

Impella RP Flex[™] with SmartAssist[™] System

with the Automated Impella Controller[™]

Circulatory Support System

Instructions for Use
& Clinical Reference Manual



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

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

IMPELLA RP FLEX™ WITH SMARTASSIST™ SYSTEM WITH THE AUTOMATED IMPELLA CONTROLLER™ 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 RP Flex™ with SmartAssist™ System Catheter with the Automated Impella Controller™. To use the system you must understand and follow these instructions. The Impella RP Flex with SmartAssist System may be used only for its intended purpose.

MANUAL OVERVIEW

This manual provides instructions for use of the Impella RP Flex with SmartAssist System Catheter 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 RP Flex with SmartAssist System 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 RP Flex with SmartAssist System Catheter with the Automated Impella Controller.
- **Section 3: The Impella RP Flex with SmartAssist System 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 RP Flex with SmartAssist System Catheter** provides the procedures for using the Impella RP Flex with SmartAssist System.
- **Section 6: Clinical Experience** provides an overview of the RECOVER RIGHT trial, which studied the use of the Impella RP System in a U.S. clinical trial. The results of this trial were reviewed by the FDA prior to its approval of the Impella RP System.
- **Section 7: Automated Impella Controller Alarms** provides a listing of Automated Impella Controller alarms as well as information on what to do to resolve them.
- **Section 8: General System Information** contains information including definitions for key terms that appear in the manual, descriptions of the abbreviations and symbols that appear on Impella RP Flex with SmartAssist System Catheter and Automated Impella Controller components and packaging, technical information pertaining to the Impella RP Flex with SmartAssist System 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 Automated Impella Controller menu structure.

1 INDICATIONS, CONTRAINDICATIONS,
AND POTENTIAL ADVERSE EVENTS



INDICATIONS (UNITED STATES) 1.1

CONTRAINDICATIONS (UNITED STATES) 1.1

POTENTIAL ADVERSE EVENTS (UNITED STATES)..... 1.1

INDICATIONS (UNITED STATES)

The Impella RP System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area $\geq 1.5 \text{ m}^2$ who develop acute right heart failure or decompensation for less than 48 hours following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery, without the presence of profound shock, end organ failure, or acute neurologic injury.

CONTRAINDICATIONS (UNITED STATES)

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

POTENTIAL ADVERSE EVENTS (UNITED STATES)

Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device Malfunction, Hemolysis, Hepatic failure, Insertion site infection, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system complication, Tricuspid valve injury, Cardiac or Vascular injury (including ventricular perforation), Venous thrombosis, Ventricular fibrillation and/or tachycardia.

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

2 WARNINGS AND CAUTIONS



WARNINGS	2.1
CAUTIONS.....	2.3

WARNINGS



The Impella RP Flex™ 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 RP Flex with SmartAssist System Catheter. The small placement guidewire must be reliably observed at all times.



Be sure that the stopcock on the 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, outlet, or sensor areas of the cannula assembly.



The sterile components of the Impella RP Flex with SmartAssist 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 RP Flex with SmartAssist System Catheter. It is a disposable device and is intended for single use only. Reuse, reprocessing, reinserting through the introducer, 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 from the pulmonary artery back into the vena cava or right atrium if the Impella RP Flex with SmartAssist System Catheter is set at performance level P-0.



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



Do **NOT** use an Impella RP Flex with SmartAssist System if any part of the system is damaged.



To prevent the risk of explosion, do **NOT** operate the Impella RP Flex with SmartAssist System near flammable anesthetics.



If at any time during the course of support with the Impella RP Flex with SmartAssist System 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 RP Flex with SmartAssist System Catheter to magnetic resonance imaging (MRI). The strong magnetic energy produced by an MRI machine may cause the Impella RP Flex with SmartAssist System components to stop working, and result in injuries to the patient. An MRI may also damage the Impella RP Flex with SmartAssist System electronics.



