

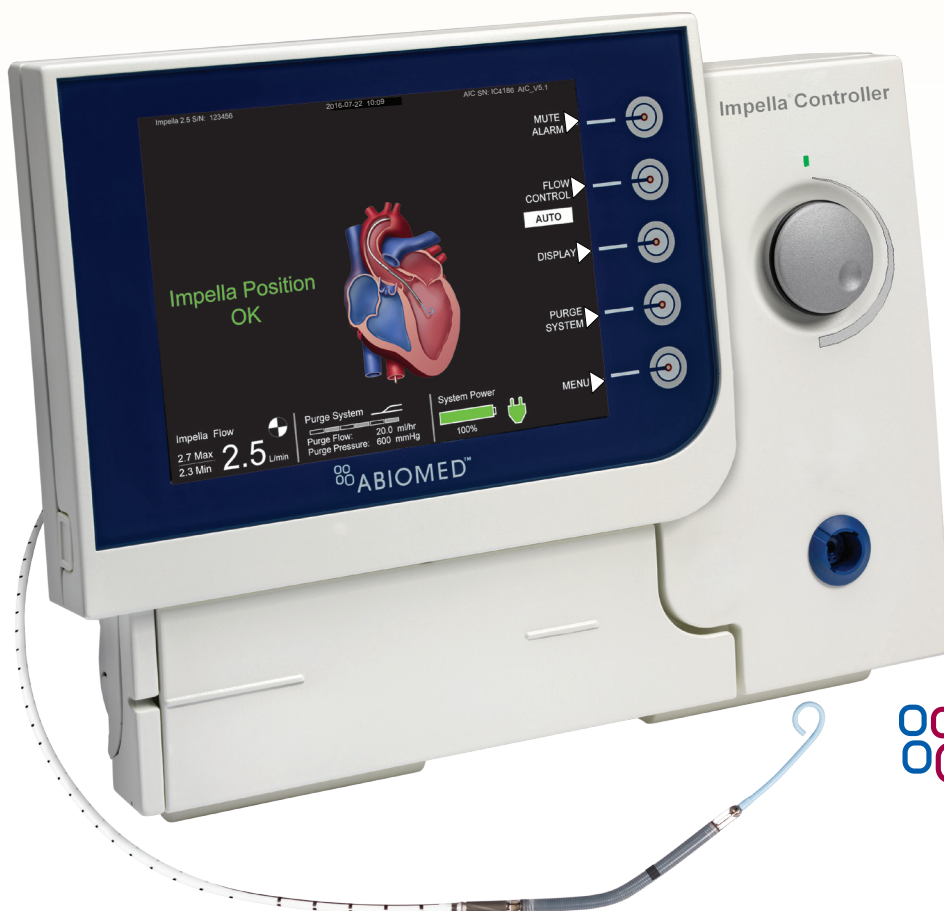
Impella Ventricular Support Systems

for Use During Cardiogenic Shock

Impella® 2.5, 5.0, LD and Impella CP®

INSTRUCTIONS FOR USE & CLINICAL REFERENCE MANUAL

(United States only)



 **ABIOMED**
Recovering hearts. Saving lives.®

IMPORTANT NOTICE: Read this entire manual before using the Automated Impella® Controller and Impella® 2.5, 5.0, LD, or Impella CP® Circulatory Support System (Impella® System). The Impella® System is to be used only in accordance with this manual. This manual is only applicable to Impella® Systems using the Automated Impella® Controller.

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IMPELLA VENTRICULAR SUPPORT SYSTEMS FOR USE DURING CARDIOGENIC SHOCK INSTRUCTIONS FOR USE & CLINICAL REFERENCE MANUAL

(UNITED STATES ONLY)

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INTRODUCTION

PURPOSE OF MANUAL

This Instructions for Use & Clinical Reference Manual is designed for healthcare professionals. It contains clinical and technical information to guide healthcare professionals in their use of the Impella® 2.5, 5.0, LD, and Impella CP® Catheters during cardiogenic shock. The Impella Ventricular Support Systems perform life-sustaining functions. To use the system you must understand and follow these instructions. The Impella Ventricular Support Systems may be used only for its intended purpose.

MANUAL OVERVIEW

This manual provides instructions for use of the Impella® 2.5, 5.0, LD, and Impella CP® Catheters with the Automated Impella® Controller. The following summarizes the contents of each section of the manual.

- **Section 1: Indications, Contraindications, and Potential Adverse Events** discusses indications for use of the Impella® Catheter with the Automated Impella® Controller, contraindications, and potential adverse events that may be associated with the use of the system.
- **Section 2: Warnings and Cautions** discusses the warnings and cautions pertaining to the use of the Impella® Catheter with the Automated Impella® Controller.
- **Section 3: The Impella® Catheter and Automated Impella® Controller** provides an overview of the system and describes its major components and features.
- **Section 4: Using the Automated Impella® Controller** describes the controls and various screen types on the Automated Impella® Controller.
- **Section 5: Using the Automated Impella® Controller with the Impella® Catheter** provides the procedures for using the Impella Ventricular Support Systems.
- **Section 6: Clinical Experience** provides an overview of clinical studies of the Impella Ventricular Support Systems.
- **Section 7: Patient Management Topics** provides key information on various topics related to management of patients with the Impella® Catheter and Automated Impella® Controller.
- **Section 8: Automated Impella® Controller Alarms** provides a listing of Automated Impella® Controller alarms as well as information on what to do to resolve them.
- **Section 9: General System Information** contains information including definitions for key terms that appear in the manual, descriptions of the abbreviations and symbols that appear on Impella® Catheter and Automated Impella® Controller components and packaging, technical information pertaining to the Impella® Catheter and Automated Impella® Controller, and instructions on cleaning and storing system components as well as returning components to Abiomed.
- **Appendices** at the end of the manual provide supplemental information about topics including the Impella® Limited Service Warranty; Abiomed-approved guidewires and introducers; and the Automated Impella® Controller menu structure.

1 INDICATIONS, CONTRAINDICATIONS, AND POTENTIAL ADVERSE EVENTS



INDICATIONS (UNITED STATES) 1.1
 Impella® 2.5, Impella CP®, Impella® 5.0, and Impella® LD 1.1

CONTRAINDICATIONS (UNITED STATES)..... 1.1

POTENTIAL ADVERSE EVENTS (UNITED STATES)1.2

INDICATIONS (UNITED STATES)

IMPELLA® 2.5, IMPELLA CP®, IMPELLA® 5.0, AND IMPELLA® LD

The Impella® 2.5, Impella CP®, Impella® 5.0, and Impella® LD Catheters, in conjunction with the Automated Impella® Controller, are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella® 2.5 and Impella CP®, and ≤ 6 days for the Impella® 5.0 and Impella® LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures.* The intent of the Impella Ventricular Support Systems therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

*Optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without IABP

CONTRAINDICATIONS (UNITED STATES)



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

The Impella® System is contraindicated in patients with:

- Mural thrombus in the left ventricle
- Mechanical aortic valve or heart constrictive device
- Aortic valve stenosis/calcification (equivalent to an orifice of 0.6 cm² or less)
- Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as $\geq +2$)
- Severe peripheral arterial disease that precludes the placement of the Impella® System
- Significant right heart failure
- Combined cardiorespiratory failure
- Presence of an atrial or ventricular septal defect (including post-infarct VSD)
- Left ventricular rupture
- Cardiac tamponade

POTENTIAL ADVERSE EVENTS (UNITED STATES)

- Acute renal dysfunction
- Aortic insufficiency
- Aortic valve injury
- Atrial fibrillation
- Bleeding
- Cardiogenic shock
- Cardiac tamponade
- Cardiopulmonary resuscitation
- Cerebral vascular accident / Stroke
- Death
- Device malfunction
- Failure to achieve angiographic success
- Hemolysis
- Hepatic failure
- Insertion site infection
- Limb ischemia
- Myocardial infarction
- Need for cardiac, thoracic or abdominal operation
- Perforation
- Renal failure
- Repeat revascularization
- Respiratory dysfunction
- Sepsis
- Severe hypotension
- Thrombocytopenia
- Thrombotic vascular (non-CNS) complication
- Transient ischemic attack
- Vascular injury
- Ventricular arrhythmia, fibrillation or tachycardia

2 WARNINGS AND CAUTIONS



WARNINGS2.1

CAUTIONS 2.3

WARNINGS



Use of the Impella Ventricular Support Systems by trained and experienced practitioners has been associated with improved outcomes. Consequently, the first use of Impella® should be preceded by the completion of a contemporary Abiomed Impella® training program and include on-site proctoring during the first use by Abiomed clinical support personnel certified in the use of Impella®.



Institution of circulatory support using Impella® has not been studied in the following conditions:

- Presence of irreversible end-organ failure
- Presence of severe anoxic brain injury



Fluoroscopy is required to guide placement of the Impella® Catheter and, for the Impella CP®, during rewire through the guidewire access port. The small placement guidewire must be reliably observed at all times.



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



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



The sterile components of the Impella Ventricular Support Systems 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® Catheter. It is a disposable device and is intended for single use only. Reuse, reprocessing, or resterilization may compromise the structural integrity of the catheter and/or lead to catheter failure which, in turn, may result in patient injury, illness, or death.



Retrograde flow will occur across the aortic valve if the flow rate of the Impella® Catheter is less than 0.5 L/min.



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



To prevent failure of the peel-away introducer, remove the 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 Ventricular Support Systems if any part of the system is damaged.



To prevent the risk of explosion, do **NOT** operate the Impella Ventricular Support Systems near flammable anesthetics.




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



MR Unsafe - Do **NOT** subject a patient who has been implanted with an Impella System 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 Impella System electronics.



Warnings

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



Cardiopulmonary support (CPR) should be initiated immediately per hospital protocol if indicated for any patient supported by the Impella® Catheter. When initiating CPR, reduce the Impella® Catheter flow rate. When cardiac function has been restored, return flow rate to the previous level and assess placement signals on the controller.



