microaxial pump.

MOTOR CURRENT WAVEFORM

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

To the left of the waveform is a display that labels the waveform, provides the units of measurement, shows the upper and lower range values, and the average value from the samples received from the last value update. The time scale at the bottom of that window can be set to 10 seconds, 5 minutes, or 5 hours using the **DISPLAY** soft button. The default time scale is 10 seconds.

5 USING THE IMPELLA® CONTROLLER WITH THE IMPELLA® 2.5

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 10 hours prior to system operation. 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.

TURNING ON THE IMPELLA® CONTROLLER

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 (Figure 5.2) appears when you successfully turn ON the Impella® Controller.

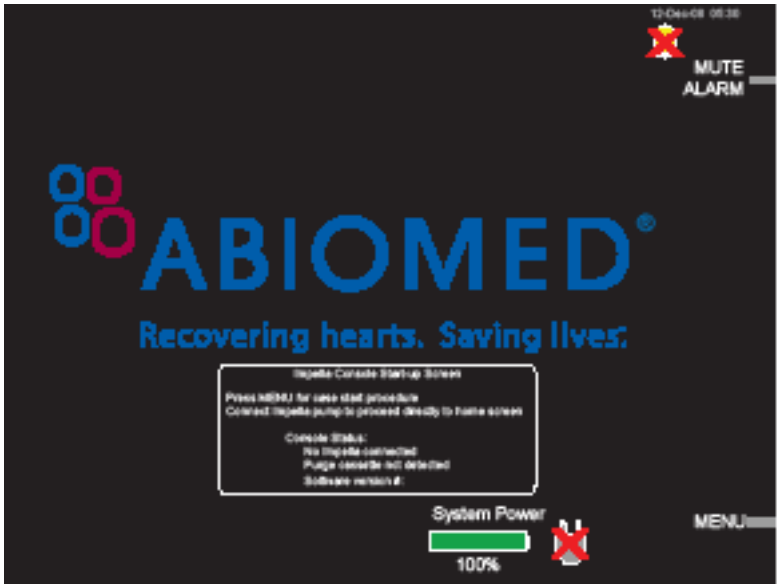


Figure 5.2 Impella® Controller Startup Screen

The startup screen displays:

- The current status of the Impella® pump (currently no pump 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.

STARTING A CASE PROCEDURE

To start a case procedure:

1. Press the **MENU** soft button from the startup screen.
2. Scroll the selector knob to "Case Start" on the pop-up menu that appears on the screen.
3. Press the selector knob to select "Case Start".

After you press the selector knob to select "Case Start" from the menu, the controller displays an 8-screen series that leads you from initial setup through the pre-insertion Impella® test.

CASE START


Fluoroscopy is required to guide placement of the Impella® 2.5. 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.


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*** touch the inlet or outlet areas of the catheter and avoid manual compression of the inlet cannula assembly while placing the device.


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

Sensitive Medical Device

The Impella® 2.5 Catheter is a sensitive medical device with a microaxial pump with extremely fine tolerances. In particular, the inflow and outflow areas of the distal and proximal areas of the pump assembly may be damaged if subjected to strong external forces.

OVERVIEW

You will need the following materials to complete the setup before starting the case:

- 500 cc bag of D20 with 50 IU of heparin per cc. (Recommended)
- IV flush solution (NaCl) with pressure bag and 96 inches of sterile infusion line.
  NOTE: The distal end of the infusion line must remain sterile.

The Impella® Controller displays eight screens of instructions to lead you through a case start:

- Initial setup
- Prime purge tubing
- Enter purge fluid data
- Plug Impella® into controller
- Prime Impella® purge lumen
- Prime blood pressure lumen
- Pre-insertion Impella® test
- Impella® test successful

INITIAL SETUP

1. Open the purge cassette package.

2. Using sterile technique, connect the purge fluid spike to the spike connector on the end of the purge fluid supply line. Secure the yellow luer connector and pass the purge cassette and supply line to the Impella® Controller operator.

Shaded Steps

All shaded steps require sterile technique.

Selector Knob Function

The selector knob function here is NOT circular (you CANNOT keep turning the knob in one direction to scroll between START and STOP). Turn the knob clockwise to scroll to STOP and counterclockwise to scroll to START.

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 5.3).
   - 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.
   - Slide the purge pressure transmitter into the slot to the right of the purge cassette until it snaps into place.
   - Extend the purge line 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 line as it exits.

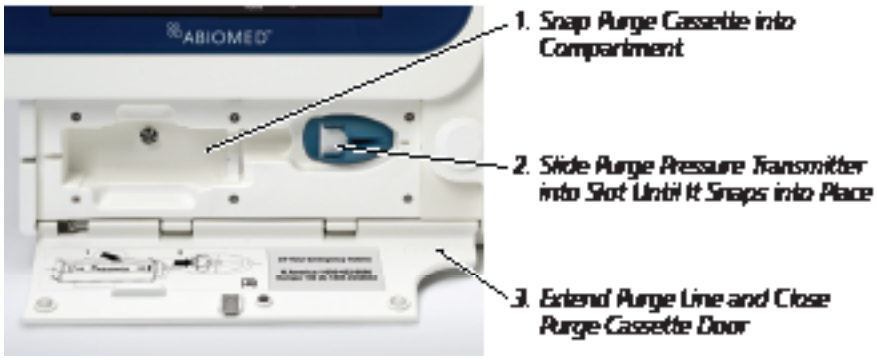


Figure 5.3 Inserting Purge Cassette into Impella® Controller

4. Spike the purge fluid bag with the purge fluid spike attached to the end of the supply line and hang the purge fluid bag.
5. Press the **NEXT** soft button to advance to the next screen.

PRIME PURGE TUBING

1. Use the selector knob to scroll to START on the screen and press the knob to begin priming the purge line. The controller will start the priming process at a bolus rate of 250 mL/hr or greater.
2. When purge fluid is discharged from the tip of the yellow Impella® connector at the end of the purge line, scroll to STOP and press the selector knob to stop the flow of purge fluid.
3. Press **NEXT** after selecting STOP to proceed to entering purge fluid data.

If you press the **BACK** button on this screen, the controller will return to step 1 of priming the purge tubing.

If you do not press STOP within 60 seconds of pressing START, you will get a message that the purger has stopped. Press **BACK** if additional purging is required. If the purge fluid has been discharged from the purge tubing and priming is complete, press **NEXT**.

ENTER PURGE FLUID DATA

The Impella® Controller displays a table of recommended default values for the purge fluid (see Figure 5.4).

1. 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 you to the next screen.

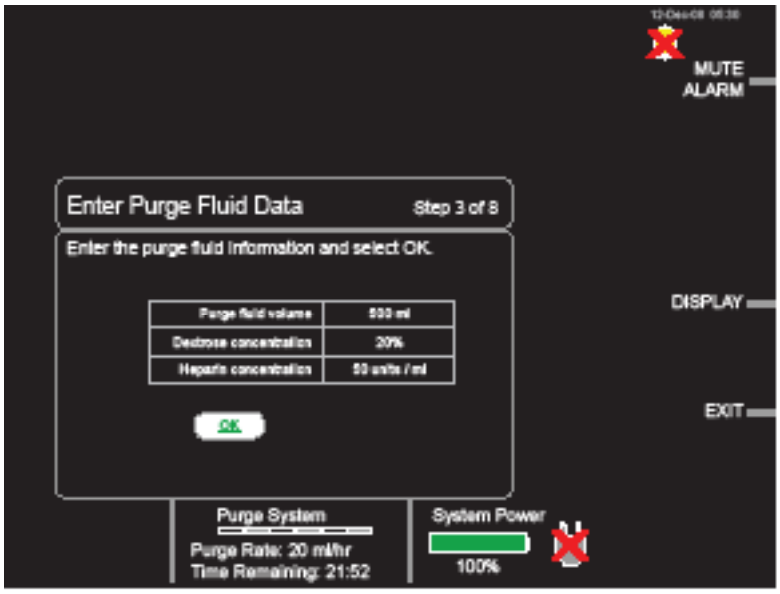


Figure 5.4 Default Values for Purge Fluid

2. To change the purge fluid information, scroll to the appropriate item 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 100 mL, 250 mL, 500 mL (the default), or 1000 mL.
   - Dextrose concentration can be set to 5%, 10%, 20% (the default), 30%, or 40%.
   - Heparin concentration can be set to 0, 5, 10, 12.5, 15, 20, 25, or 50 units/mL. (50 units/mL is the default.)

System Timeout

The purger will stop after 60 seconds if the user does not press STOP. If this happens, press **BACK** *for additional priming or* **NEXT** *if purge fluid has been discharged.*

PLUG IMPELLA® INTO CONTROLLER

Important Step

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

1. Open the Impella® Catheter package using sterile technique and snap the plastic hook (located on the pressure reservoir of the clear sidearm) to the connector cable as shown in Figure 5.5.

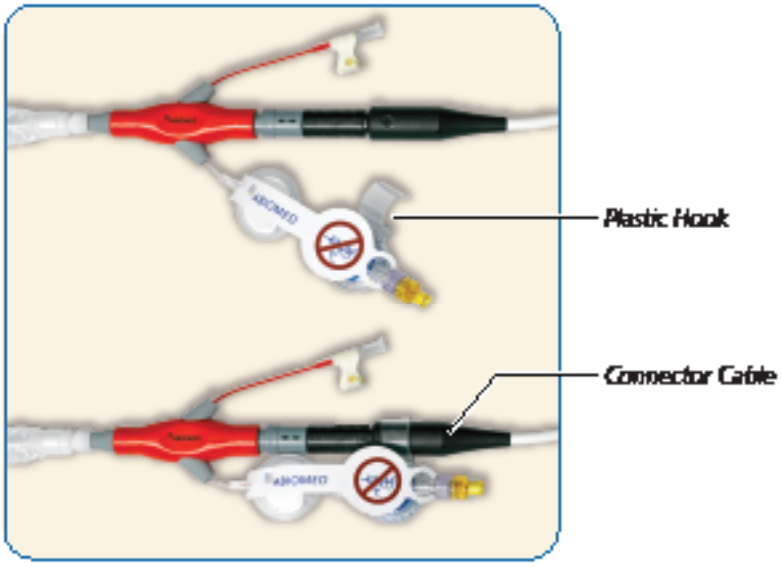


Figure 5.5 Snapping Plastic Hook to Connector Cable

Time Delay

Expect a 5 to 10 second time delay after plugging in the Impella® pump and before the Impella® Controller automatically advances to the next screen.