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



During defibrillation, do **NOT** touch the Impella RP Flex with SmartAssist System Catheter, cables, or Automated Impella Controller.



Anti-coagulate patients as needed to maintain recommended ACT (160-180s), in particular when indwelling central venous lines or cannulas (i.e. hemodialysis, PA catheters, ECMO) are present. ACT below this level may increase the risk of thrombus formation or deposition. If either internal thrombus forms within or external thrombus deposits in the Impella RP Flex with SmartAssist, this may result in reduced flow, loss of support, or hemolysis.



Thrombus formation or deposits on indwelling central venous lines or cannulas (i.e. hemodialysis catheters, PA catheters, ECMO) may break free and enter into the Impella RP Flex with SmartAssist inlet, resulting in reduced flow, loss of support, or hemolysis. Assess the risk for extraluminal thrombus on indwelling lines placed prior to initiation of support.



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

Warnings

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



Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the electromagnetic compatibility (EMC) information provided in section 8 of this manual.



The Automated Impella Controller (AIC) performs as intended when exposed to radiofrequency (RF) disturbances below 20 V/m. During transport, the AIC may be exposed to RF disturbances above 20 V/m, which could cause minor problems, such as intermittent displays of soft button menu selections, which have no effect on the operating parameters of the Impella support system, and will resolve readily once the disturbance ends. It could also potentially result in loss of support. Patients must be closely monitored at all times during transport.



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.



Avoid overinserting the Impella RP Flex with SmartAssist System Catheter and possibly impinging the catheter tip against the walls of the vasculature, atrium, or ventricle.



To reduce the risk of cardiac or vascular injury (including ventricular perforation) when advancing or torquing the Impella, adjustments should be performed under imaging guidance.



Do **NOT** advance or withdraw the Impella RP Flex with SmartAssist System Catheter against resistance without using fluoroscopy to determine the cause of the resistance. Doing so could result in separation of the catheter or guidewire tip, damage to the catheter or vessel, or perforation.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Impella System, including cables specified by Abiomed. Otherwise, degradation of the performance of this equipment could result.



Do not transport an Impella patient via commercial aircraft. Loss of support may occur aboard a commercial aircraft due to exposure to radiofrequency (RF) disturbances above the compliance level (<20 V/m) of the Automated Impella Controller.



To reduce the risk of cardiac or vascular injury (including perforation) when manipulating the heart during cardiac surgery, evaluate the position of the pump using imaging guidance prior to manipulating the heart, and monitor position



To reduce the risk of cardiac or vascular injury (including ventricular perforation) physicians should exercise special care when inserting the Impella Catheter in patients with complex anatomy. This includes patients with known or suspected: decreased ventricular cavity size, ventricular aneurysms, thin-walled ventricles due to chronic dilation, congenital heart disease, or compromised cardiac tissue quality.



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, introducing the risk of cardiac or vascular injury (including ventricular perforation). Check that the pump is positioned correctly after CPR with chest x-ray guidance.



To reduce the possibility of fibers being drawn into the Impella, customers should avoid exposing the inlet and cannula section of the Impella Heart Pumps to any surfaces or fluid baths where the device can come into contact with loose or floating fibers.



Operating the pump at a high flow rate while inserting, manipulating, or removing guidewires, indwelling central venous lines or devices poses a risk of the device tip interacting with the pump inlet. This may cause damage to the pump sensors, damage to the interacting device, or loss of support. Reduce the P-level to P-2 and use imaging guidance during insertion, manipulation and removal of guidewires, indwelling central venous lines or devices.

CAUTIONS



Handle with care. The Impella RP Flex with SmartAssist System 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.



Inspect the Impella RP Flex with SmartAssist System Set packaging while opening. In the event that any key components, including its end seal labels, are damaged excessively during shipment, the use of a back-up Impella RP Flex with SmartAssist System Set should be considered.



Function of a bioprosthetic valve in the tricuspid or pulmonary position may be compromised by the use of the Impella RP Flex with SmartAssist.