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



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



Lithium-ion battery replacement by inadequately trained personnel could result in excessive temperatures, fire, or explosion. Only technicians authorized by Abiomed should remove or change the battery.



To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



No modification of this equipment is allowed.



Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the electromagnetic compatibility (EMC) information provided in section 9 of this manual.



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



Portable and mobile RF communications equipment can affect medical electrical equipment.



The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.



Use of cables, other than those sold by Abiomed, may result in increased emissions or decreased immunity of the Automated Impella® Controller.



The Automated Impella® Controller uses RFID (radio frequency identification) to identify and communicate with the purge cassette. Other equipment may interfere with the Automated Impella® Controller even if that other equipment complies with CISPR emission requirements.



Infusion through the sideport of the introducer can be done only after all air is removed from the introducer. If performed, the infusion should be done for flushing purposes only and **NOT** for delivering therapy or monitoring blood pressure.



Do **NOT** use the guidewire access port on the Impella CP® as an arterial line. The stylet should remain in place until guidewire access is required through the Impella® Catheter.

CAUTIONS



Handle with care. The Impella® 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.



Physicians should exercise special care when inserting the Impella® Catheter during active Cardiopulmonary Resuscitation (CPR). In addition, active CPR maneuvers may change the position of the Impella device. Check that the pump is positioned correctly in the left ventricle after CPR with echocardiography guidance.



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



Partial circulatory support with Impella® has been associated with more extensive use of rotational atherectomy. Extensive use of rotational atherectomy has been associated with a periprocedural increase in cardiac biomarkers indicative of myocardial injury. Rotational atherectomy, with or without the use of hemodynamic support, should be used in accordance with the manufacturer's instructions for use.



Physicians should exercise special care when inserting the Impella® Catheter in patients with known or suspected unrepaired abdominal aortic aneurysm or significant descending thoracic aortic aneurysm or dissection of the ascending, transverse, or descending aorta.



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® Catheter until the guidewire has been removed.



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



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



To prevent malfunction of the Automated 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 Automated Impella® Controller while it is operating.



Do **NOT** kink or clamp the Impella® Catheter with anything other than a soft jaw vascular clamp. Do **NOT** kink or clamp the peel-away introducer.



During case start, make sure the yellow luer connection between the purge tubing and Y connector is tightened and not leaking.



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

Cautions

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



Minimize exposure of Impella Ventricular Support Systems 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.



During use with the Remote Link, a Medical Device Data System (MDDS), if the Automated Impella® Controller is exposed to strong electromagnetic disturbances, the Remote Link may either restart or shut down. Operators should be aware that, under these conditions, the Automated Impella® Controller operating parameters are not affected. If the Remote Link stops working because of electromagnetic disturbances, a hard restart (by first disconnecting, and then reconnecting its AC power) will correct the problem.



Operation of Impella Ventricular Support Systems components may interfere with the operation of other devices. If interference occurs, increase the distance between the device and system components.



Have a backup Automated Impella® Controller, purge cassette, connector cable, and Impella® Catheter available in the unlikely event of a device failure.



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



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



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



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



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



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



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



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 or bleeding, physicians should use their clinical judgment to assess the risks versus benefits of operating the Impella Ventricular Support Systems without heparin. If it is in the best interest of the patient to operate the system without heparin, the dextrose solution is still required, and physicians should consider systemic delivery of an alternative anticoagulant. Do **NOT** add any alternative anticoagulant (such as a direct thrombin inhibitor) to the purge fluid. The Impella® Catheter has not been tested with any alternative anticoagulants in the purge solution.

3 THE IMPELLA® CATHETER AND AUTOMATED IMPELLA® CONTROLLER



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OVERVIEW

The Impella® Catheter is an intravascular microaxial blood pump that supports a patient's circulatory system during cardiogenic shock, low output syndrome, or other conditions. The Impella® 2.5, 5.0, and Impella® CP Catheters can be inserted percutaneously through the femoral or axillary artery and into the left ventricle. The Impella® LD is inserted directly through the ascending aorta and into the left ventricle.

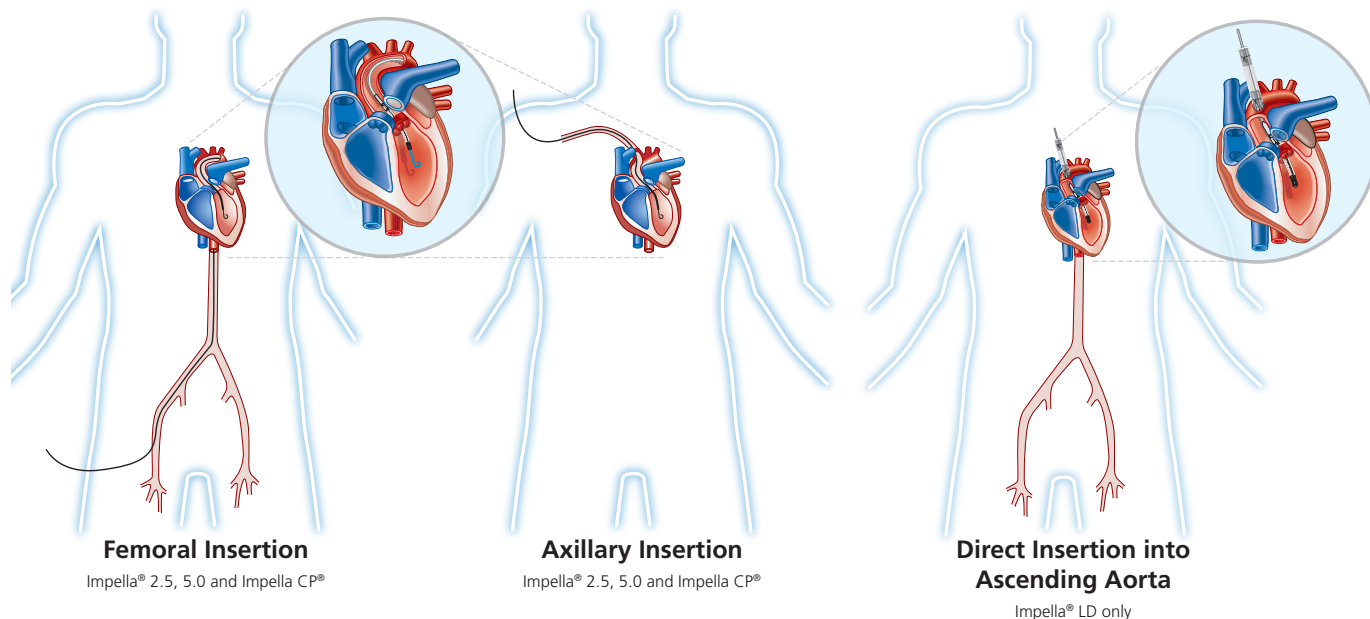


Figure 3.1 *Impella® Catheter in the Heart*

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

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

REUSABLE SYSTEM COMPONENTS

The Impella Ventricular Support Systems consist of the following reusable components:

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

SINGLE-USE SYSTEM COMPONENTS

The Impella Ventricular Support Systems also include the following single-use components:

- Impella® Catheter
- Purge cassette
- Introducer kit (Impella® 2.5 and Impella CP®)
- 0.018 inch, 260 cm placement guidewire (Impella® 2.5, 5.0, and Impella CP®)
- Impella® Axillary Insertion kit (Impella® 2.5, 5.0, and Impella CP®)
- Connector cable
- Incision template (Impella® LD)

IMPELLA® SET-UP AND INSERTION KITS (IMPELLA® 2.5 AND IMPELLA CP®)

The components of the Impella® 2.5 and Impella CP® Systems are each packaged into a single box called the Impella® Set-up and Insertion kit. Table 3.1 describes the contents of these kits.

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

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

- Impella® Catheter
- 0.018 inch, 260 cm placement guidewire
- Connector cable
- Purge cassette
- Introducer kit
 - » Peel-away introducer (13 Fr for Impella® 2.5, 14 Fr for Impella CP®)
 - » Dilator(s) (13 Fr for Impella® 2.5, 8 Fr, 10 Fr, 12 Fr, and 14 Fr for Impella CP®)
 - » 18 G Seldinger needle (Impella® 2.5)
 - » 12 cc syringe (Impella® 2.5)
 - » 0.035 inch stiff access guidewire

IMPELLA® AXILLARY INSERTION KIT (IMPELLA® 2.5, 5.0 AND IMPELLA CP®)

Table 3.2 describes the contents of the Impella® Axillary Insertion kit.

Table 3.2 *Impella® Axillary Insertion Kit*

The Impella® Axillary Insertion kit contains the following:

- 23 Fr diameter x 6 cm length peel-away introducer
- 2 graft locks used to attach a graft onto the introducer (*Note: Only one graft lock is required when used with the recommended Hemashield Platinum graft; a back-up is provided.*)
- 8 Fr silicone-coated lubrication dilator
- 2 silicone plugs

It is recommended that the Impella® Axillary Insertion kit be used in conjunction with a 10 mm diameter x 20 cm length Hemashield Platinum graft.