2. Pass the sterile white connector cable from the Impella® pump off the sterile field. Line up the notch on the Impella® connector cable with the notch in the blue pump plug on the front of the Impella® Controller and plug the cable into the controller.
3. When the Impella® Controller detects that an operational Impella® pump is plugged in, the Impella® flow icon appears on the screen. The controller automatically advances to the next screen.

Infusion Bag Pressure

If the infusion bag is underinflated, the progress bar will not be activated. If the infusion bag is overinflated, an alarm will occur.

If a "Sensor Value not Reliable" alarm appears while priming the catheter, check that the pressurized saline bag is inflated to a pressure between 300 and 350 mmHg and not overinflated.

PRIME IMPELLA® PURGE LUMEN

1. Connect the yellow connector on the end of the purge line to the yellow luer connector on the clear sidearm of the Impella® pump.
2. Select START to begin priming the Impella® purge lumen. The Impella® Controller will start at a bolus rate of 250 mL/hour or greater.
3. When purge fluid is discharged from the Impella® pump, scroll to and select STOP. When you press STOP, the bolus stops but purge fluid continues to flow at a low rate.
4. Press **NEXT** to advance to the next screen.

PRIME BLOOD PRESSURE LUMEN

1. Using sterile technique, connect the flush solution tubing to the red luer connector on the red sidearm of the Impella® pump.

2. Blood pressure lumen priming starts automatically. Prime the Impella® Catheter pressure lumen by squeezing the white flush valve until the Impella® Controller beeps. (see Figure 5.6).

   When the system detects the target flush solution pressure within the required amount of time (60 seconds), the system will go to the next step automatically.

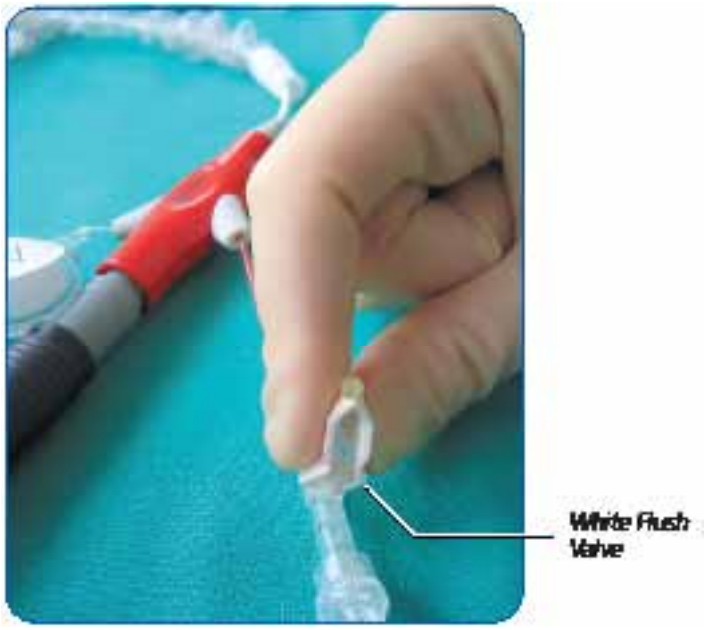


Figure 5.6 Squeezing the White Flush Valve to Prime the Impella® Catheter Pressure Lumen

PRE-INSERTION IMPELLA® TEST

1. Select TEST to start the pre-insertion Impella® test.

   The test runs for 2 seconds. When the system detects that the pump is spinning, it automatically advances to the next step.

   If the pre-insertion test fails, the system will instruct you to unplug the Impella® from the controller and disconnect the purge and flush lines from the Impella® luer connectors. You can then press **NEXT** to set up a new Impella® pump.

IMPELLA® TEST SUCCESSFUL

1. This screen tells you that the Impella® test was successful. Press **NEXT** to finish Startup.

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.

Use Fluoroscopy for Placement

Impella® 2.5 performance will be compromised if correct placement cannot be confirmed. While other imaging techniques, such as transesophageal echocardiography (TEE), can help confirm the position of the Impella® 2.5 after placement, TEE does not allow visualization of the entire catheter assembly and is inadequate for reliably placing the Impella® 2.5 across the aortic valve.

Maintaining ACT

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

⚠	Fluoroscopy is required to guide placement of the Impella® 2.5. The small placement guidewire must be reliably observed at all times.
⚠	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.
⚠	Do ***NOT*** touch the inlet or outlet areas of the catheter and avoid manual compression of the inlet cannula assembly while placing the device.

1. Obtain access to the femoral artery.
2. Insert a 6–8 Fr introducer over the 0.035 guidewire (provided) to pre-dilate the vessel.
3. Remove the 6–8 Fr introducer over the 0.035 guidewire and insert the 13 Fr peel-away introducer with dilator (see Figure 5.7). While inserting the 13 Fr introducer, hold the shaft of the introducer to slide it into the artery.

Figure 5.7 Inserting the 13 Fr Peel-Away Introducer

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

5. Insert a 6 Fr diagnostic catheter with diagnostic guidewire with no side holes (Judkins Right, Multipurpose, or pigtail recommended, see Figure 5.8) into the 13 Fr introducer and advance it over a diagnostic guidewire into the left ventricle.

Figure 5.8 Inserting the 6 Fr Diagnostic Catheter

6. Remove the diagnostic guidewire and insert the supplied 0.018 in/260 cm placement guidewire.
7. Advance the placement guidewire into the left ventricle until the floppy end and 3 to 4 cm of the stiffer part of the guidewire are visible in the left ventricle.
8. Remove the 6 Fr diagnostic catheter.
9. Wet the cannula with sterile water and backload the pigtail section of the catheter onto the placement guidewire. One or two people can load the catheter on the guidewire.

One-person technique

a. Advance the guidewire into the Impella® Catheter and stabilize the cannula between the fingers as shown in Figure 5.9. This prevents pinching of the inlet port. The guidewire must exit the outlet port on the inner radius of the cannula, as shown by the arrow in Figure 5.9 and in Figure 5.10. The catheter 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 port on the inner radius of the catheter, as shown by the arrow in Figure 5.9 and in Figure 5.10. The physician can focus on advancing the guidewire and, if the cannula needs to be hyperextended, the scrub assistant is available to assist.

Impella® 2.5 Use in Open Heart Surgery

If the Impella® 2.5 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 pump assembly through the aorta or ventricle may result in serious damage to the Impella® 2.5 device and serious injury to the patient.

Avoid Damaging Inflow Area

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

Figure 5.9 Loading the Catheter on the Guidewire

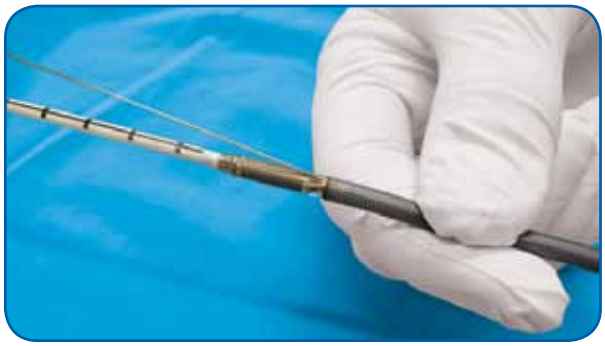


Figure 5.10 Exiting of the Placement Guidewire from the Catheter

Do NOT Touch Inlet or Outlet Areas

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

10. Advance the catheter through the hemostatic valve into the femoral artery (see Figure 5.11) and along the placement guidewire into the left ventricle using a fixed-wire technique. Follow the catheter under fluoroscopy as it is advanced into the left ventricle, being careful not to coil the guidewire in the left ventricle.

Figure 5.11 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 that a ventricular waveform is displayed on the Impella® Controller.

POSITIONING AND STARTING THE IMPELLA® 2.5 CATHETER

Retrograde flow will occur across the aortic valve if the Impella® 2.5 is set at a flow rate of 0 L/min.

1. Place the catheter plug at the same level as the patient's heart.
2. Confirm that a ventricular waveform is displayed on the Impella® Controller (see Figure 5.12). If a ventricular waveform is not present, gently advance the catheter forward until a ventricular waveform is present on the placement signal screen.

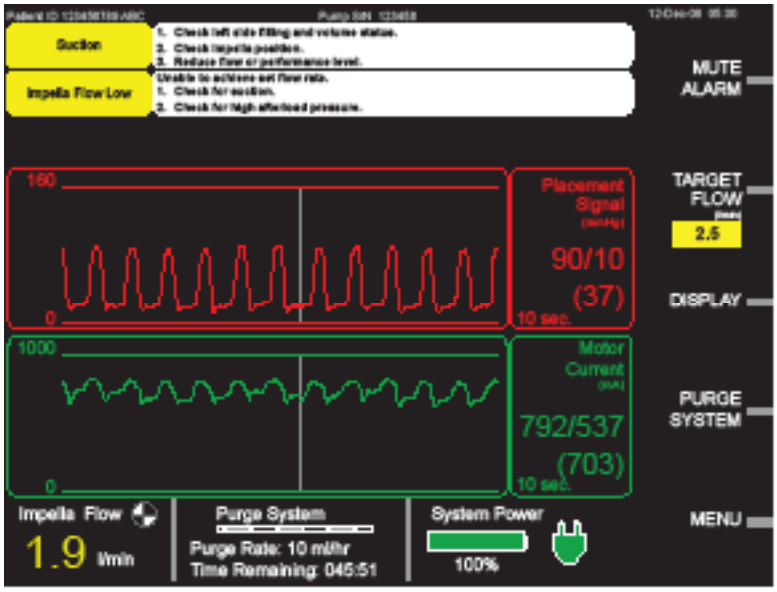


Figure 5.12 Ventricular Waveform on Placement Signal Screen

Importance of Proper Pump Placement

When the pump is not correctly placed, the patient does not profit from the flow rate shown on the controller and there is no effective unloading of the ventricle (hydraulic short circuit).

3. Pull the catheter back until an aortic waveform is present on the placement signal screen (see Figure 5.13).

4. 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 pump should now be centered across the aortic valve.