Patient with tricuspid or pulmonary valve stenosis or insufficiency may be compromised by the use of the Impella RP Flex with SmartAssist System Catheter.



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 RP Flex with SmartAssist System Catheter until the placement guidewire has been removed.



Do **NOT** remove the Impella RP Flex with SmartAssist System Catheter over the length of the placement guidewire.



When replacing the purge cassette, the replacement process must be completed within 90 seconds of disconnecting luer. The Impella RP Flex with SmartAssist System Catheter may be damaged if replacement takes longer than 90 seconds.



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 any part of the Impella RP Flex with SmartAssist System Catheter.



Do **NOT** use the Impella RP Flex with SmartAssist System Catheter with a damaged or kinked introducer. Replace the introducer if a kink is observed.



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.



Minimize exposure of Impella RP Flex with SmartAssist 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 RP Flex with SmartAssist System components may interfere with the operation of other devices. If interference occurs, increase the distance between the device and system components.



In the event that a patient is intolerant to heparin or in whom heparin is contraindicated (e.g., due to heparin-induced thrombocytopenia or bleeding), sodium bicarbonate (25 or 50 mEq/L) may be added to the purge solution instead of heparin. The Impella catheter has not been tested with any other anticoagulants, such as direct thrombin inhibitors, in the purge solution. Therefore, avoid the use of any alternative anticoagulants in the purge solution to prevent damage to the Impella catheter.



Have a backup Automated Impella Controller, purge cassette, and Impella RP Flex with SmartAssist System Catheter available in the unlikely event of a device failure.



Do NOT use the bed mount as a handle.



When inserting through the internal jugular vein, the right internal jugular vein is preferred due to anatomy presenting the least tortuous path from that side. This translates to an easier delivery.



Do not insert any unauthorized devices into the USB port. This includes chargers, memory sticks, wireless dongles and other unauthorized devices.



During use with the Impella Connect™, a Medical Device Data System (MDDS), if the Automated Impella Controller is exposed to strong electromagnetic disturbances, the Impella Connect may either restart or shut down. Operators should be aware that, under these conditions, the Automated Impella Controller operating parameters are not affected.



Keep patient cable away from power cables and other high voltage signal cables.



Impella is compatible with High Frequency surgical equipment. However, when using HF surgical equipment, the Impella cannot come in contact with the surgical equipment.



Benefits of Impella RP Flex with SmartAssist in salvage patients have not been proven.



Flush the Impella kit sheath and dilator with saline to help minimize the potential for air embolism and clot formation.



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.



Pump metrics software is intended for use solely as an informational tool to monitor Impella pump performance during Impella support.



The pump performance metrics derived from the Impella pump signals are not valid surrogates for monitoring the overall clinical status of the patient and should be used for informational purposes only.



The pump performance metrics derived from the Impella pump signals are not intended for diagnostic use. All parameters displayed must be verified independently using either a cleared or approved diagnostic device, and must not be used for patient monitoring.



Displayed flow and metrics may be inaccurate due to differential pressure sensor drift. Sensor accuracy can also be affected by physical contact including handling during insertion, presence of thrombus in the inlet, contact with concomitant lines or devices, or contact with patient anatomy. Table 5.4 P-Level Flow Rates should be relied on over the AIC displayed flow. Clinicians should continue to use pump metrics to monitor Impella pump performance, monitor patient hemodynamics using cleared or approved diagnostic devices, and monitor Impella positioning with imaging. An abrupt change in flow or abrupt discrepancy from the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics.



Insertion through the left femoral vein may result in repeated attempts to properly position the Impella RP Flex with SmartAssist System, which could cause excessive manipulation and pump damage. As a result, left femoral insertion should be avoided whenever possible.