SYSTEM CONFIGURATIONS

Initial set-up configuration for Impella® 2.5 and Impella CP®

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

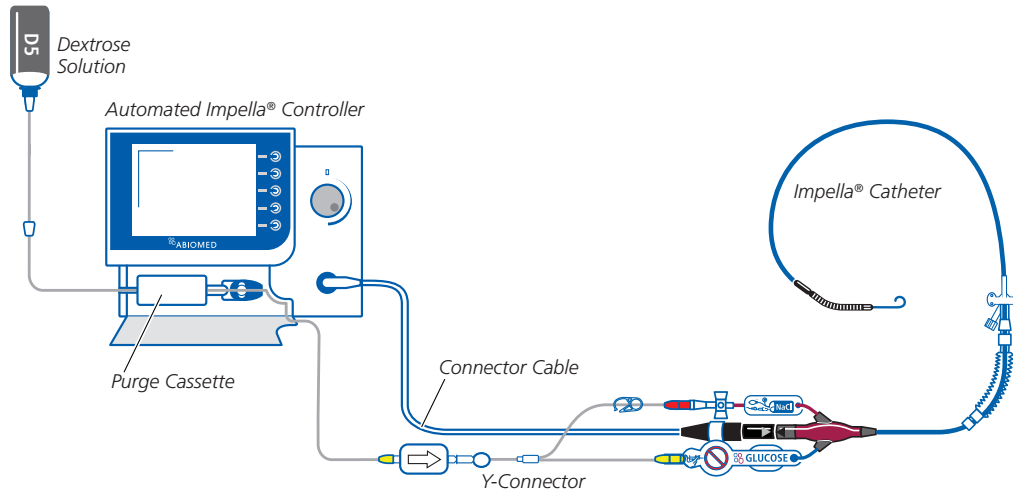


Figure 3.2a Set-up Configuration of the Automated Impella® Controller, Impella® 2.5 or Impella CP® Catheter, and Accessories (Impella CP® shown)

Standard configuration for Impella® 2.5 and Impella CP®

Figure 3.2b illustrates the standard configuration of the Impella® 2.5 or Impella CP® Catheter, Automated Impella® Controller, and accessory components.

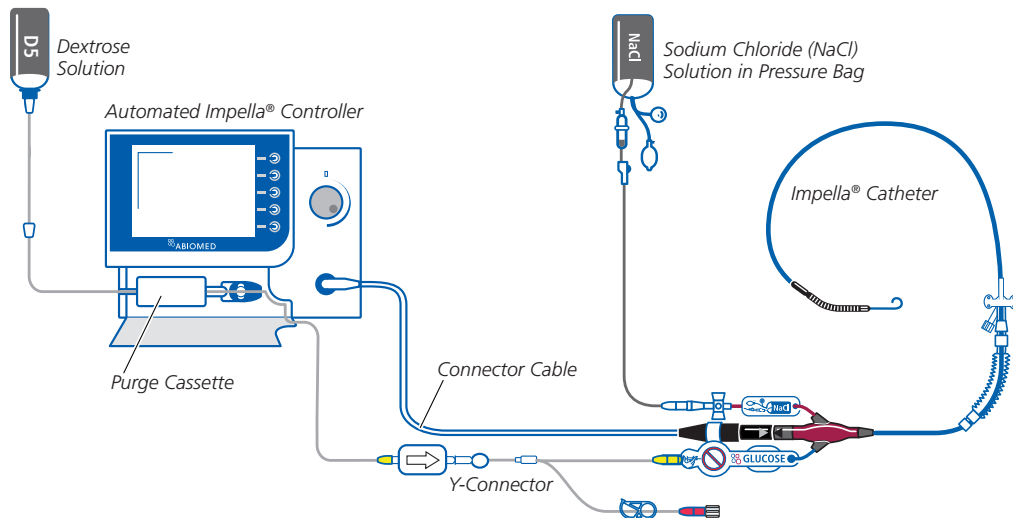


Figure 3.2b Standard Configuration of the Automated Impella® Controller, Impella® 2.5 or Impella CP® Catheter, and Accessories (Impella CP® shown)

System configuration for Impella® 5.0 and LD

Figure 3.3 illustrates how the Automated Impella® Controller connects to the Impella® 5.0 or LD Catheter and accessory components in the initial set-up configuration.

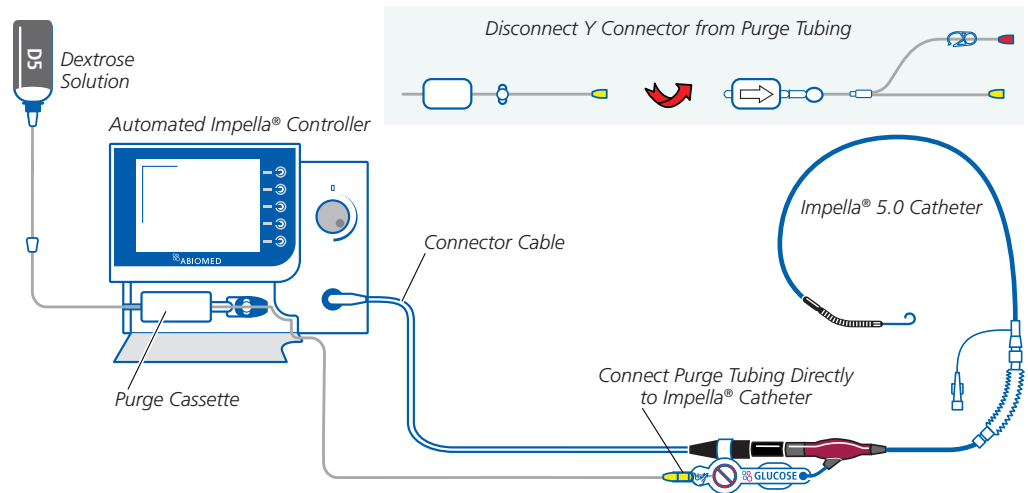


Figure 3.3 Set-up Configuration of the Automated Impella® Controller, Impella® 5.0 or LD Catheter, and Accessories (Impella® 5.0 shown)

IMPELLA® CATHETER

The Impella® Catheter is an intravascular microaxial blood pump that delivers up to 2.5 liters (Impella® 2.5), 3.3 liters (Impella CP®) or 5.0 liters (Impella® 5.0 and LD) of blood per minute from the left ventricle into the aorta. Figure 3.4 illustrates the Impella® Catheters. Table 3.3 describes each component from the pigtail at one end to the check valve on the other end.

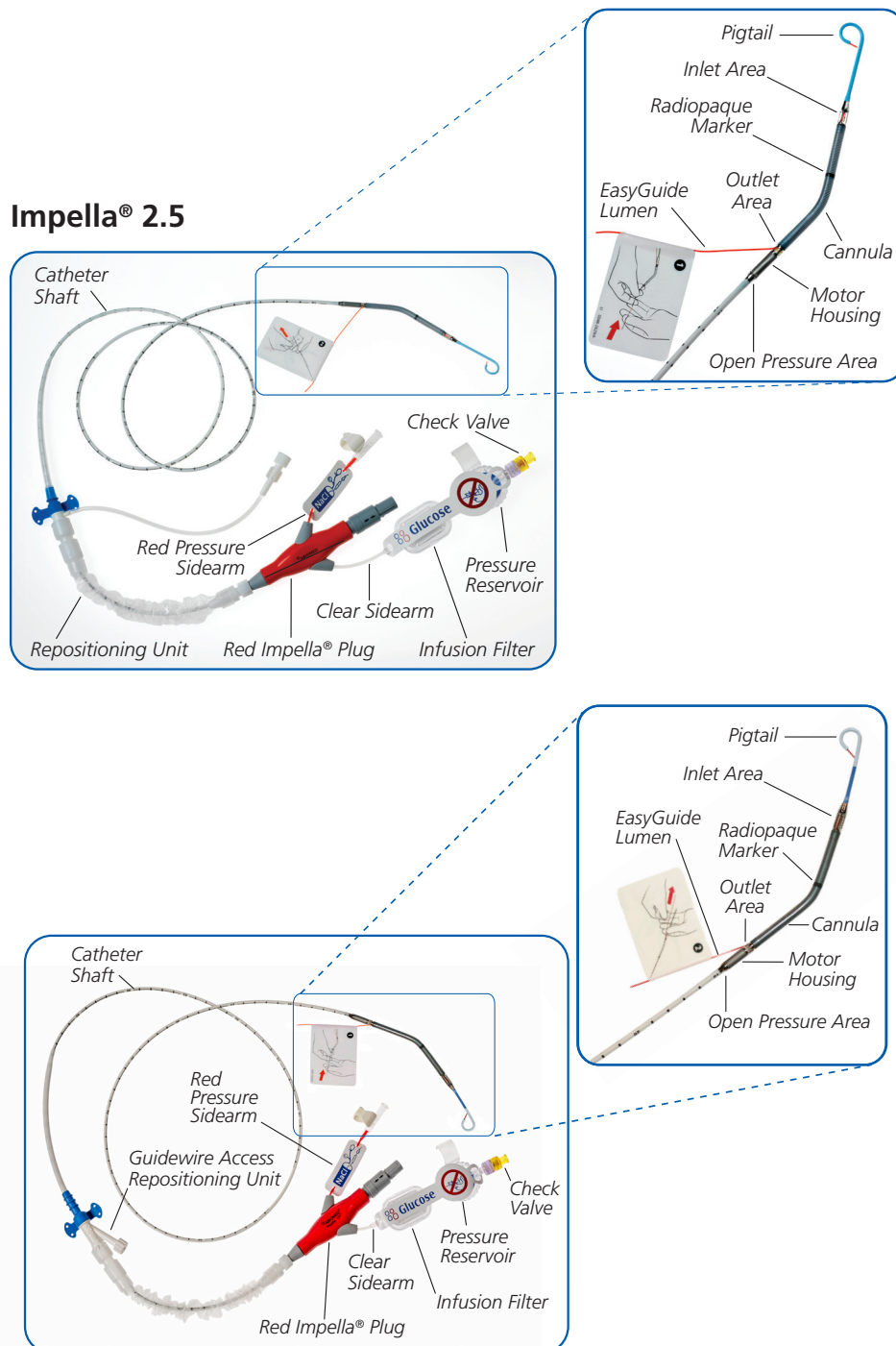
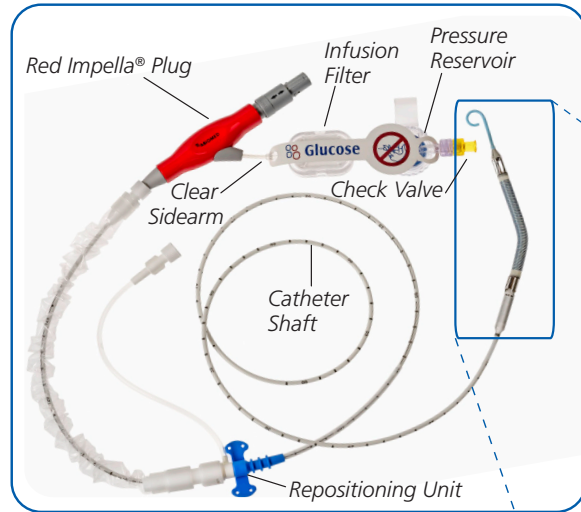
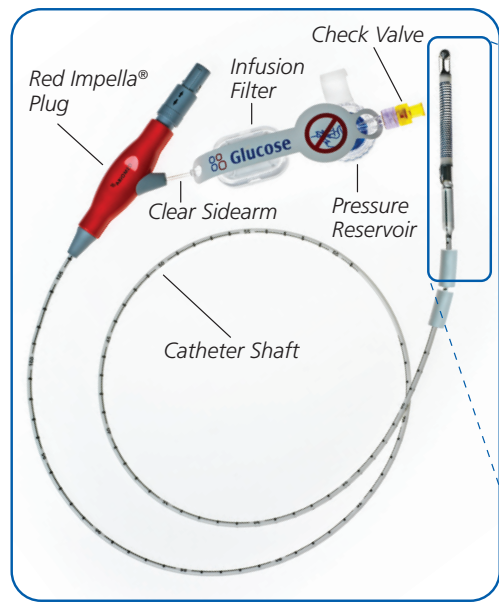
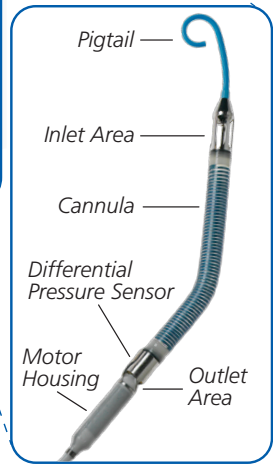