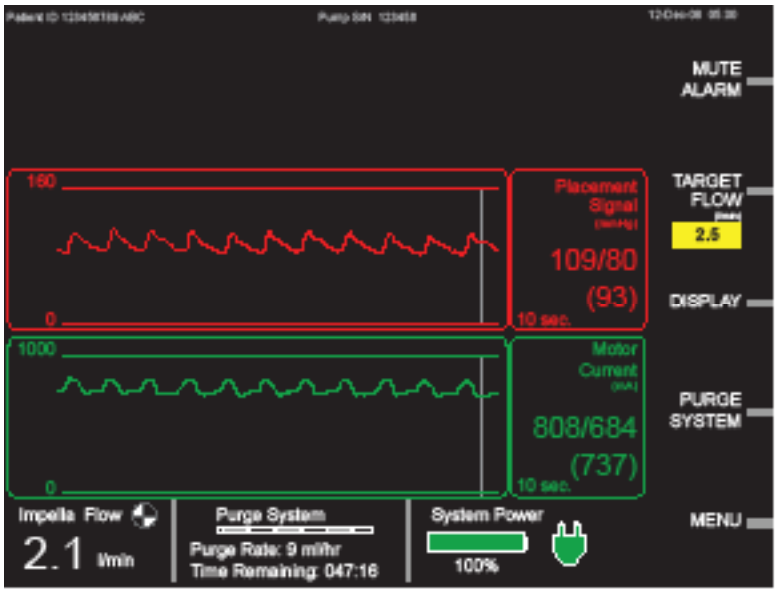


Figure 5.13 Aortic Waveform on Placement Signal Screen

5. Press the **TARGET FLOW** soft button to open the flow icon (see Figure 5.14)

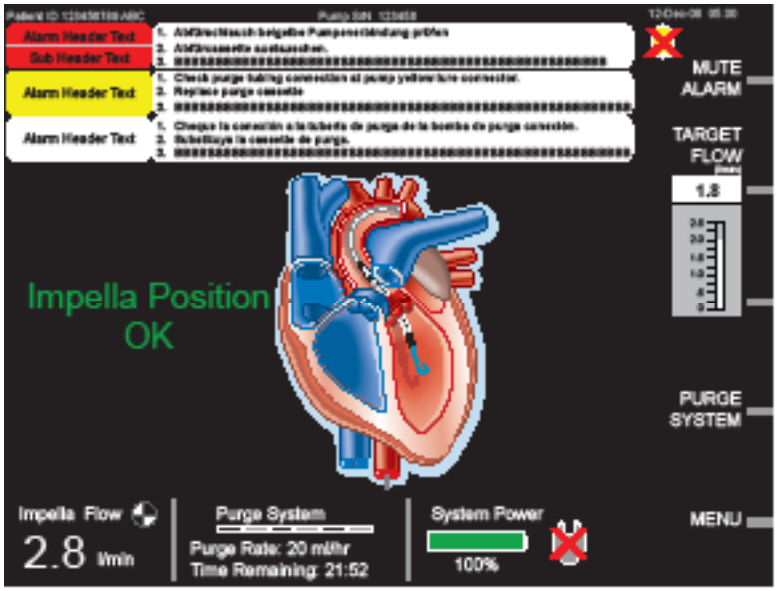


Figure 5.14 Selecting Target Flow

6. Turn the selector knob to change the flow rate from 0 L/min to 0.5 L/min.
7. Press the selector knob to select the new flow rate.
8. The flow icon in the lower left corner of the screen begins rotating when the Impella® pump begins to operate.
9. Increase the flow rate to 2.5 L/min to confirm correct and stable placement. Placement should be verified with fluoroscopy and with the placement signal screen (see Figure 5.15).

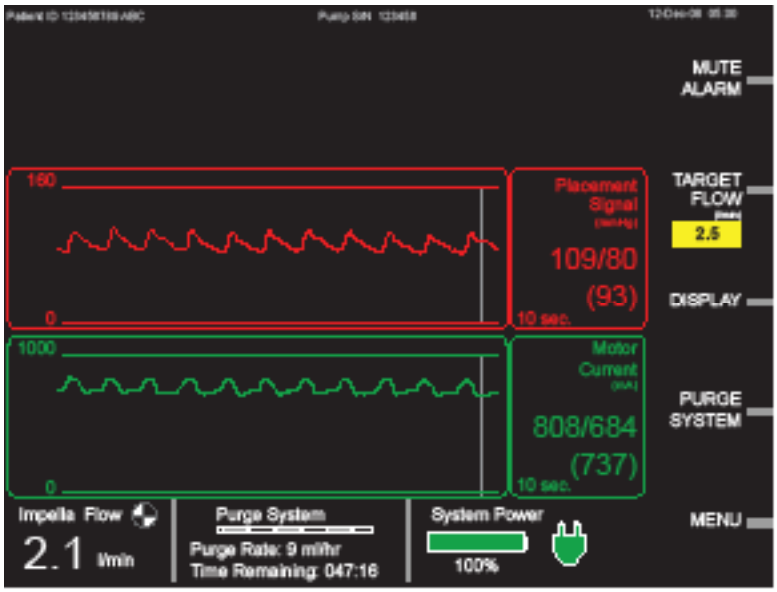


Figure 5.15 Confirming Placement on the Placement Signal Screen

10. After correct placement has been achieved, adjust the flow rate to the desired flow. Flow rates of TBD L/min will default back to TBD L/min after 5 minutes.
11. Reposition the catheter as necessary.

Check Positioning at Maximum Flow

When the flow rate is increased to maximum flow, the device has a tendency to be drawn into the ventricle. Check positioning at maximum flow to ensure proper placement throughout the performance level setting range.

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

Alternative to Waiting Until ACT < 150

If you do not want to wait until ACT is below 150 seconds before removing the device, you can remove the device and exchange the peel-away sheath with 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.

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.

1. Flush the sidearm of the repositioning introducer located on the catheter shaft.
2. Carefully flush the sidearm of the 13 Fr introducer and remove the 13 Fr peel-away introducer completely from the artery over the catheter shaft and apply manual pressure above the puncture site.
3. 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 5.16).

Figure 5.16 Removing the 13 Fr Peel-Away Introducer

4. Attach a stopcock and flush the repositioning sheath prior to advancing the sheath.
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 introducer over the catheter shaft and advance it into the artery to the yellow eyelet.
7. Secure the yellow section of the repositioning introducer by suturing it to the skin using the provided eyelet.

8. Slide the proximal end of the anticontamination sleeve onto the yellow section of the repositioning introducer. 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 by tightening the distal anchoring ring.

PURGER PROCEDURES

When replacing the purge cassette, the replacement process must be completed within 4 minutes. The Impella® 2.5 Catheter may be damaged if replacement takes longer than 4 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 4 minutes. Replacement should always be performed as quickly as possible.

There are four procedures for maintaining the Impella® purge system:

- Purge system change (cassette and purge fluid)
- Purge fluid change
- Purge cassette change
- De-air purge system

Each procedure can be accessed using the **PURGE SYSTEM** soft button.

This section describes each of those purger procedures.

PURGE SYSTEM CHANGE

These are the steps you will follow to change out the purge cassette and purge fluid.

1. The purge system change out procedure begins with delivery of a bolus to the pressure reservoir so that the reservoir can maintain purge pressure during the change out. After the bolus is delivered, the controller automatically proceeds to the next screen.
2. Disconnect and remove the used purge cassette. If you do not remove the cassette within 20 seconds, the system will cancel and exit the purge system change procedure.
3. Insert a new purge cassette into the controller. Be sure to slide the purge pressure transmitter into place and extend the purge line through the gap in the purge cassette door when you close the door.
4. Turn the selector knob to select START. Press the knob to begin priming the purge line.
5. When purge fluid is discharged from the purge line, scroll to STOP and press the selector knob.
6. Press **NEXT** to advance to the next screen and enter purge fluid information.

7A. To select the default purge fluid values displayed on the screen, scroll to and select **OK**. This will select those values and automatically advance you to the next screen.

7B. 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 Startup 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.

8. Connect the yellow luer connector on the end of the purge line to the yellow luer connector on the clear sidearm of the Impella® pump.

9. Press **NEXT** to exit and complete the procedure.

Purge Solution Bottles

If the purge solution is supplied in bottles, follow the same procedure as if supplied in bags.

PURGE FLUID CHANGE

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

1. The purge fluid change procedure begins with delivery of a bolus to the pressure reservoir so that the reservoir can maintain purge pressure during the change. After the bolus is delivered, the controller automatically proceeds to the next screen.

2. Replace the purge fluid bag. Press **NEXT** to advance to the next screen and enter purge fluid information.

3A. To select the default purge fluid values displayed on the screen, scroll to and select OK. This will select those values and automatically advance you to the next screen.

3B. 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 Startup 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.

PURGE CASSETTE CHANGE

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

1. The purge cassette change procedure begins with delivery of a bolus to the pressure reservoir so that the reservoir can maintains purge pressure during the change. After the bolus is delivered, the controller automatically proceeds to the next screen.

2. Disconnect and remove the used purge cassette. If you do not remove the cassette within 20 seconds, the system will cancel and exit the purge cassette change procedure.

3. Insert a new purge cassette into the controller. Be sure to slide the purge pressure transmitter into place and extend the purge line through the gap in the purge cassette door when you close the door.

4. Turn the selector knob to select START. Press the knob to begin priming the purge line.

5. When purge fluid is discharged from the purge line, scroll to STOP and press the selector knob.
6. Press **NEXT** to advance to the next screen and connect the purge cassette to the Impella® pump.
7. Connect the yellow luer connector on the end of the purge line to the yellow luer connector on the clear sidearm of the Impella® pump.
8. Press **NEXT** to exit and complete the procedure.

DE-AIR PURGE SYSTEM

These are the steps you will follow to de-air the purge system. This procedure starts automatically when the "Air in Purge System" alarm occurs.

1. Make sure that the purge fluid bag is NOT empty or inverted.
2. Disconnect the purge line from the yellow luer connector on the Impella® pump.
3. Press START to initiate the de-air function. The system automatically advances to the next screen.
4. The next screen explains that the de-air procedure is taking place. Wait until the air is removed from the purge system and the system automatically advances to the next screen.
5. Confirm that the purge fluid has been discharged from the purge line. If it has not, press **BACK** to repeat the air removal process.
6. Connect the yellow luer connector on the end of the purge line to the yellow luer connector on the clear sidearm of the Impella® pump.
7. Press **EXIT** 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®, the Impella® Controller alarms "Impella Failure: Sudden Purge Pressure Drop," follow the instructions below.