3 THE IMPELLA RP FLEX WITH SMARTASSIST™ SYSTEM CATHETER AND AUTOMATED IMPELLA CONTROLLER™

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OVERVIEW

The Impella RP Flex with SmartAssist System Catheter is an intracardiac microaxial blood pump that supports a patient's pulmonary circulation. The Impella RP Flex with SmartAssist System Catheter is inserted percutaneously through the internal jugular or femoral vein and into the pulmonary artery (see Figure 3.1).

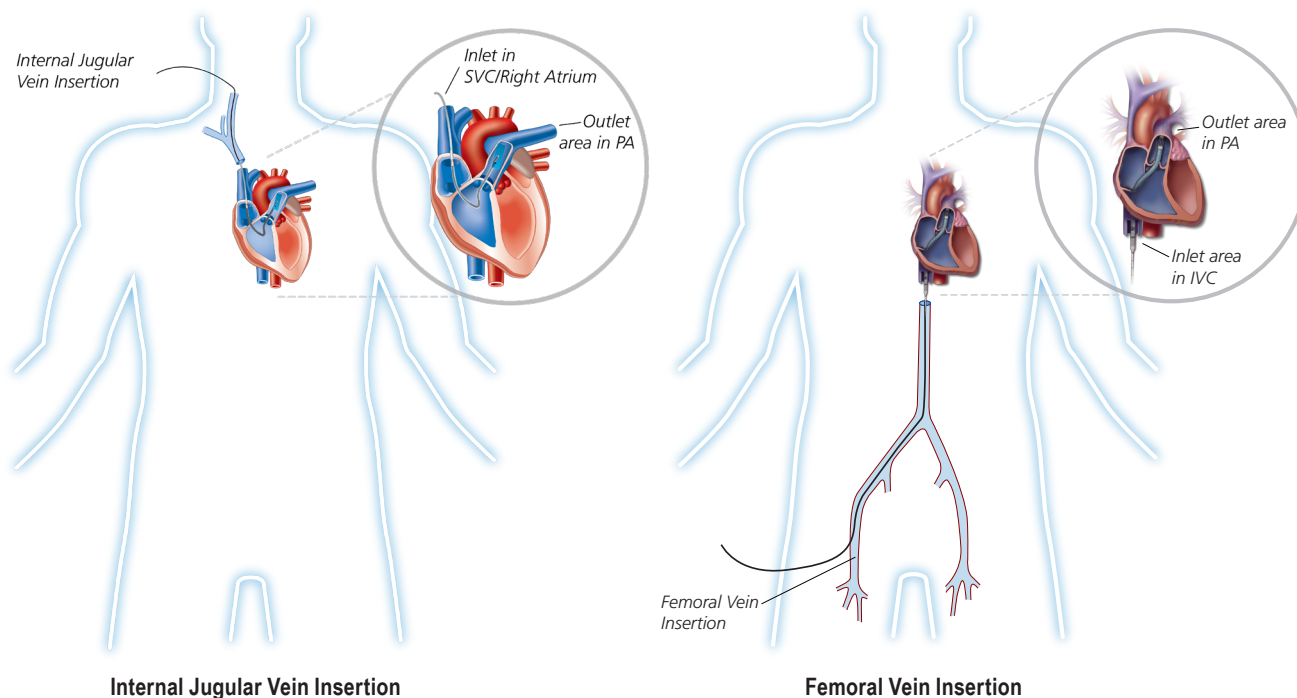


Figure 3.1 *Impella RP Flex with SmartAssist™ System Catheter in the Heart*

When properly positioned, the Impella RP Flex with SmartAssist System Catheter delivers blood from the inlet area, which sits within the vena cava or right atrium, through the cannula, to the outlet opening in the pulmonary artery. Physicians and device operators monitor Impella RP Flex with SmartAssist System Catheter function on the display screen of the Automated Impella Controller.

The intent of the therapy with the Impella RP Flex with SmartAssist System is to provide a percutaneous circulatory support system to restore normal right heart hemodynamics, reduce right ventricular work, and allow the right heart time to potentially recover adequate contractile function or to be bridged to the next therapy.