Figure 3.4 Impella® Catheters



Impella® 5.0



Impella® LD

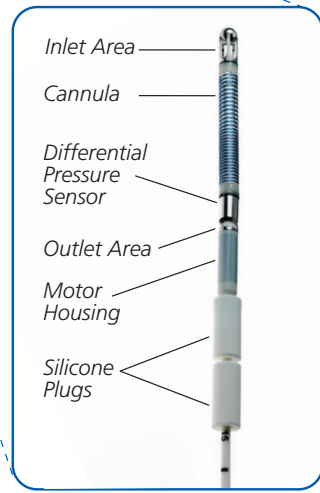


Figure 3.4 Impella® Catheters (continued)

Table 3.3 Impella® 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 Impella® 2.5, 5.0, and Impella CP® Catheters in the correct position in the left ventricle.
Inlet area	The inlet area, located at the distal tip of the cannula, has four openings (windows) (five for the Impella® 5.0 and LD) that allow blood to be drawn into the inlet and channeled through the cannula.
Radiopaque marker	The radiopaque marker on the catheter shaft of the Impella® 2.5 and Impella CP® Catheters is visible with fluoroscopy and, when properly positioned, appears at the level of the aortic valve annulus.
Cannula	The cannula (12 Fr for the Impella® 2.5, 14 Fr for the Impella CP®, 21 Fr for the Impella® 5.0 and LD) has a spiral-shaped reinforced body that is angled for the Impella® 2.5, 5.0 and Impella CP® Catheters and straight for the Impella® LD. The cannula is made of nitinol and covered in polyurethane.
Differential pressure sensor	This sensor on the Impella® 5.0 and LD Catheters measures the pressure difference between the inside and outside of the cannula. The pressure value is used for positioning during placement and for monitoring flow and position during catheter operation.
Outlet area	The proximal end of the cannula is attached to the outlet area where the blood exits the cannula.
EasyGuide lumen	The red loading lumen on the Impella® 2.5 and Impella CP® runs from the tip of the pigtail through the outlet area of the cannula to facilitate loading the catheter onto the guidewire
Motor housing	The motor housing (12 Fr for the Impella® 2.5, 14 Fr for Impella CP®, 21 Fr for Impella® 5.0 and LD) consists of an encapsulated motor.
Silicone plugs	The two silicone plugs on the catheter shaft of the Impella® LD help control bleeding during and after the Impella® LD Catheter insertion process and while advancing the catheter through the Dacron® vascular graft.
Open pressure area	The open pressure area on the Impella® 2.5 and Impella CP® Catheters is an opening located between the motor housing and the distal end of the catheter shaft.
Catheter shaft	A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, a pressure measurement lumen (Impella® 2.5 and Impella CP®), a nitinol wire, and an electrical cable. The catheter shaft has longitudinal and transversal marks: <ul style="list-style-type: none"> • The longitudinal mark along the inner radius shows correct position of the placement guidewire once backloaded on the Impella® Catheter. • The transversal marks at 1 cm intervals with numbers every 5 cm aid in proper positioning.

Table 3.3 Impella® Catheter Components (continued)

Component	Description
Repositioning unit	<p>The repositioning unit on the Impella® 2.5, 5.0, and Impella CP® Catheters consists of a sheath, an anticontamination sleeve with an anchoring ring, and suture pads.</p> <ul style="list-style-type: none"> • The sheath (with hemostatic valve) is graduated from 9 Fr to 15 Fr. It is located on the catheter shaft and allows repositioning of the catheter. • A guidewire access port on the Impella CP® may be used to facilitate insertion of a 0.035" (or smaller) guidewire into the arteriotomy prior to removal of the Impella® Catheter. A stylet maintains the patency of the guidewire lumen. • The anchoring ring of the anticontamination sleeve secures the sheath to the catheter. • The StatLock® compatible suture pads help secure the repositioning sheath to the patient's skin.
Red Impella® plug	<p>The red Impella® plug at the proximal end of the catheter connects the catheter to the Automated Impella® Controller through a connector cable. It contains:</p> <ul style="list-style-type: none"> • Memory that retains operating parameters in case the patient needs to be transferred to another controller • A pressure transducer (Impella® 2.5 and Impella CP® Catheters) that translates pressure for the pressure lumen proximal to the motor • The placement signal lumen (Impella® 2.5 and Impella CP® Catheters) that allows for pressure and waveform displays <p>The Impella® 2.5 and Impella CP® Catheters have two sidearms: a red pressure sidearm and a clear sidearm. The Impella® 5.0 and LD Catheters have only a clear sidearm.</p>
Red pressure sidearm	<p>The red pressure sidearm on the Impella® 2.5 and Impella CP® Catheters is attached to a standard pressure bag and is used to prime the line of the pressure measurement system.</p>
Clear sidearm	<p>The clear sidearm is attached to the purge cassette tubing. It leads to the infusion filter, the pressure reservoir, and the check valve.</p>
Infusion filter	<p>The infusion filter prevents bacterial contamination and air from entering the purge lumen.</p>
Pressure reservoir	<p>The pressure reservoir includes a flexible rubber diaphragm that provides additional filling volume by means of an expansion chamber during purge solution change.</p>
Check valve	<p>The yellow check valve ensures that purge fluid does not flow in the reverse direction when the purge solution is exchanged.</p>

DIFFERENTIAL PRESSURE SENSOR FOR IMPELLA® 5.0 AND LD

The Impella® 5.0 and LD Catheters have an electronic differential pressure sensor located at the proximal end of the 21 Fr cannula. The purpose of the pressure sensor is to generate the placement signal, which is used by operators and the controller to monitor the position of the Impella® cannula relative to the aortic valve.

The pressure sensor is a flexible membrane integrated into the cannula (see Figure 3.5). One side of the sensor is exposed to the blood pressure on the outside of the cannula and the other side is exposed to the pressure of the blood inside the cannula. The sensor generates an electrical signal proportional to the difference between the pressure outside the cannula and the pressure inside. This signal is displayed on the Automated Impella® Controller as the placement signal.

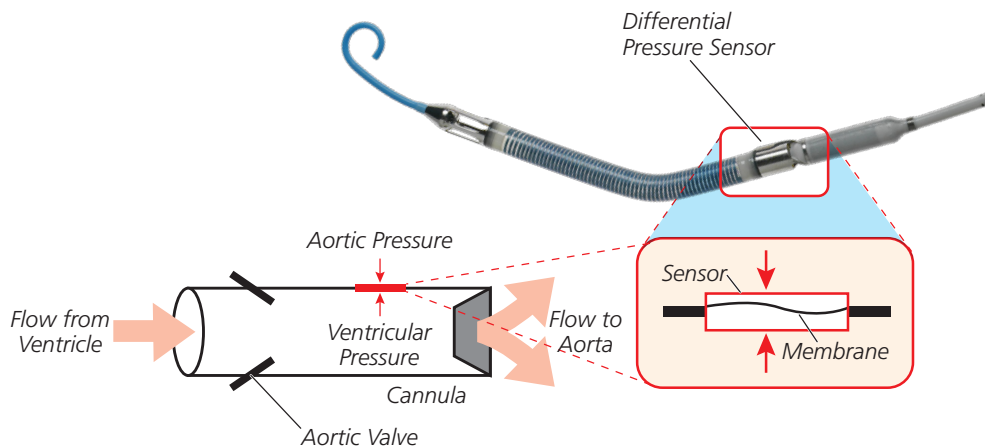


Figure 3.5 Impella® 5.0 and LD Differential Pressure Sensor (Impella® 5.0 shown)

The pressure sensor membrane flexes when the pressure on one side is different from the pressure on the other side, and the electrical properties of the membrane change when it flexes. This allows the sensor to generate an electrical signal proportional to how much the membrane is flexed, and thus proportional to the difference between the pressure on the outside of the cannula and the pressure inside. When the Impella® 5.0 or LD Catheter is placed in the correct position across the aortic valve, the top (outer surface) of the sensor is exposed to the aortic pressure and the bottom (inner surface) of the sensor is exposed to the ventricular pressure. Therefore, the placement signal is approximately equal to the difference between the aortic pressure and the ventricular pressure (see Figure 3.6).