Purge Pressure

Purge pressure can range from 300mmHg to 1100 mmHg.

The Impella® Controller purge algorithm maintains purge pressure within 50 mmHg of the target pressure.

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 "Purge Fluid Change". Follow the instructions on the screen. (Refer to "Purger Procedures" earlier in this section.)
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 alarms remain unresolved for more than 5 minutes, this may be a sign of pump damage. Complete the following steps immediately:
   a. Open the flow icon and reduce the flow rate to 0.5 L/min.
   b. Slowly pull back on the Impella® 2.5 Catheter until the pump is in the descending aorta (approximately 20 cm for an average size patient; 1 cm marks are available on the catheter).
   c. Confirm that the pump is still running at a flow rate of 0.5 L/min. Open the flow icon and reduce the flow rate to 0 L/min.
   d. Stop the Impella® pump and turn off the purge system.
   e. Remove the Impella® 2.5 Catheter with the use of fluoroscopic imaging. If no fluoroscopy is available, leave the pump in the descending aorta until imaging is available for visual assistance with pump integrity during removal.

Unresolved High Purge Pressure Alarms

High purge pressure alarms that are not resolved by the recommendations provided could be an indication of a kink in the catheter located within the artery. In this case, the motor is no longer being purged and will eventually stop. Clinicians should consider replacing the Impella® pump.

HIGH PURGE PRESSURE

If the purge pressure exceeds 1100 mmHg, the Impella® Controller displays the high purge pressure alarm message.

1. Inspect the purge system for kinks in the tubing.
2. If pressure remains high, decrease the concentration of dextrose in the purge solution (eg, dextrose 10%).

PURGE SYSTEM BLOCKED

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

1. Check the purge system tubing 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 is at the discretion of the physician. (For more information, refer to "Guidelines for Explant" in Section 6: Patient Management Topics.)

The following weaning protocols are provided as guidance only.

RAPID WEANING

1. Initiate rapid weaning by decreasing the Impella® flow rate by 0.5 L/min at intervals of several minutes. Do ***NOT*** decrease the Impella® flow rate below 0.5 L/min as long as the pump is in the ventricle.
2. When the Impella® flow rate has been reduced by 0.5 L/min, maintain the patient at 0.5 L/min for *at least 10 minutes* before discontinuing circulatory support.
3. If the patient's hemodynamics remain stable, decrease the Impella® flow rate to 0.1 L/min, pull the catheter into the aorta, and stop the pump by reducing the flow rate to 0 L/min.
4. Explant the catheter.
5. Follow institutional guidelines for percutaneous arterial closure.
6. Disconnect the connector cable from the Impella® Controller and turn the controller OFF.

SLOW WEANING

1. Initiate slow weaning by decreasing the Impella® flow rate by 0.5 L/min at intervals of 2 to 3 hours. Do ***NOT*** decrease the Impella® flow rate below 0.5 L/min as long as the pump is in the ventricle.
2. When the Impella® flow rate has been reduced to 0.5 L/min, maintain the patient at 0.5 L/min for *at least 2 to 3 hours* before discontinuing circulatory support.
3. If the patient's hemodynamics remain stable, decrease the Impella® flow rate to 0.1 L/min, pull the catheter into the aorta, and stop the pump by reducing the flow rate to 0 L/min.
4. Explant the catheter.
5. Follow institutional guidelines for percutaneous arterial closure.
6. Disconnect the connector cable from the Impella® Controller and turn the controller OFF.

Remove the Impella® 2.5 With Care

Removal of the Impella® 2.5 device must be completed with care to avoid damage to the pump 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® Catheter when transferring a patient from one bed to another
- 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.

Considerations for transport within the hospital:

- The Impella® Controller and Impella® 2.5 System 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 Impella® pump cable from the controller to the Impella® red plug.

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 the controller will turn back on.

RIGHT HEART FAILURE

The Impella® 2.5 is a left-side support device only. Patients being supported by the Impella® 2.5 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
- 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.

If CPR is indicated, the following actions are recommended:

1. Initiate CPR per hospital protocol.
2. Reduce the Impella® 2.5 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 device and sufficient filling of left ventricle. If placement and filling are not satisfactory, it may be an indication that the device has been damaged.

DEFIBRILLATION

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

Patients supported by the Impella® 2.5 System can be defibrillated. However, caregivers should use caution during defibrillation to ensure they do not touch the pump, 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 off AC power.

LATEX

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

POSITIONING AND PLACEMENT DEVICES

High quality fluoroscopic imaging is the best method for determining pump position and is required for pump placement.

Alternative methods for determining pump position include:

- Portable C-Arm fluoroscopy
- Transesophageal echocardiography (TEE)
- Chest x-ray

Use Fluoroscopy for Placement

Impella® 2.5 performance will be compromised if correct placement cannot be confirmed. While other imaging techniques, such as transesophageal echocardiography (TEE), can help confirm the position of the Impella® 2.5 after placement, TEE does not allow visualization of the entire catheter assembly and is inadequate for reliably placing the Impella® 2.5 across the aortic valve.

Notes on Imaging:
All imaging technology represents the anatomy in two dimensions (2D). It is not possible to assess the interactions between the device and the intraventricular anatomy that occur in three dimensions (3D). If a positioning alarm occurs, Abiomed strongly recommends that the device be repositioned, even if the imaging view shows correct position. Abiomed strongly recommends using fluoroscopy to guide placement and positioning of the Impella® Circulatory Support device.

Alternative imaging techniques, such as transesophageal echocardiography (TEE), can be useful to confirm the position of the Impella® 2.5 after placement. However, TEE is inadequate to reliably perform correct placement across the aortic valve. TEE does not allow visualization of the entire catheter assembly.

SUCTION

Suction may occur if the blood volume available for the Impella® 2.5 pump is inadequate or restricted. Suction limits the amount of support that the Impella® 2.5 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 in the alarm display by decreasing the flow rate.

1. Check the pump for correct positioning using imaging. Reposition the device 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 device away from the interior ventricular wall.
2. Assess patient's fluid intake and output to confirm adequate volume status.
3. Confirm right ventricular function by assessing CVP or right side function on echo. If CVP is not an option, check the pulmonary artery diastolic pressure to assess the patient volume status.
4. Return flow rate 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 support device (VAD) support. Patient conditions—including pump 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® inlet area in close proximity to intraventricular wall	• Suction alarms • Lower than expected flows	Imaging (see note)	• Reposition the device by rotating or moving the device into or out of the ventricle slightly. Either or both of these actions could help move the inlet of the device away from the intraventricular wall. • If repositioning will be delayed, reduce the flow rate if tolerated by patient hemodynamics. Return to the target flow rate after repositioning. • Reassess position after flow rate has returned to desired target value.
Wrong pump position	• Position alarms • Suction alarms • Lower than expected flows	Imaging (see note)	• Reposition the device by rotating or moving the device into or out of the ventricle slightly. Either or both of these actions could help move the inlet of the device away from the intraventricular wall. • If repositioning will be delayed, reduce the flow rate if tolerated by patient hemodynamics. Return to the target flow rate after repositioning. • Reassess position after flow rate has returned to desired target value.
Higher than needed flow setting	• There may be no controller indicators • Suction alarms	• Normal hemodynamics • Native recovery	1. Reduce flow rate until patient pressure starts to drop. 2. Slowly increase flow rate.
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 flow rate 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 device and the intraventricular anatomy that occur in three dimensions (3D). Abiomed strongly recommends that the device be repositioned, even if the imaging view shows correct position.*

UNDERSTANDING AND MANAGING IMPELLA® 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 below, fluoroscopic imaging is the best method for confirming position. You can also use TEE or a standard chest X-ray.

If the Impella® is either partly (just the pigtail) or completely in the ventricle, reposition the device 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® is completely out of the ventricle, do not attempt to reposition the device 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 6.1.

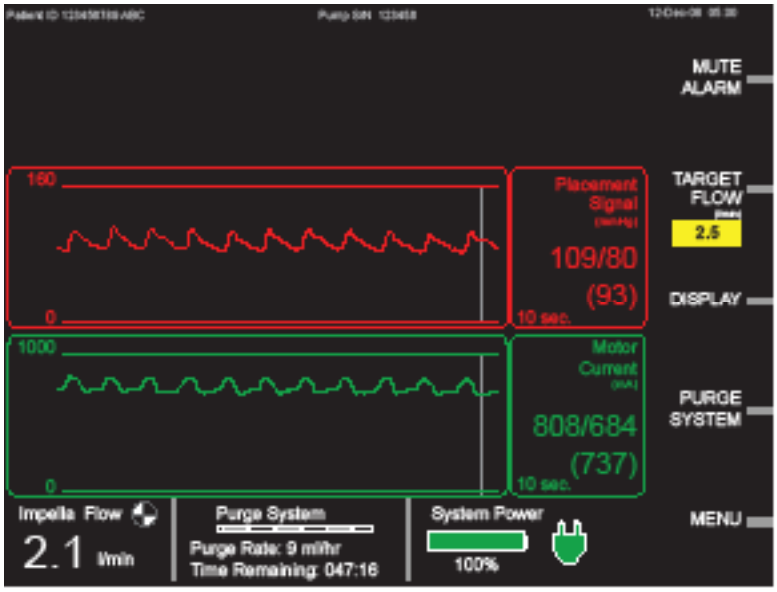


Figure 6.1 Correct Catheter Position

IMPELLA® FULLY IN VENTRICLE

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

Pump Position Wrong

In this situation, the waveform screen will appear as shown in Figure 6.2.