This section describes the components of the Impella RP Flex with SmartAssist System Catheter and the Automated Impella Controller, as well as the accessory components.

REUSABLE SYSTEM COMPONENTS

The Impella RP Flex with SmartAssist™ System consists 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 RP Flex with SmartAssist System also includes the following single-use components:

- Impella RP Flex with SmartAssist System Catheter
- Purge cassette
- Introducer kit
- 0.027 inch, 260 cm placement guidewire
- Purge Sidearm Retainer
- 3 pt Fixation Accessory

Single-Use System Components

Do **NOT** resterilize or reuse the Impella RP Flex System Catheter. It is a disposable device and is intended for single use only. Reuse, reprocessing, reinserting through the introducer, 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.

SYSTEM CONFIGURATION

Figure 3.2 illustrates how the Automated Impella Controller connects to the Impella RP Flex with SmartAssist System Catheter and accessory components.

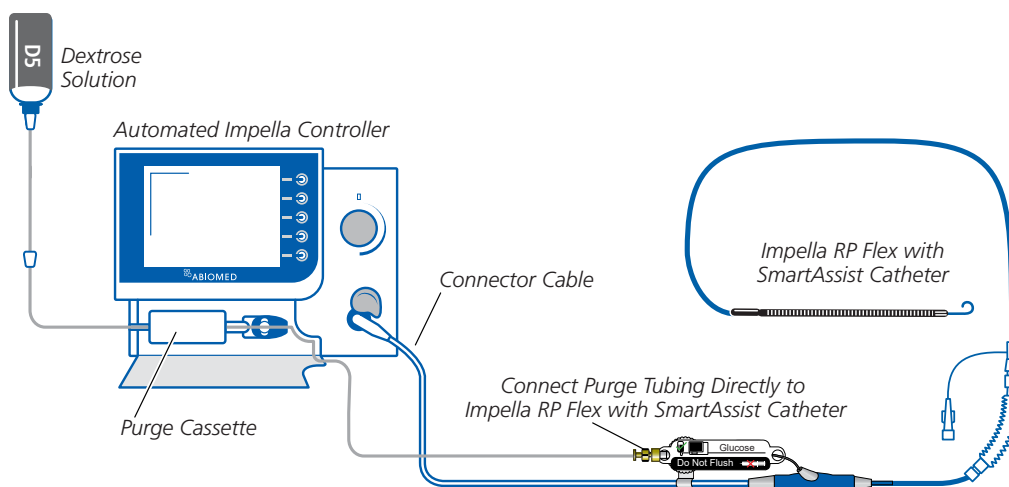


Figure 3.2 Automated Impella Controller, Impella RP Flex with SmartAssist System Catheter, and Accessories

IMPELLA RP FLEX WITH SMARTASSIST™ SYSTEM CATHETER

The Impella RP Flex with SmartAssist System Catheter is an intracardiac microaxial blood pump that delivers up to 4.0 liters of blood per minute from within the vena cava or right atrium into the pulmonary artery. Figure 3.3 illustrates the Impella RP Flex with SmartAssist System Catheter. The Impella RP Flex with SmartAssist System Catheter has a specially designed flexible cannula that is sized to fit through the vessels and hearts of pediatric and adult patients with a Body Surface Area (BSA) equal to or greater than 1.5 m². Table 3.1 describes each component from the pigtail at one end to the check valve on the other end.