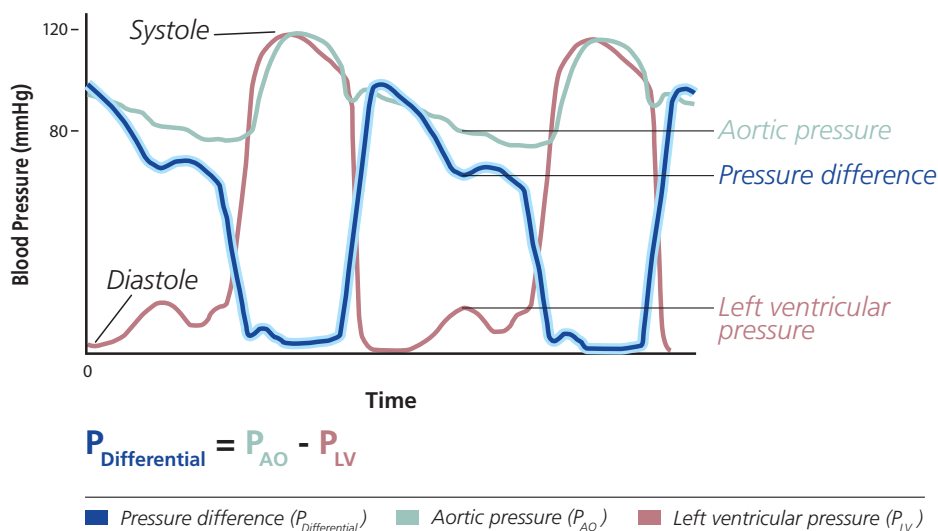


Figure 3.6 Electrical Signal Generated by the Cardiac Cycle

When the Impella® 5.0 or LD Catheter is correctly positioned across the aortic valve, the changes in pressure associated with the cardiac cycle result in a pulsatile placement signal (see Figure 3.7). During diastole (time zero in Figure 3.6), the large pressure difference between the aorta and the left ventricle creates a large electrical signal. Then at the peak of systole, when the aortic valve opens, the pressure difference between the aorta and the left ventricle—and thus the electrical signal—is zero. Thus, the continual pressure changes associated with the cardiac cycle produce the pulsatile (up and down) waveform seen on the Automated Impella® Controller display.

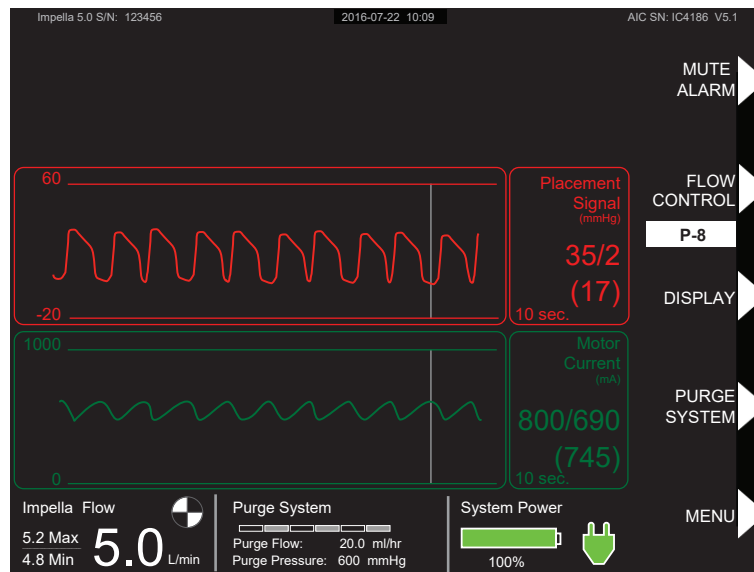


Figure 3.7 Correct Impella® 5.0/LD Catheter Positioning and Pulsatile Placement Signal

When the Impella® 5.0 or LD Catheter is not properly placed across the aortic valve, or when it is fully in the aorta or fully in the ventricle, the pressures outside and inside the cannula are the same throughout the cardiac cycle. As a result, the pressure on either side of the sensor membrane is the same, resulting in a flat placement signal (see Figure 3.8).

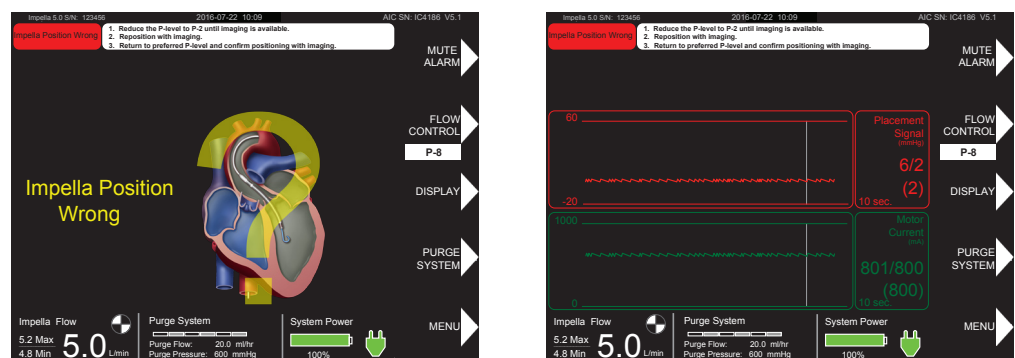


Figure 3.8 Incorrect Impella® 5.0/LD Catheter Positioning and Flat Placement Signal

AUTOMATED IMPELLA® CONTROLLER

The Automated Impella® Controller (see Figure 3.9) provides three vital functions to the operation of the Impella® Catheter:

- The controller provides an interface for monitoring and controlling the function of the Impella® Catheter
- The controller provides a purge fluid to the Impella® Catheter
- The controller provides backup power when the Impella Ventricular Support Systems are 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.

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



Figure 3.9 Automated Impella® Controller – Front View

Automated Impella® Controller Battery Power

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

Automated Impella® Controller Power Cord

Use caution when moving equipment to prevent damaging the controller's power cord.

PURGE CASSETTE



Do not use saline in the purge system.

The purge cassette delivers rinsing fluid to the Impella® Catheter. The purge fluid (typically 5% dextrose solution) flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor. When the purge cassette is properly installed in the Automated Impella® Controller, the Abiomed logo is upright and facing you. Figure 3.10 illustrates the purge cassette and related components. Table 3.4 describes each component.

Y connector

The Y connector attached to the purge tubing is used for the initial set-up configuration of the Impella® 2.5 and Impella CP® Systems (see Figure 3.2a). Switch to the standard configuration (see Figure 3.2b) as soon as practical.

Disconnect and discard the Y connector from the purge tubing when setting up the Impella® 5.0 or LD Systems and connect the yellow luer on the end of the purge tubing directly to the yellow luer on the Impella® 5.0 or LD Catheter as shown in Figure 3.3.

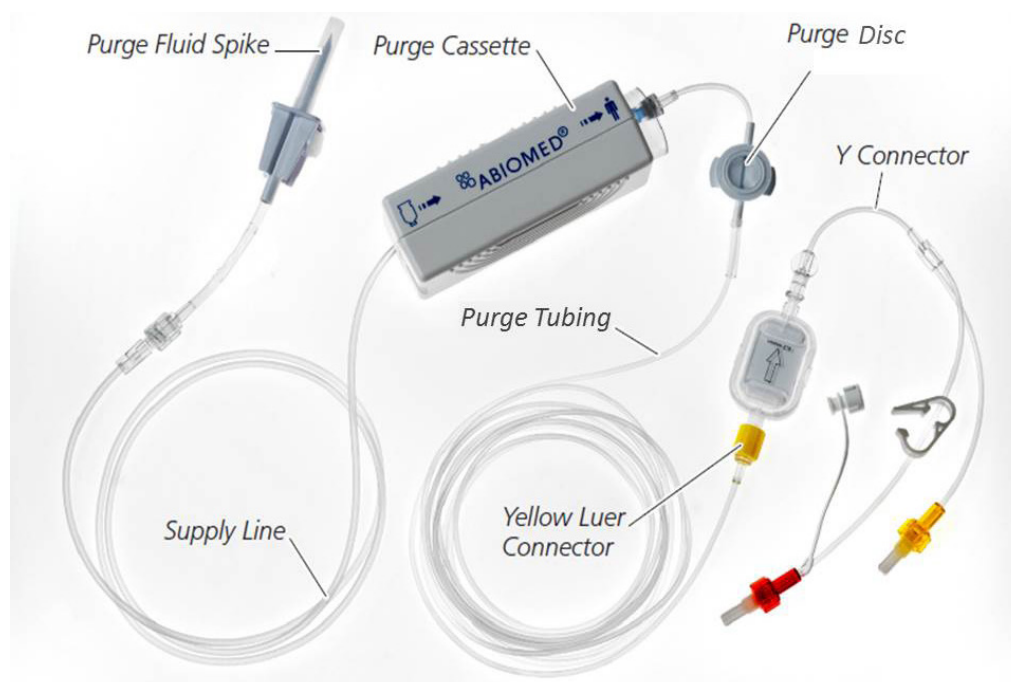


Figure 3.10 Purge Cassette



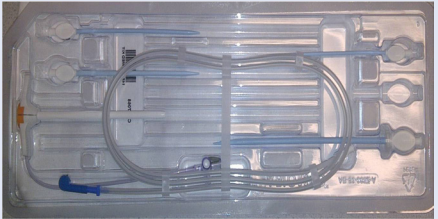

Table 3.4 Purge Cassette Components

Component	Description
Purge fluid spike	One end spikes the purge fluid bag and the other end connects the bag to the purge cassette supply line
Supply line	Carries fluid from the purge fluid bag to the purge cassette
Purge cassette	Contains the components for delivering the purge fluid; the purge fluid maintains the pressure barrier between the blood and the motor to prevent blood from entering the motor
Purge disc	Transmits pressure to the controller based on the purge pressure in the purge tubing; a sensor in the controller measures the pressure so that it can be displayed on the screen and used by the purge pressure algorithm to maintain the purge pressure
Purge tubing	Carries purge fluid from the purge cassette to the Impella® Catheter
Yellow luer connector	Connects the purge tubing to the Y connector at case start (for Impella® 2.5 and Impella CP®) and to the check valve (yellow luer lock) on the Impella® Catheter after system change and initial setup of Impella® 5.0 and LD.
Y connector (for Impella® 2.5 and Impella CP® only)	Adapter that connects the purge tubing to the sidearms of the Impella® 2.5 or Impella CP® Catheter during case start. The Y connector consist of: <ul style="list-style-type: none"> • Yellow luer that connects to the clear sidearm • Red luer that connects to the red sidearm • Cap for the red luer when it is disconnected from the sidearm for transfer to the standard configuration • Clamp for the purge tubing leading to the red sidearm • Rectangular antibacterial air filter