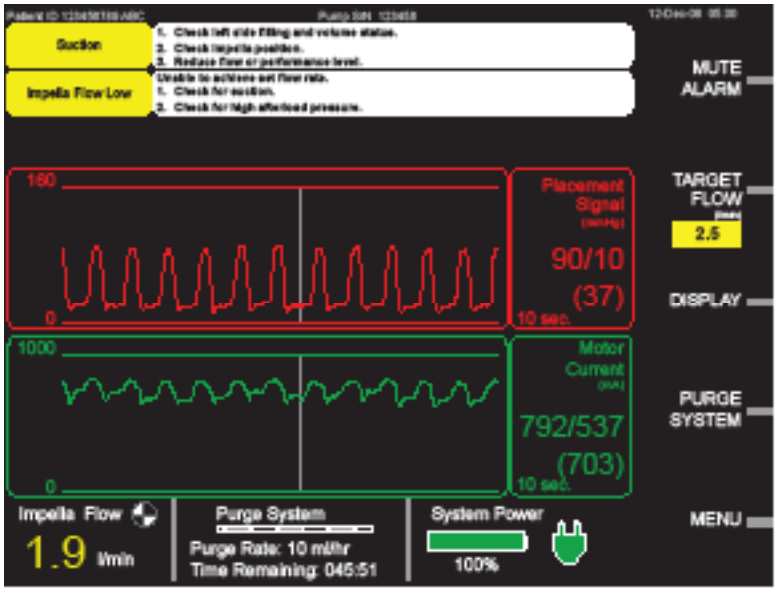


Figure 6.2 Catheter Fully in Ventricle

Actions to take:

1. Under fluoroscopic guidance, if available, reduce the flow rate to 0.5 L/min and carefully pull back the Impella® 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® positioning.

IMPELLA® COMPLETELY IN THE AORTA or INLET AND OUTLET AREA IN VENTRICLE AND PRESSURE PORT 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 pressure port is in the aorta, the following alarm will appear:

Pump Position Wrong

In this situation, the waveform screen will appear as shown in Figure 6.3.

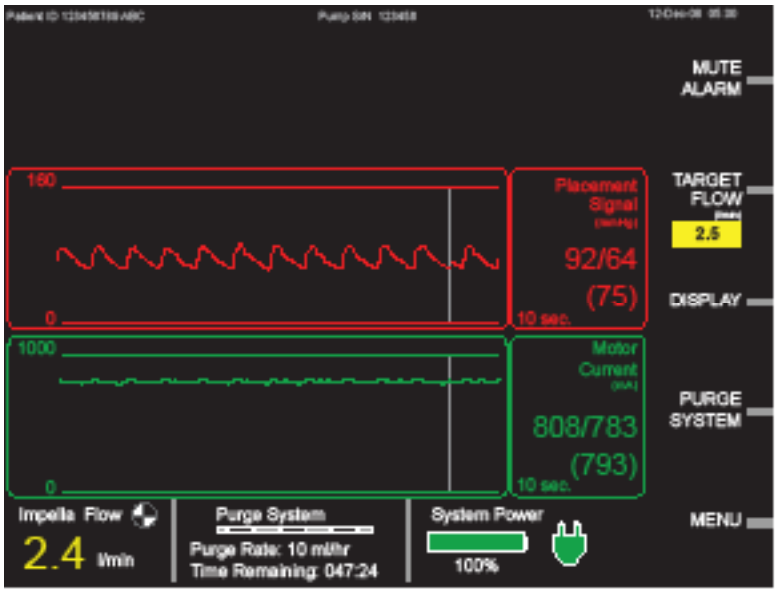


Figure 6.3 Impella® Completely in the Aorta or Inlet and Outlet Area in Ventricle and Pressure Port in Aorta

Actions to take:

1. Under fluoroscopic guidance, determine the pump position.
2. Reduce flow rate to 0.5 L/min and reposition the pump as necessary.
3. If fluoroscopic imaging is not available, reposition the pump according to the repositioning guide.
4. If step 3 does not provide correct positioning, check the pump position by imaging methods (fluoroscopy, TEE, or chest x-ray).

LOW NATIVE HEART PULSATILITY

In a situation of low native heart pulsatility, the Impella® Controller may not be able to determine the pump position. You may see the following alarm:

Pump position unknown due to low pulsatility.

In this situation, the waveform screen will appear as shown in Figure 6.4.

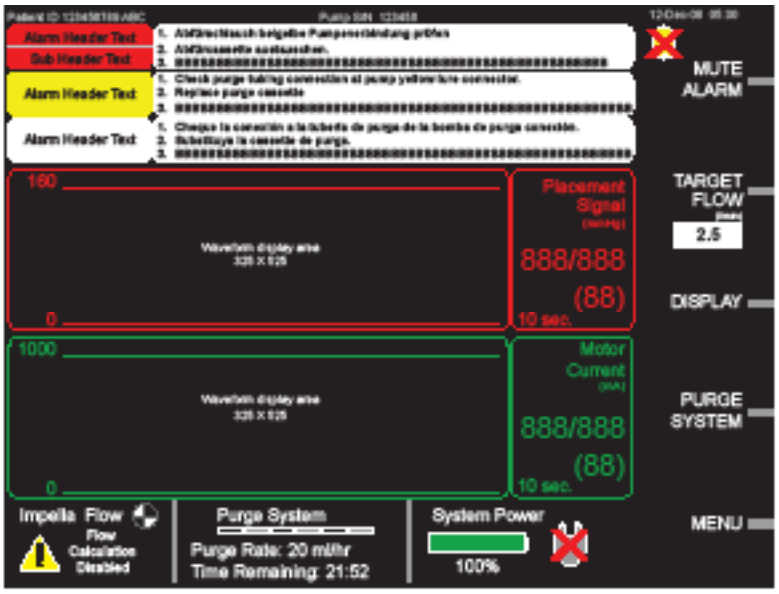


Figure 6.4 Pump Position Unknown Due to Low Pulsatility [Waveform TBD; Motor Current y-axis scale to be revised]

Actions to take:

1. Assess cardiac function.

IMPELLA® OUTLET AREA ON OR NEAR AORTIC VALVE

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

Impella Outflow Blocked

In this situation, the waveform screen will appear as shown in Figure 6.5.

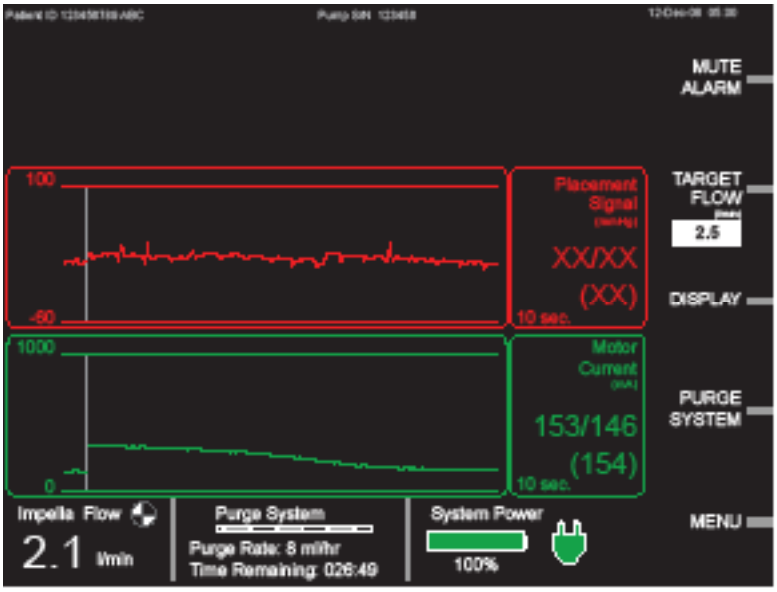


Figure 6.5 Impella® Outlet Area on or near Aortic Valve

Actions to take:

1. Assess and adjust pump position under fluoroscopic guidance, if available.
2. If fluoroscopic guidance is not available, reduce the flow rate to 0.5 L/min and gently pull the catheter back 2 cm and see if the condition resolves.

REPOSITIONING GUIDE

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

To use the repositioning guide:

1. Press **MENU** and scroll to "Start Repositioning Guide." Press the selector knob to initiation the repositioning guide algorithm.

   Figure 6.6 shows the first screen of the repositioning guide. Follow the instructions in the white instructional display area under the headline "Repositioning Guide Active".

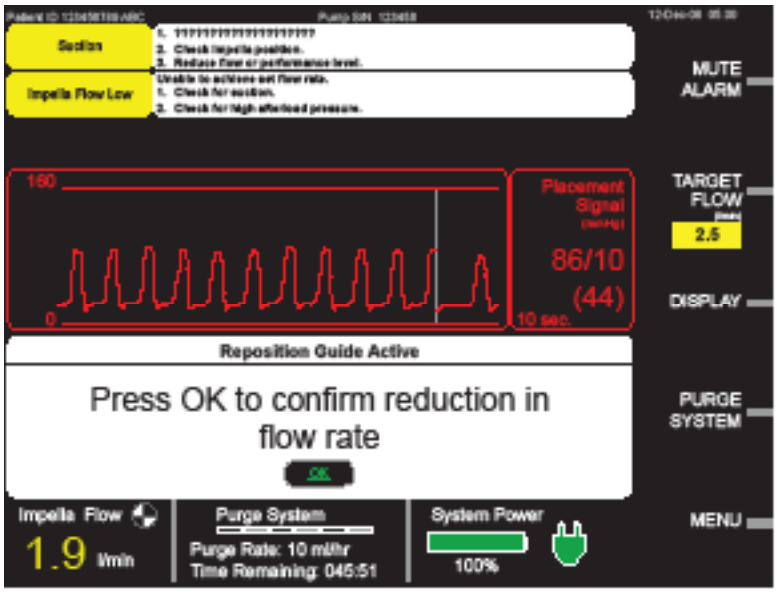


Figure 6.6 First Repositioning Guide Screen

2. Press OK to confirm reduction in flow rate. The system will reduce flow rate to 1 L/min.
3. Push the Impella® pump forward until the placement signal shows ventricular pressure (see Figure 6.7).