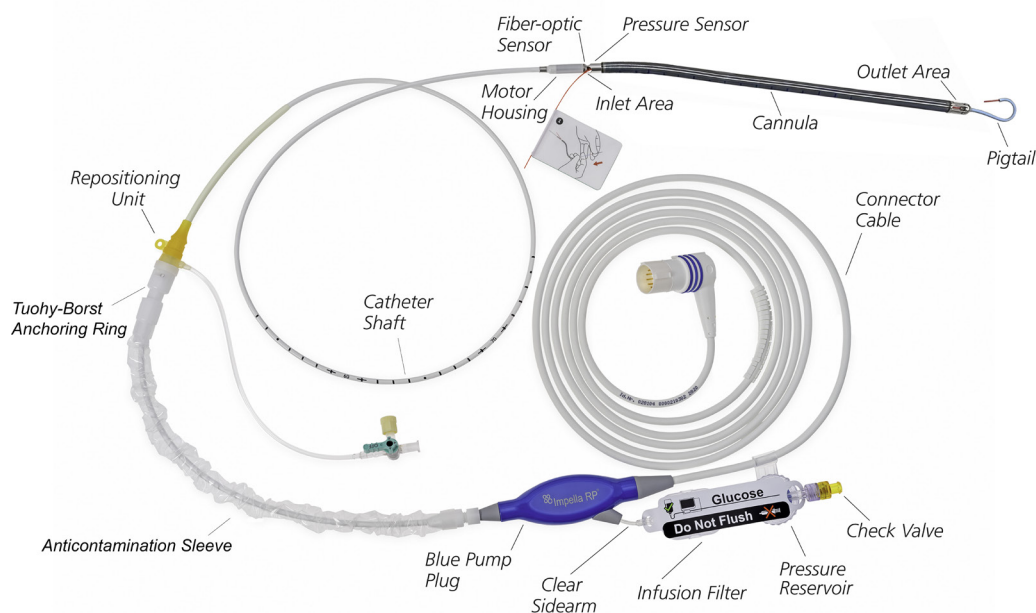


Figure 3.3 Impella RP Flex with SmartAssist System Catheter

Table 3.1 Impella RP Flex with SmartAssist System Catheter Components

Component	Description
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the outlet area. It assists with stabilizing the catheter in the correct position in the pulmonary artery.
Outlet area	The outlet area, located at the distal tip of the cannula, has 5 openings (windows) that allow blood to exit the cannula.
Cannula	The 22 Fr cannula is designed for the anatomy of the right heart, to provide optimal and stable position during operation. The cannula is made of nitinol and covered in polyurethane with spiral shaped reinforcement integrated into the cannula.
Differential pressure sensor	A sensor that measures the pressure difference between the inside and outside of the cannula. The pressure value is used for calculating displayed flow and as an input to the pulmonary artery placement signal and the central venous placement signal during catheter operation. The differential pressure sensor is a flexible membrane integrated into the cannula. One side of the sensor is exposed to the blood pressure on the outside of the inlet area and the other side is exposed to the pressure of the blood on the inside of the cannula. The sensor generates an electrical signal proportional to the difference between the pressure outside the inlet area and the pressure inside the cannula. Sensor measurements may be impacted by malfunction or by physical contact with the sensor and therefore contact should be avoided; this includes manual compression during implant, contact with concomitant lines or devices, contact with patient anatomy, or thrombus in the inlet.
Fiber-optic sensor	This sensor on the Impella RP Flex with SmartAssist is located at the proximal end of the inlet area. This sensor is used as an input to the pulmonary artery placement signal and the central venous placement signal during catheter operation.

Table 3.1 Impella RP Flex with SmartAssist System Catheter Components (continued)