ACCESSORIES

Table 3.5 illustrates and describes the accessories used with the Impella® Catheter and Automated Impella® Controller.

Table 3.5 Impella® Catheter and Automated Impella® Controller Accessories

Component	Description
 <p>A coiled white connector cable with a black socket at one end and a white plug at the other. A black pen is placed next to it for scale.</p>	<p>The white connector cable connects the Impella® Catheter to the Automated Impella® Controller. Clips on the cable are used to secure the purge tubing to the cable.</p> <ul style="list-style-type: none"> • 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 catheter plug on the front of the Automated Impella® Controller.
<p>Figure 3.11 White Connector Cable</p>	
 <p>A collection of medical instruments including a peel-away introducer, a dilator, an 18 G Seldinger needle, a 12 cc syringe, and a 0.035 inch stiff access guidewire.</p>	<p>The Impella® 2.5 introducer kit is used to gain arterial access for the Impella® 2.5 Catheter. It contains:</p> <ul style="list-style-type: none"> • Peel-away introducer—with hemostatic valve for tight fit around components and single-step “break-away” configuration • Dilator—easy to insert and remove with soft design for atraumatic approach into femoral artery • 18 G Seldinger needle • 12 cc syringe • 0.035 inch stiff access guidewire
<p>Figure 3.12 Impella® 2.5 Introducer Kit</p>	
 <p>A collection of medical instruments including a peel-away introducer, dilators of various sizes (8 Fr, 10 Fr, 12 Fr, 14 Fr), and a 0.035 inch stiff access guidewire, all in a clear plastic tray.</p>	<p>The Impella CP® introducer kit is used to gain arterial access for the Impella CP® Catheter. It contains:</p> <ul style="list-style-type: none"> • 14 Fr peel-away introducer—with hemostatic valve for tight fit around components and single-step “break-away” configuration • 8 Fr, 10 Fr, 12 Fr, and 14 Fr dilators—easy to insert and remove with soft design for atraumatic approach into femoral artery • 0.035 inch stiff access guidewire
<p>Figure 3.13 Impella CP® Introducer Kit</p>	
 <p>Two white cylindrical silicone plugs, one standing upright and one lying on its side.</p>	<p>The two silicone plugs can be placed around the catheter shaft to help control bleeding during and after Impella® 5.0 or LD Catheter insertion and while advancing the catheter through the vascular graft. (Note: The two silicone plugs are preassembled on the Impella® LD catheter shaft.)</p>
<p>Figure 3.14 Silicone Plugs (Impella® 5.0/LD)</p>	

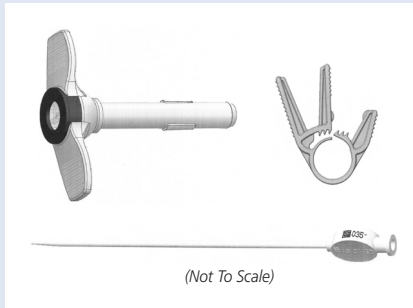
Component**Description**

Figure 3.15 Impella® Axillary Insertion Kit (Impella® 2.5, 5.0, and Impella CP®)

The Impella® Axillary Insertion kit facilitates placement of the Impella® 2.5, 5.0, or Impella CP® Catheter via the axillary artery. It contains a 23 Fr diameter x 6 cm length peel-away introducer and two (2) graft locks used to attach a graft onto the introducer. (Note: Only one graft lock is required when used with the recommended Hemashield Platinum graft; a back-up is provided.) The kit is packaged with an 8 Fr silicone-coated lubrication dilator and 2 silicone plugs (not shown). It is recommended to be used in conjunction with a 10 mm diameter x 20 cm length Hemashield Platinum graft.

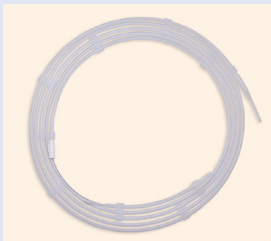


Figure 3.16 Placement Guidewire

The 0.018 inch, 260 cm placement guidewire is used for the placement of the Impella® 2.5, 5.0, or Impella CP® Catheter. The guidewire has a radiopaque, shapable tip.



Figure 3.17 Dextrose Solution

Hospital Provided:

Dextrose solution (typically 5% dextrose in water with 50 IU/mL of heparin) is used as the purge fluid through the Impella® Catheter.



Figure 3.18 Automated Impella® Controller Cart

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

Guidewire Use

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

4 USING THE AUTOMATED IMPELLA® CONTROLLER



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OVERVIEW

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

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

AUTOMATED IMPELLA® CONTROLLER FEATURES

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

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

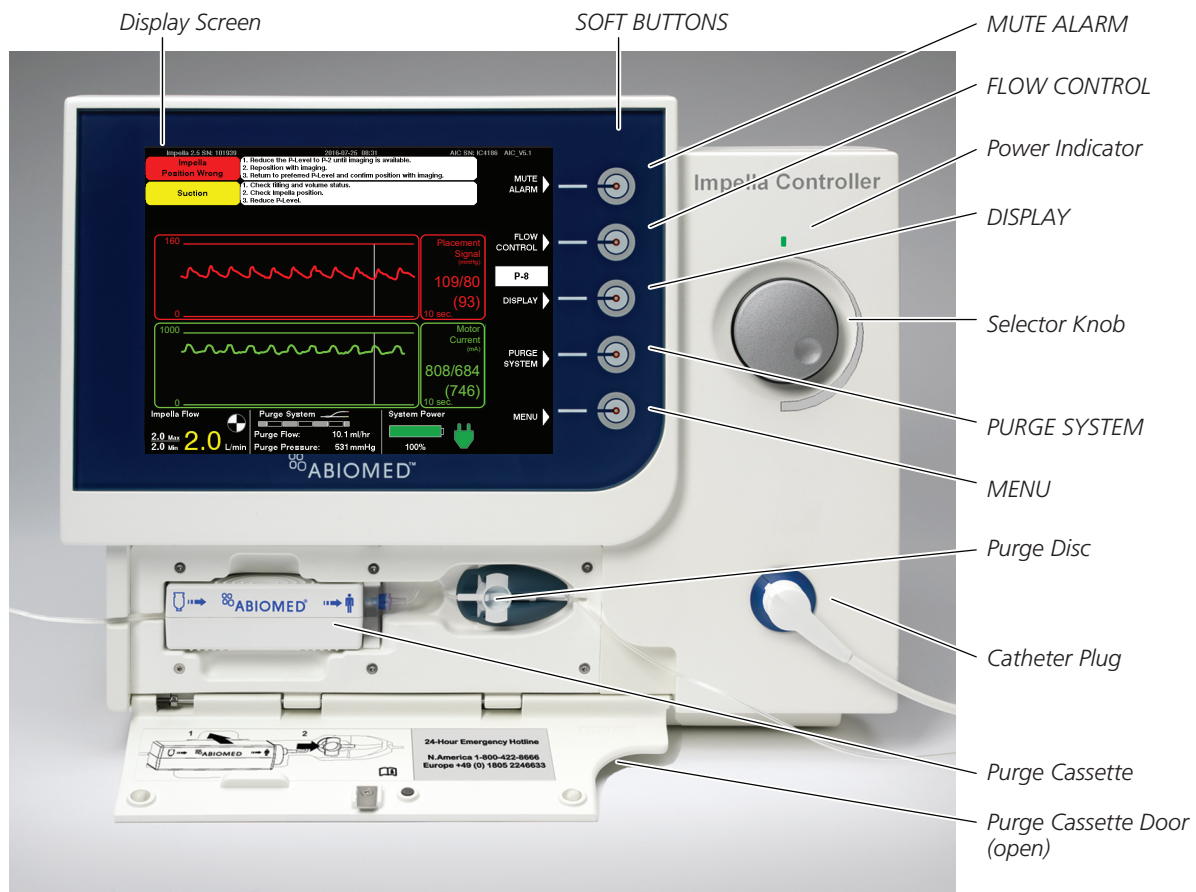


Figure 4.1 Automated Impella® Controller Features – Front View

Table 4.1 Automated Impella® Controller Front View Features

Feature	Description
Display screen	Displays user information, including the labels for the soft buttons. (Display screen elements described in detail later in this section.)
Soft buttons	<p>Display, open, and close menus. The function for each soft button is defined by labels adjacent to the button on the display screen; function changes depending on the screen. (Soft button functions are described in Table 4.3.)</p> <p>When the Impella® Catheter is running, the default soft button labels are as follows:</p> <ul style="list-style-type: none"> • MUTE ALARM • FLOW CONTROL • DISPLAY • PURGE SYSTEM • MENU
Power indicator	<p>LED light above the selector knob; indicates the power status of the Automated Impella® Controller.</p> <ul style="list-style-type: none"> • Green light—controller is on and plugged into AC power or running on battery power • Amber light—controller is off but plugged into AC power • No light—controller is off and not plugged into AC power
Selector knob	Rotating push button; turn clockwise and counterclockwise to navigate through menu items; push to make a selection.
Purge disc	A flexible diaphragm on the purge cassette tubing used to monitor purge pressure and regulate purge flow.
Catheter plug	Connection point on the controller for the connector cable that connects to the Impella® Catheter.
Purge cassette	Contains the components for delivering the purge fluid; maintains the pressure barrier between the blood and the motor to prevent blood from entering the motor. (The purge cassette and its components are described in section 3 of this manual.)
Purge cassette door	Spring-loaded door that opens to provide access to the purge cassette.