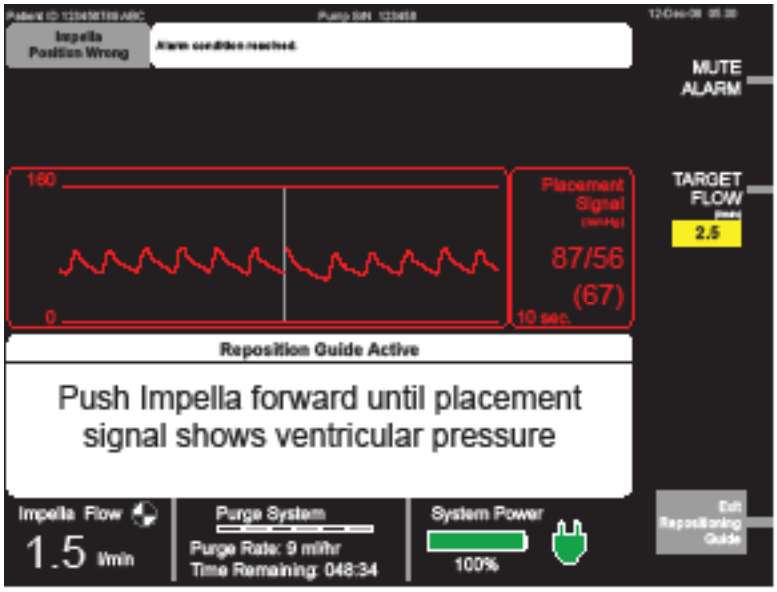


Figure 6.7 Second Repositioning Guide Screen

4. Pull the Impella® pump back until the placement signal shows aortic pressure (see figure 6.8).

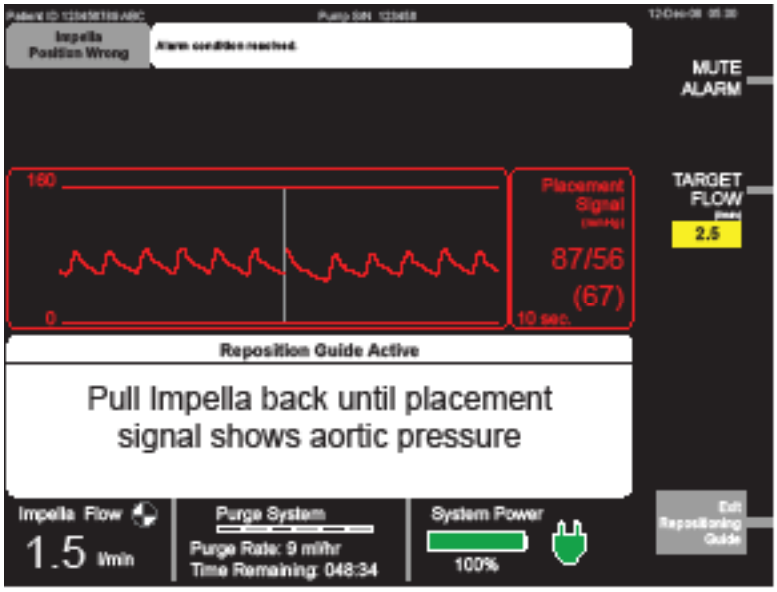


Figure 6.8 Third Repositioning Guide Screen

5. Pull the Impella® pump back 4 marks on the catheter. Each mark equals 1 centimeter.
6. Exit the Repositioning Guide using the **Exit Repositioning Guide** soft button (see Figure 6.9). When you exit, the controller returns to the original flow rate level.

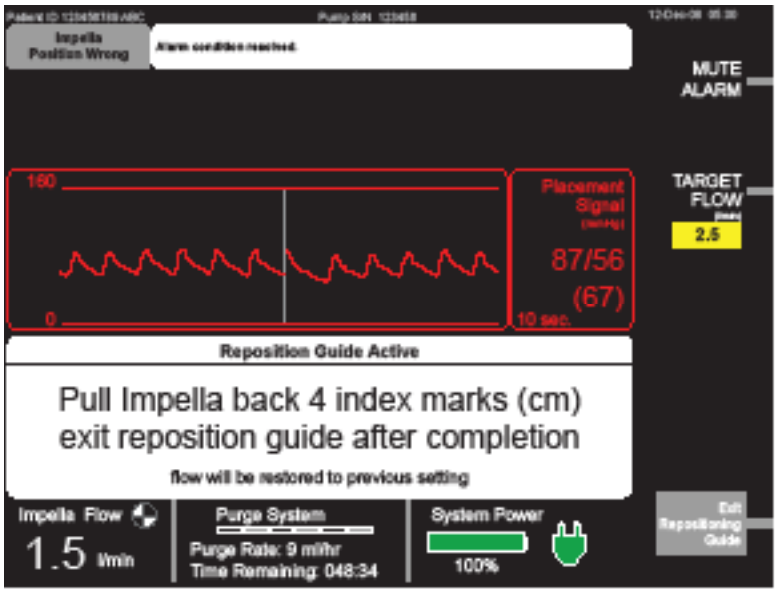


Figure 6.9 Exit Repositioning Guide Screen

DATA SNAP SHOT RECORDING

The Impella® Controller can save real-time operating data for later analysis using the Data Snap Shot feature. Data Snap Shot is automatically turned on during certain alarm conditions to capture data for analysis. The user 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. To stop recording data before the 10-minute time-out, select "Stop Data Snapshot" from the **MENU**.

Saving Snap Shot Data

If you select "Start Data Snap Shot" while the controller is already saving snap shot data, the controller will start saving data to a different snap shot file. Note: Old data will be overwritten by new data if the snap shot data memory is full.

INFUSION HISTORY

The Impella® Controller has an Infusion History screen that displays the amount of heparin and dextrose infused each hour. The calculations begin when the case start procedure is completed and flow rate is greater than 0. The system stores at least 8 hours of data. Figure 6.10 shows a sample Infusion History screen.

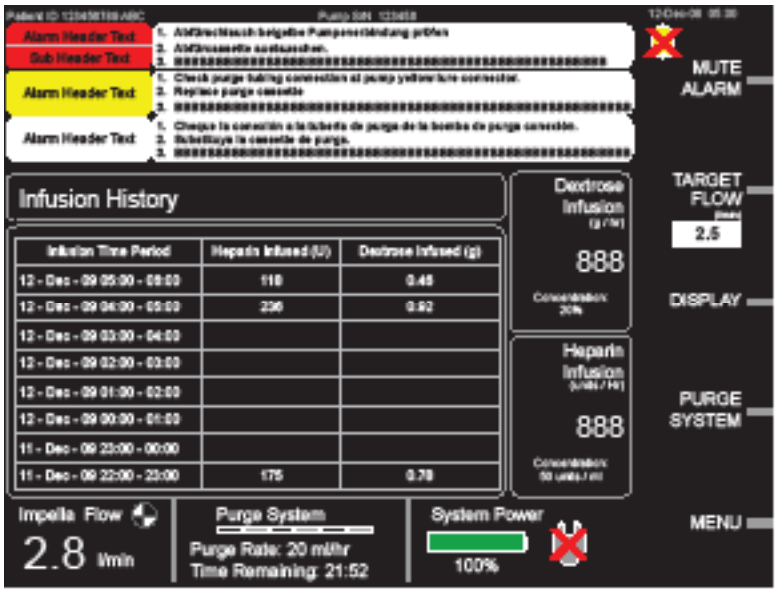


Figure 6.10 Infusion History Screen

As you can see, the current time period is displayed at the top of the list. This entry provides the heparin and dextrose infusion rates from the top of the current hour to the current time.

OPERATING THE IMPELLA® 2.5 WITHOUT HEPARIN IN THE PURGE SOLUTION

The Impella® 2.5 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 in assessing 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 an alternative anticoagulant delivered systemically.

Do not add any alternative anticoagulant (such as a direct thrombin inhibitor) to the purge solution. The Impella® 2.5 has not been tested with any alternative anticoagulants present in the purge solution.

GUIDELINES FOR EXPLANT

Patients being supported with the Impella® 2.5 System should be evaluated for explant on a regular basis.

To evaluate patients for explant, reduce the Impella® 2.5 flow rate and look for the following signs of native heart recovery:

- AO and CVP pressure remain stable
- Native ejections are visible on the patient pressure monitor
- Native ejections increase after volume loading challenge
- Echocardiography reveals pronounced aortic valve opening

If physicians see these signs of native heart recovery and the patient has demonstrated stable, ongoing recovery—including stable organ (eg, liver, kidney, lung) function—the patient should be considered for explant.

If the patient does not meet the criteria for explant, the patient should remain on Impella® 2.5 support, or be transitioned to a longer term device.

HOW TO CHANGE TO 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® pump to the backup controller.

1. Confirm that the backup controller is powered ON and ready.
2. Transfer the purge cassette and purge solution from the primary controller to the backup controller.
3. Remove the white Impella® connector cable from the primary controller and plug it into the pump plug on the front of the backup controller.
4. Once the Impella® pump is connected to the backup controller, the "Quick Start" message will appear on the screen asking the user to confirm re-starting the Impella® 2.5 at the previously set flow rate.
5. Press OK within 10 seconds to confirm restarting the Impella® 2.5 at the previously set flow rate.

EMERGENCY SHUTDOWN PROCEDURE

1. Press and hold the black power button for 30 seconds.
2. An "Emergency Shutdown Imminent" alarm will sound at 15 seconds.
3. The controller will shut down after 30 seconds.
   NOTE: The Impella® pump will continue running at the last setting.
4. Restart the controller.

7 CLEANING, STORAGE, DISPOSAL, AND RETURNS

CLEANING

CLEANING THE IMPELLA® CONTROLLER AND CONNECTOR CABLE

- Clean the Impella® Controller keypad and display with 70% isopropyl alcohol, or soap and water.
- 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 10 hours prior to system operation. 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 and switched to the ON position when it is stored.

DISPOSING OF THE PUMP AND ACCESSORIES (EU)

The Impella® pump 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® PUMP TO ABIOMED (US)

To return an Impella® pump to Abiomed, contact your local Clinical Consultant for an Abiomed-approved return kit (part number 0046-4000).* The kit includes instructions for returning the pump to Abiomed.