Component	Description
Inlet area	The proximal end of the cannula is attached to the inlet area where blood enters the cannula.
Motor housing	The 21 Fr motor housing consists of an encapsulated motor.
Catheter shaft	An 11 Fr catheter shaft is located between the motor housing and the blue Impella plug. The catheter lumen also contains optical fiber for optical pressure sensor. The catheter shaft has transversal marks: • The transversal marks at 1 cm intervals aid in proper positioning.
Repositioning unit and Anticontamination Sleeve	The repositioning unit consists of a sheath and an anticontamination sleeve with an Tuohy-Borst anchoring ring. • The 11 Fr sheath (15 Fr outer diameter) with hemostatic valve is located on the catheter shaft and allows repositioning of the catheter. • The Tuohy-Borst of the anticontamination sleeve secures the sheath to the catheter; turning in the counterclockwise direction enables movement of the catheter and turning in the clockwise direction disables movement.
Blue Impella plug	The blue Impella plug has a clear sidearm and contains memory that retains operating parameters in case the patient needs to be transferred to another controller. The plug connects the Impella RP Flex with SmartAssist System Catheter to the Automated Impella Controller.
Clear sidearm	The clear sidearm is attached to the purge cassette tubing. It leads to the infusion filter, the pressure reservoir, and the check valve.
Infusion filter	The infusion filter prevents bacterial contamination and prevents air from entering the purge lumen.
Pressure reservoir	The pressure reservoir includes a flexible rubber diaphragm that provides additional filling volume by means of an expansion chamber during purge solution change.
Check valve	The yellow check valve ensures that purge fluid does not flow in the reverse direction when the purge solution is exchanged.
EasyGuide Lumen	The red loading lumen on the Impella RP Flex with SmartAssist runs from the tip of the pigtail through the inlet area of the cannula to facilitate loading the catheter onto the guidewire.

Automated Impella Controller Power Cord

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

AUTOMATED IMPELLA CONTROLLER

The Automated Impella Controller (see Figure 3.4) provides three vital functions to the operation of the Impella RP Flex with SmartAssist System Catheter:

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

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.

The controller weighs 26.8 lbs (12.2 kg) and can operate on its internal battery for at least 60 minutes when fully charged. Using the controller, the Impella RP Flex with SmartAssist System can be used by trained healthcare professionals in healthcare facilities and during medical transport (i.e., ambulance, helicopter, or fixed-winged aircraft) environments.