Display Options

If equipped with a VGA connector, the controller can be connected to a monitor to display information on another screen as described under “Slave Monitor Connection” in section 9 of this manual.

Selector Knob Function

Rotate the selector knob on the controller to navigate through menu items.

Push the selector knob to confirm your selection.

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

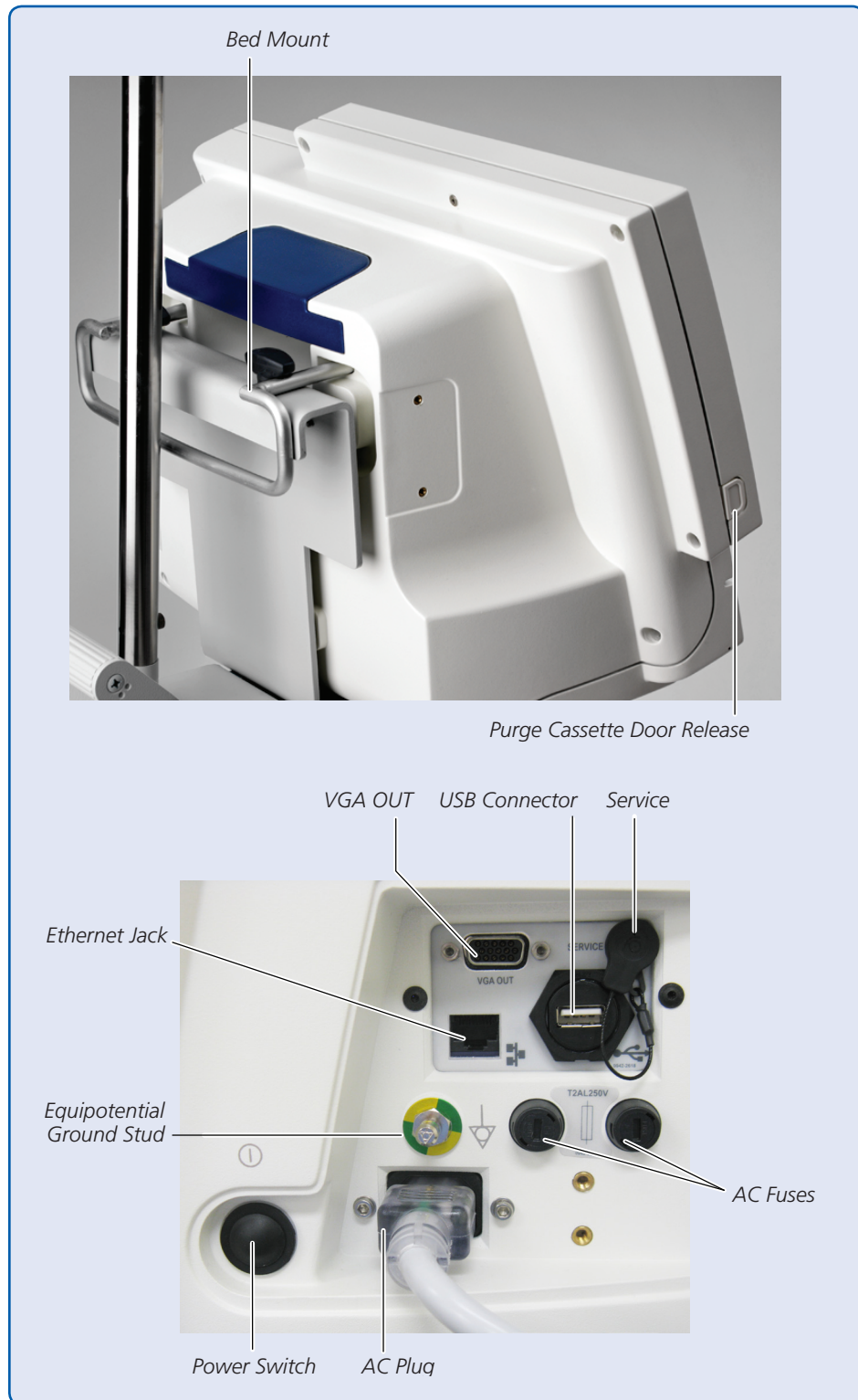


Figure 4.2 Automated Impella® Controller Features – Side Views

Table 4.2 Automated Impella® Controller Side View Features

Feature	Description
Bed mount	Metal bracket on the back of the controller; attaches controller to the cart or bed
Purge cassette door release	Button located on the left side of the controller; press to open the purge cassette door
VGA OUT	Connection for connecting the controller to another monitor to slave the display
USB connector	Interface for data transfer by Abiomed maintenance or service personnel
Service	Connection used by Abiomed maintenance or service personnel
AC fuses	Electrical safety device in the event of current overload
AC plug	Connection point on the controller for the AC power cord
Power switch	<p>Button that turns the controller on or off</p> <ul style="list-style-type: none"> • ON: Press and hold the power switch for 3 seconds • OFF: (1) Disconnect the Impella® Catheter from the Automated Impella® Controller (2) Press and hold the power switch for 3 seconds (3) A pop-up confirmation box will appear (4) Press OK using the selector knob to confirm that the controller should be turned off <p>NOTE: Holding down the power switch for longer than 30 seconds during operation will cause the controller to initiate an emergency shutdown</p>
Equipotential ground stud	Used to ground the Automated Impella® Controller according to hospital procedures
Ethernet jack	Connection for downloading data

HOME SCREEN

The home screen displays operating parameters and information for the entire Impella Ventricular Support Systems.

Figure 4.3 illustrates the home screen. Each element of the display is described in Table 4.3.

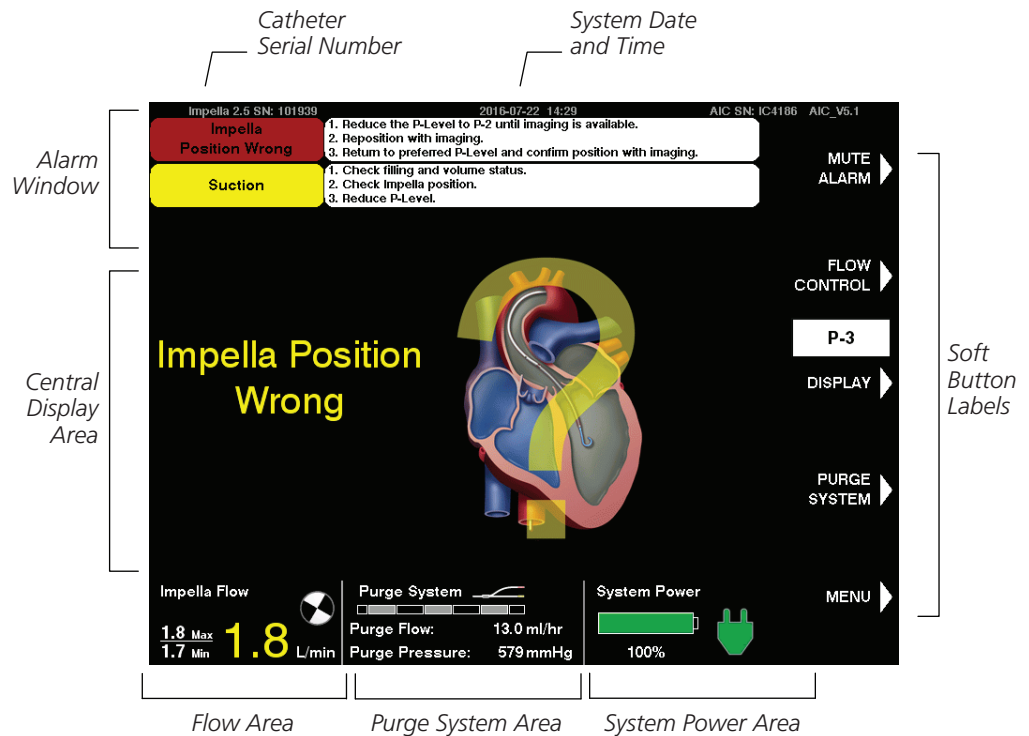


Figure 4.3 Home Screen

Table 4.3 Automated Impella® Controller Display Elements

Display Element	Description
Alarm window	<p>The alarm window displays up to 3 alarms simultaneously, in order of priority from top to bottom.</p> <p>For each alarm, the alarm window displays:</p> <ul style="list-style-type: none"> Alarm header – displayed in the left column; window is color-coded red for critical alarms, yellow for serious alarms, white for advisory notifications, gray for resolved alarms 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 <p>(See section 8 of this manual for further discussion of alarms.)</p>
Catheter serial number	Displayed in the upper left of the display screen if a catheter is connected to the controller.
System date and time	The current date (YYYY-DD-MM) and time (24-hour format; HH:MM) are displayed in the upper center of the screen display. (In this example it is July 22, 2016 at 2:29pm.)