** Only available in the United States*

8 TERMINOLOGY, ABBREVIATIONS, AND SYMBOLS

TERMINOLOGY, ABBREVIATIONS, AND SYMBOLS

Table 8.1 Terminology and Abbreviations

Hz	Hertz
Pump identification number	Identification number of the pump; stated on the package label and on the display screen
Pump housing	Enclosure of the Impella®
Pump	Central delivery unit of the Impella® 2.5, consisting of the motor, motor housing, pump housing, cannula with inlet and outlet, and pigtail at the tip
Purge pressure	Pressure present in the Impella® 2.5 and in the infusion line
Purge system	Impella® purge cassette used for rinsing the Impella® 2.5
Retrograde flow	Reverse flow through the intracardiac pump when the pump is at a standstill (eg, regurgitation)
V	Volt
VA	Volt ampere (Watt)

Table 8.2 Symbols

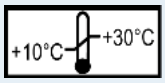
	Caution; comply with documents (eg, Instructions for Use)
	Defibrillator-proof type CF equipment
	Keep dry
	Storage temperature (eg, 0°C to 30°C)
	Declares conformity with directive 93/42/EEC for medical devices
 **2009-02**	Date of manufacture (eg, February 2009)
	Protect from sunlight!
	Symbol for lot designation; the manufacturer's lot designation must be stated after the LOT symbol

Table 8.2 Symbols (cont'd)

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
 **2010-06**	Use-by date (eg, use before June 2010)
	Do not reuse
	Sterilized using ethylene oxide
	Electric scrap; must be disposed of separately. Must not be disposed of as domestic waste.
	Protective Earth
	Protection Class II equipment

9 SYSTEM SPECIFICATIONS

IMPELLA® CONTROLLER MECHANICAL

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
	Width:	443 mm
	Depth:	236 mm
Dimensions – Packaged	Height:	508 mm
	Width:	559 mm
	Depth:	406 mm
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

AC operation	100-230 VAC (nominal); 47-63 Hz; 1.1A
Internal battery operation	14.4 VDC (nominal); lithium ion
Characteristic values	
Max. power consumption under load	120 VA
Device fuse	2x2 A slow-blow
Running time without AC power with fully charged batteries	At least 60 minutes (charging duration of at least 10 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 the accompanying documents.

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.

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	±8 kV contact ±15 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 50/60Hz 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
Conducted RF	10 Vrms	V1 = 10 Vrms	Portable and mobile RF communications equipment should be separated from the Impella® Controller by no less than the recommended separation distances calculated/listed below:
IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	
Radiated RF	10 V/m	E1 = 10 V/m	
IEC 61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 GHz	$D = (3.5 / E1)\sqrt{P}$ $D = (3.5 / E1)\sqrt{P}$ 80 to 800 MHz $D = (7 / E1)\sqrt{P}$ 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, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

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.

Maximum Output Power (Watts)	Recommended Separation Distances for the Impella® Controller (m)		
	150 KHz to 80 MHz	80 to 800 MHz	800 MHz to 2.5 GHz
	$d = 2.3333\sqrt{P}$	$d = 2.3333\sqrt{P}$	$d = 2.3333\sqrt{P}$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

RFID Transmitter / Receiver Specifications

Frequency	13.56 MHz
Receiver bandwidth	TBD
Effective radiated power	TBD
Modulation	TBD

PATIENT ENVIRONMENT

The Impella® Controller and the components of the Impella® Controller System are approved for use within the patient environment defined in IEC 60601-1-1 and in Figure 9.1 below.

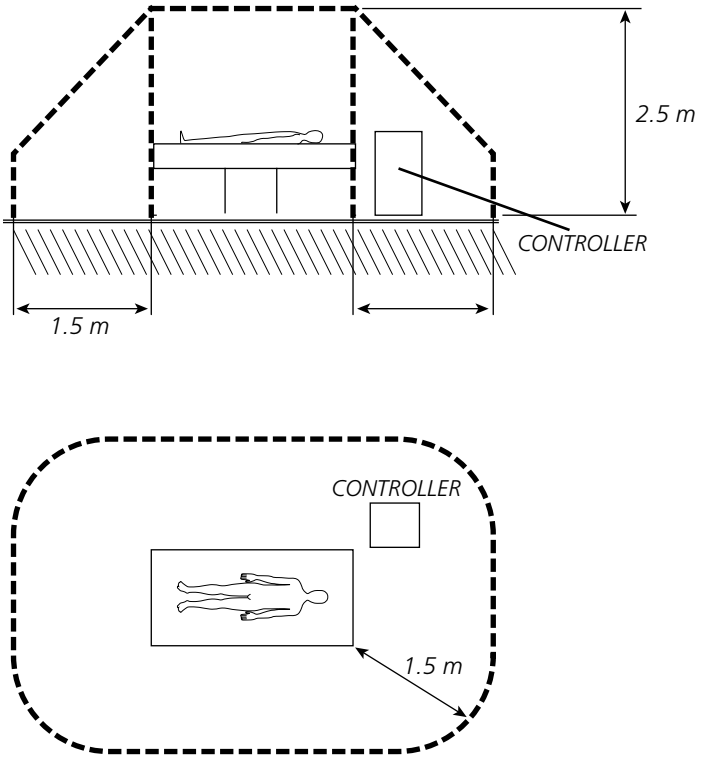


Figure 9.1 Impella® Controller Patient Environment

WHITE CONNECTOR CABLE

Length	2.5 m
Service life	Single use only

PUMP PARAMETERS

Latex Free

All versions of the Impella® Controller and Impella® pump, including all accessories, are latex free.

Speed range	0 to 51,000 rpm
Power consumption	Less than 0.99 A
Voltage	Max. 18 V
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	10% to 40%
Purge pressure	300 to 1100 mmHg
Infusion rate	4 to 20 mL/hr
Maximum duration of use	6 hours (US) Up to 5 days (EU and Canada)
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 pump)
Classification per MDD/93/42/EEC	Class III
Latex free	Yes

IMPELLA® 2.5 DIMENSIONS

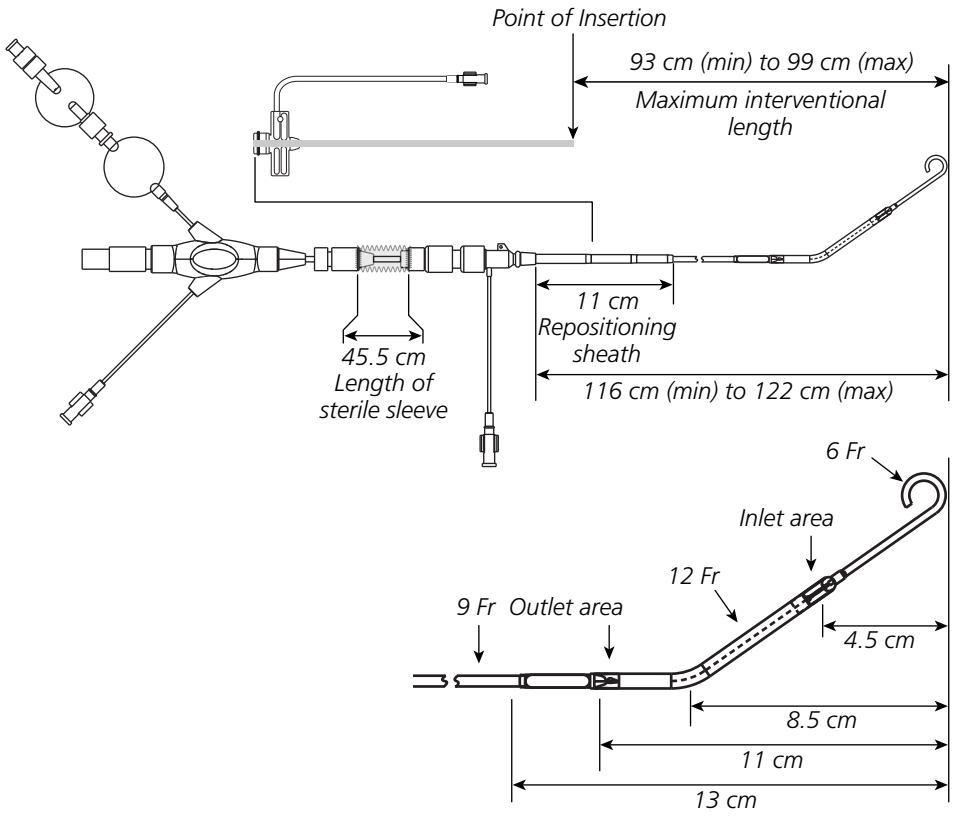


Figure 9.2 Impella® 2.5 Dimensions

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

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

Condition	Effect
The size and tortuosity of the femoral and iliac arteries	Limits the ability of the Impella® 2.5 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
Systolic left ventricular (LV) long axis < 7 cm	The Impella® 2.5 may interfere with the mitral valve
Systolic LV long axis > 11 cm	The Impella® 2.5 pigtail will not have a surface to push against to help stabilize its position, and may have a tendency to swing or bounce

10 IMPELLA® CONTROLLER ALARMS

IMPELLA® CONTROLLER ALARMS

ALARM OVERVIEW

The Impella® Controller monitors various functions to determine whether its operating parameters are within expected limits. When a parameter goes outside of allowed limits, the Impella® Controller displays a message on the display screen and sounds an audible alarm. When an audible alarm sounds, the operator will need to look at the display screen on the front of the Impella® Controller to see the text of the message.

The Impella® Controller generates three types of alarms and notifications: critical alarms, warning alarms, and advisory notifications. Each type has a different audible indicator (see Table 10.1).

Table 10.1 Audible Alarm and Notification Indicators

Category	Audible Indicator*
Critical alarms (high priority)	10 beeps every 6.7 seconds
Warning alarms (medium priority)	3 beeps every 15 seconds
Advisory notifications (low priority)	2 beeps every 30 seconds or no audible sound

* All audible indicators have a sound pressure >80dBA.

The Impella® Controller displays a maximum of three alarm/notification messages at one time. The critical (red) alarms are displayed first, followed by any warning (yellow) alarms and then any advisory (white) notifications. If more than one alarm condition is present, the alarm with the highest priority is displayed first. The message for the highest priority alarm will flash on the screen.

When an alarm condition occurs, help text is automatically displayed next to the alarm message. The help text describes the action(s) to take to resolve the alarm.

The system logs the occurrence and the identity of alarms generated. These logs are maintained when the controller is powered down and after a power failure. The logs are only retrievable by Abiomed service personnel.

You may look at the Alarm History screen to see a log of the alarms generated and resolved during a particular case. These logs are not maintained when the controller is powered down or after a power failure.

Some alarms may be delayed several seconds after the associated event has occurred (see sidebar). This is due to the logic and/or calculations required to trigger certain alarms.

Alarm Delays

"Impella Defective"
…8 second delay

"Impella Pump Flow Too High"
…10±1 second delay

"Impella Pump Flow Too Low"
…10±1 second delay

"Impella Position Wrong"
…11±5 second delay

"Emergency Shutdown Imminent"
…15±1 second delay

"Battery Failure"
…28±8 second delay

"Battery Communication"
…38±8 second delay

"Purge Flow Low"
…TBD±TBD

"Purge Pressure High"
…TBD±TBD

"Purge System Blocked"
…TBD±TBD

TYPES OF ALARMS

The Impella® Controller monitors the motor current of the Impella® 2.5. The motor current is used to calculate the blood flow rate of the Impella® pump. The controller issues an alarm when the actual flow is more than 0.5 L/min below or above the target flow or if there is suction within the ventricle. The controller also issues alarms when there is a mechanical or electrical failure of the pump. The alarm display message provides instructions for either managing the patient or replacing the Impella®. The alarm continues until the alarm condition is resolved.