Table 4.3 Automated Impella® Controller Display Elements (continued)

Display Element	Description
Mute alarm indicator	<p>Displayed in place of the words “MUTE ALARM” when an alarm is silenced. (See section 8 of this manual for more information about the mute alarm function; Figure 8.1 illustrates the mute alarm indicator.)</p> <ul style="list-style-type: none"> • 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	<p>The soft buttons on the Automated Impella® Controller have corresponding labels adjacent to them on the display screen. These labels change depending on the type of screen displayed. (Refer to Appendix C in this manual for more details about the menu structure.)</p> <p>MUTE ALARM</p> <ul style="list-style-type: none"> • Mutes (silences) active alarms <p>FLOW CONTROL (or NEXT)</p> <ul style="list-style-type: none"> • FLOW CONTROL – Allows you to control the flow of the Impella® Catheter • NEXT – Advances to the next screen <p>DISPLAY (or BACK)</p> <ul style="list-style-type: none"> • DISPLAY – Brings up the Display menu for viewing waveforms and navigating to other screen displays • BACK – Returns to the previous screen <p>PURGE SYSTEM (or EXIT)</p> <ul style="list-style-type: none"> • PURGE SYSTEM – Brings up the Purge System menu for changing the purge fluid, purge cassette, or purge system; de-airing the purge system; or transferring to the standard configuration • EXIT – Exits the current procedure <p>MENU (or CANCEL)</p> <ul style="list-style-type: none"> • MENU – Brings up a menu of options related to controller settings, alarm history, and starting a case • CANCEL – Exits out of current Menu
System power area	<p>System power information is displayed to the right of the purge system information on the bottom of the display screen.</p> <p>Battery status – Bar within battery symbol indicates the overall remaining capacity of the batteries</p> <ul style="list-style-type: none"> • Full green bar for fully charged battery • Partial green bar for battery that is at least 50% charged • Partial yellow bar for battery that is between 16% and 50% charged • Partial red bar for battery that is less than or equal to 15% charged • Moving gray bar for battery that is in charging mode • Percentage of battery power remaining displayed below the battery icon <p>AC plug indicator</p> <ul style="list-style-type: none"> • Green plug indicates that the controller is running on AC power • Gray plug with a red X indicates no AC power detected and the controller is running on battery power

Table 4.3 Automated Impella® Controller Display Elements (continued)

Display Element	Description
Purge system area	<p>Information about the purge system is displayed to the right of the flow area at the bottom of the display screen.</p> <p>Purge system marquee—scrolls from left to right when purge system is operating</p> <ul style="list-style-type: none"> • Slow scrolling represents normal purge flow rate • Fast scrolling represents bolus flow rate and priming flow rate <p>Y connector icon (for Impella® 2.5 and Impella CP®)</p> <ul style="list-style-type: none"> • Appears above the purge system marquee when the Impella Ventricular Support Systems are configured using the Y connector in the set-up configuration <p>Purge flow</p> <ul style="list-style-type: none"> • Current purge flow displayed in mL/hr below the purge system marquee if the purge flow is known • Not displayed when the purge system is stabilizing, when there is no purge cassette, or when the procedure has not yet started <p>Purge pressure</p> <ul style="list-style-type: none"> • Current purge pressure (pressure of the purge fluid delivered through the catheter to the motor) displayed in mmHg below the purge flow
Flow area	<p>Information about Impella® Catheter flow is displayed in the lower left corner of the display screen.</p> <p>Max/Min</p> <ul style="list-style-type: none"> • Max/Min displays the range for the flow rate <p>Current flow rate</p> <ul style="list-style-type: none"> • Mean catheter flow displayed in liters per minute (L/min)—the numbers appear in <i>white</i> if the catheter position is correct; <i>yellow</i> if the catheter position is incorrect or unknown • If the system is unable to calculate flow, a yellow triangular caution icon is displayed with the message “Flow Calculation Disabled” <p>Catheter operation icon</p> <ul style="list-style-type: none"> • The circular catheter operation icon rotates when the Impella® Catheter is running

Purge System Stabilization

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

PLACEMENT SCREEN

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

Use the **DISPLAY** soft button to navigate to the placement screen.

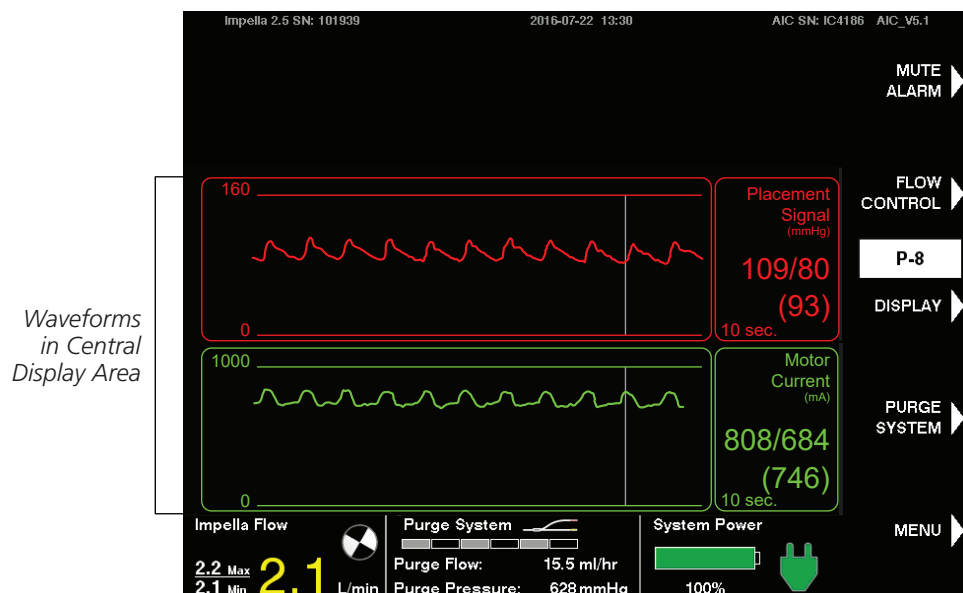


Figure 4.4 Placement Screen

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

- Placement signal waveform
- Motor current waveform

PLACEMENT SIGNAL WAVEFORM

The placement signal waveform displays a pressure measurement that is useful for determining the location of the open pressure area of the catheter with respect to the aortic valve. The placement signal is used to verify whether the Impella® Catheter is in the aorta or in the ventricle by evaluating the current pressure waveform as an aortic or ventricular waveform (Impella® 2.5 and Impella CP®) or by evaluating the differential pressure as pulsatile or flattened (Impella® 5.0 and LD). The scale for the placement signal waveform is displayed to the left of the waveform. The default scaling is 0–160 mmHg (Impella® 2.5 and Impella CP®) or -20–60 mmHg (Impella® 5.0 and LD). For Impella® 2.5 and Impella CP®, it can be adjusted in 20 mmHg increments, with a minimum upper limit of 100 mmHg and a maximum upper limit of 240 mmHg. For Impella® 5.0 and LD, the maximum display range is -60–100 mmHg.

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

Retrograde Flow

A setting of P-0 will result in retrograde flow when the Impella® Catheter is placed across the aortic valve. Retrograde flow may also occur at P-1.

MOTOR CURRENT WAVEFORM

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

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

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

PURGE SCREEN

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

Use the **DISPLAY** soft button to navigate to the purge screen.

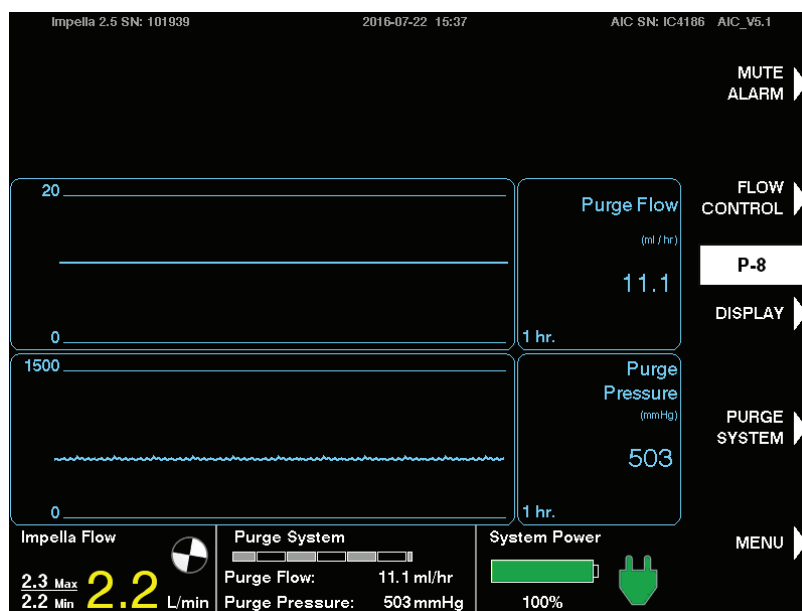


Figure 4.5 Purge Screen

PURGE FLOW

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

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

A purge flow change notification can be enabled to indicate when the purge flow rate increases or decreases by 2.5 mL/h. The message is intended to aid patient management by alerting the clinician to changes in the rates of dextrose and heparin infusion through the purge fluid. The alarm clears when you press the **MUTE ALARM** button. This alarm is disabled by default. To enable this alarm, press **MENU**, select Settings/Service, and select Enable Purge Flow Change Notification.

PURGE PRESSURE

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

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

INFUSION HISTORY SCREEN

The infusion history screen displays the infusion volume as well as the amount of heparin and dextrose infused each hour. The current time period is displayed at the top of the list.

Use the **DISPLAY** soft button to navigate to the infusion history screen.

Figure 4.6 shows a sample infusion history screen.

Purge Flow

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

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

Purge Pressure Depends on System Configuration

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



Figure 4.6 Infusion History Screen

MOBILE OPERATION



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

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

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