The Impella® Controller monitors the pressure generated by a sensor on the Impella® pump. The pressure is used to determine position across the aortic valve. If the position is wrong or unknown, the controller issues an alarm with instructions for how to reposition the Impella® pump.

The Impella® Controller monitors the electrical components within the system. If there is a problem with any of these components, a "Controller Failure" or "Controller Error" alarm occurs. In the rare event that either of these alarms occur, switch to the backup controller and call Abiomed service.

The Impella® Controller monitors the purge pressure, flow levels, and fluid remaining in the system as well as any errors that may occur within the purge system. If air is detected in the system, an "Air in Purge System" alarm is generated. The alarm prompts you to complete a de-air procedure to clear the air. Alarms are generated if the pressure does not stay within 300 to 1100 mmHg or flow levels fall outside the range of 2 to 20 mL/hr. Alarms are also triggered if the purge system is open or blocked, or if the purge flow increases or decreases by 2.5 mL/hr. The purge flow alarm limit is automatically adjusted when you acknowledge the alarm by pressing the **MUTE ALARM** button, clearing the alarm. All other alarms continue until the condition is resolved.

The Impella® Controller monitors the characteristics of the internal batteries. The batteries send information to the microprocessor in the Impella® Controller. This information is used to calculate the percentage of power remaining for the system. If the battery percentage falls below the alarm threshold, an alarm is generated until the system is plugged into an AC power source. Alarms are also generated if communication with the batteries is lost or if battery temperature is too high. All of these alarms continue until the condition is resolved.

MUTE ALARM FUNCTION

You can mute alarms by pressing the **MUTE ALARM** button. This will silence the audible alarm indicator for 2 minutes. The text of the alarm will remain on the display. By pressing **MUTE ALARM**, you are also acknowledging receipt of the alarm. After muting an alarm, if another alarm occurs it will be displayed, but the sound that occurs will be for the highest priority alarm. When a condition resolves after you have muted the alarm, the alarm will clear from the screen. If you do not press the **MUTE ALARM** button and the condition resolves, a gray alarm is displayed to inform you that the alarm has been resolved.

HANDLING ALARMS

The following tables list the Impella® Controller alarms from highest to lowest priority, as indicated by the priority number in the left column. Higher priority alarms override lower priority alarms. Note that alarm limits cannot be adjusted.

Additional alarms specific to the Impella® 5.0 or LD System are not listed in these tables.

Table 10.2 Critical (Red) Alarms

Priority	Alarm Message	Action	Cause
1	**Impella Stopped** **Controller Failure**	1. Replace controller. 2. Restart Impella.	There is a problem with the controller electronics.
2, 3, 7, 20	**Controller Failure***	Switch to backup controller.	There is a problem with the controller electronics. * NOTE: More than one condition that may trigger this alarm.
4	**Impella Stopped**	1. Restart Impella. 2. Replace Impella after 3rd unsuccessful restart attempt.	There may be a mechanical or electrical problem in the Impella pump.
5	**Impella Disconnected**	1. Check cable connection to console. 2. Check Impella connection to cable.	Running pump disconnected.
6	**Emergency Shutdown Imminent**	Release ON/OFF push button.	ON/OFF pressed for 15 seconds but the Impella pump still connected.
8	**Battery Temperature High**	Switch to backup controller.	Battery temperature is greater than 60°C.
9	**Battery Critically Low**	Plug controller into AC power.	Battery power has 15% remaining capacity.
10	**Battery Failure**	Plug controller into AC power.	One of the batteries has failed.
11	**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 line.
12	**Purge System Failure**	Switch to backup controller and replace purge cassette	There is a problem with the purger unit driver.

Table 10.2 Critical (Red) Alarms (continued)

Priority	Alarm Message	Action	Cause
13	**Impella Stopped** **Reverse Flow**	Restart Impella, or Remove Impella from ventricle.	Impella is not running, possible reverse flow through Impella pump.
14	**Impella Position Wrong**	1. Confirm Impella position with imaging. 2. Follow repositioning guide if needed.	Wrong placement detection for up to 14 seconds.
15	**Purge Pressure Low**	1. Check purge system tubing for leaks. 2. Increase concentration of dextrose in the purge solution.	Purge pressure has dropped below 300 mmHg with the purge flow ≥ 20 mL/hr.
16	**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.
17	**Impella Failure**	Replace Impella.	There is a problem with the Impella pump motor.
18	**Impella Motor Current High**	Replace Impella.	There is a problem with the Impella pump motor.
19	**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 10 mL or fewer remaining in the purge fluid bag.
21	**Purge System Open**	Check the purge system tubing for open connections or leaks.	Purge pressure has dropped below 100 mmHg.
22	**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.
23	**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 10.3 Warning (Yellow) Alarms

Priority	Alarm Message	Action	Cause
24, 37, 41, 42, 44	**Controller Error***	Switch to backup controller.	There is a problem with the controller electronics. * NOTE: More than one condition that may trigger this alarm.
25	**Impella Defective**	Do not use Impella. Replace Impella.	There is a problem with the Impella Pump electronics.
26	**Impella Position Wrong**	1. Confirm Impella position with imaging. 2. Pull Impella back 2 cm. 3. Follow repositioning guide if needed.	Wrong placement detection—Cardiac valve close on pump outlet openings (within 3 seconds).
27, 28	**Suction***	1. Check left side filling and volume status. 2. Check Impella position. 3. Reduce flow or performance level.	Suction is detected. * NOTE: More than one condition that may trigger this alarm.
29	**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.
30	**Impella Flow Low**	Unable to achieve set flow rate. 1. Check for suction. 2. Check for high afterload pressure.	Actual flow is more than 0.5 L/min below the target flow.
31	**Impella Flow High**	Unable to achieve set flow rate. Check for low afterload.	Actual flow is more than 0.5 L/min above the target flow.
34, 35	**Impella Sensor Failure** **Placement Monitoring is Suspended***	1. Monitor patient hemodynamics. 2. Monitor Impella position with imaging.	There is a problem with the Impella pump sensor signal. * NOTE: More than one condition that may trigger this alarm.
38	**Purge Volume Low**	1. Open **PURGE SYSTEM** menu and select Change Purge Fluid. 2. Follow the instructions to change the purge fluid.	There are 20 mL or fewer remaining in the purge fluid bag.
39	**Battery Level Low**	Plug the controller into AC power.	Battery power has 50% remaining capacity.
40	**Battery Comm. Failure**	Plug controller into AC power.	Loss of communication to the battery.
43	**Purge Cassette Failure**	Replace purge cassette.	There is a problem with the purge cassette software.

Table 10.4 Advisory (White) Notifications

Priority	Alarm Message	Action	Cause
45	**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.
46	**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.
47	**Mains Disconnected**	Controller is running on battery power	AC Mains was disconnected.

APPENDICES

APPENDIX A: IMPELLA® SYSTEM LIMITED SERVICE WARRANTY

IMPELLA® SYSTEM LIMITED SERVICE WARRANTY (US)

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 installation or title transfer. 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, Inc.

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 2010. However, the stipulations in the medical product logbook are binding in any case.

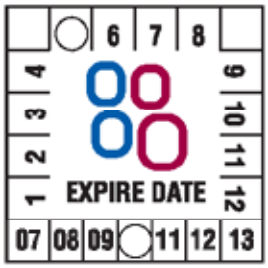


Figure B.1 Inspection Sticker Showing Inspection Required in May 2010

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 24-month 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

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 Circulatory Support System. Guidewires and catheters should always be used in accordance with Abiomed's instructions.

The following alternative guidewires have been tested and approved for use with the Impella® 2.5 System:

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

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**
- **TARGET FLOW**
- **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 appears 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 audio for all alarms for 2 minutes or until another alarm arises. Pressing **MUTE ALARM** also clears any resolved alarm on the display. (Refer to Section 10 for more information about Impella® Controller Alarms.)

TARGET FLOW

The **TARGET FLOW** soft button opens the flow icon enabling you to select the desired flow rate. The target flow icon is shown in Figure 5.14 in section 5 of this manual and the procedure for setting flow rate 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. The time scale options for the placement signal and motor current waveforms are 10 seconds, 5 minutes, and 5 hours. For the purge screen, the options are 1 hour, 8 hours, and 12 hours.
- **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 amount of heparin and dextrose delivered for the past 8 hours or longer, if applicable. The top entry in the table shows the amount of heparin and dextrose infused from the top of the hour through the current time. (See Figure 6.10 in section 6.)
- **Purge** – displays the purge system waveforms and pressure and flow values.
- **Placement** – opens the placement signal / motor current waveform screen (shown in Figure 4.3 and described in section 4 under "Impella® Controller Waveform Screen Display").
- **Home** – opens the home screen (shown in Figure 4.2 and described in section 4 under "Impella® Controller Waveform Home Screen Display").

PURGE SYSTEM

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

- **Change Purge Fluid** – starts the procedure to change the purge fluid
- **Change Purge Cassette** – starts the procedure to change 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

These procedures are described in section 6 under "Purger Procedures."

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 the current time zone, set screen brightness, view error history, or select the language for the system displays.

  Time Zone. Opens the Time Zone selection box. Turn the selector knob clockwise to scroll down the list of selections and counterclockwise to scroll up the list. Press the knob to make your selection and the new time zone is immediately displayed on the controller.

  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.

- **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® pump and the actions required to reposition the pump. 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 under "Case Start."

Clinical support 24 hours per day, 7 days a week:

1-800-422-8666 (US)

+49 (0) 1805 2246633 (EU)

www.abiomed.com

Abiomed, Inc.
22 Cherry Hill Drive
Danvers, Massachusetts 01923 USA
Voice: 978-777-5410
Facsimile: 978-777-8411
Email: clinical@abiomed.com

Abiomed Europe GmbH
Neuenhofer Weg 3
52074 Aachen, Germany
Voice: +49 (241) 8860-0
Facsimile: +49 (241) 8860-111
Email: europe@abiomed.com