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

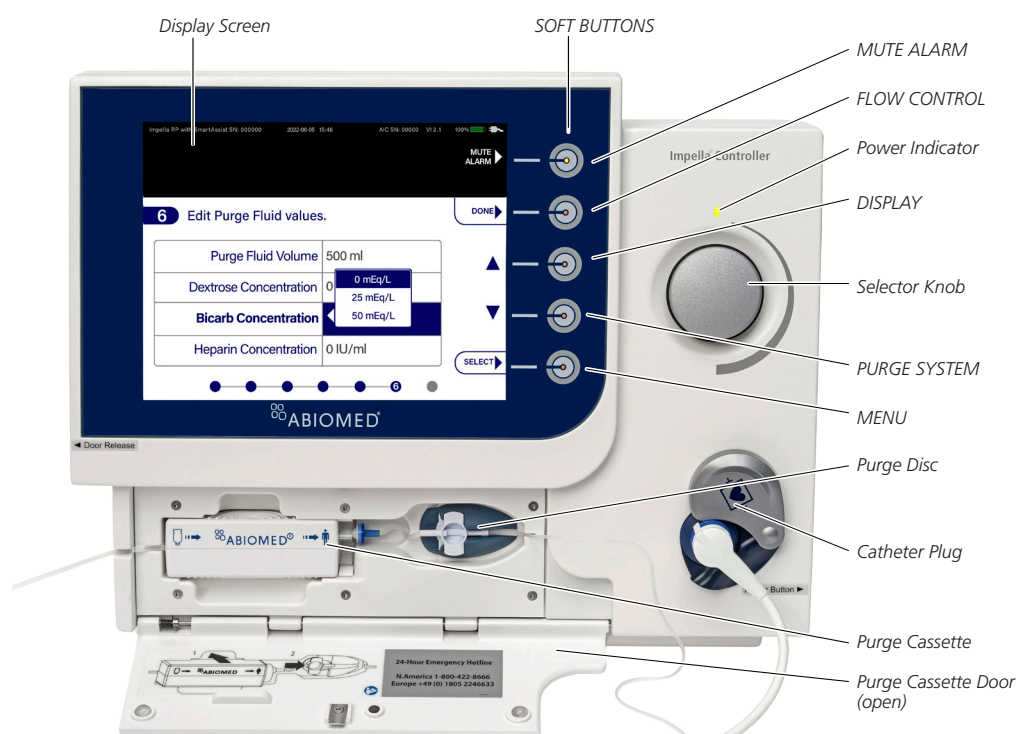


Figure 3.4 Automated Impella Controller – Front View

PURGE CASSETTE



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

The purge cassette delivers rinsing fluid to the Impella RP Flex with SmartAssist™ System Catheter. The purge fluid (typically 5% dextrose solution in water with heparin or if heparin is contraindicated, sodium bicarbonate) 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 3.5 illustrates the purge cassette and related components. Table 3.2 describes each component.

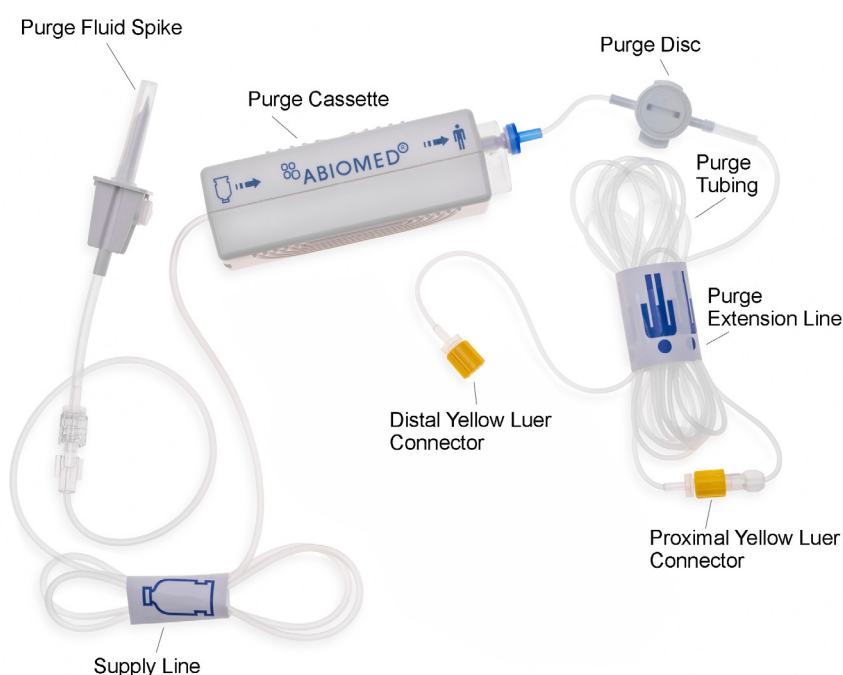


Figure 3.5 Purge Cassette

Table 3.2 Purge Cassette Components

Component	Description
Purge fluid spike	One end spikes the purge fluid bag and the other end connects the bag to the purge cassette supply line
Supply line	Carries fluid from the purge fluid bag to the purge cassette
Purge cassette	Contains the components for delivering the purge fluid; maintains the pressure barrier between the blood and the motor to prevent blood from entering the motor
Purge 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 RP Flex with SmartAssist System Catheter
Yellow luer connector	Connects the purge tubing to the check valve (yellow luer lock) on the Impella RP Flex with SmartAssist System Catheter

ACCESSORIES

Table 3.3 illustrates and describes the accessories used with the Impella RP Flex with SmartAssist™ System Catheter and Automated Impella Controller.

Table 3.3 *Impella RP Flex with SmartAssist System Catheter and Automated Impella Controller Accessories*

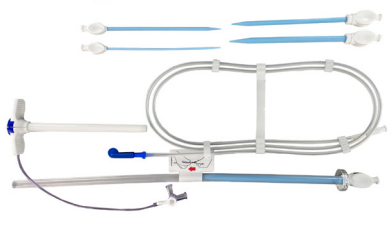
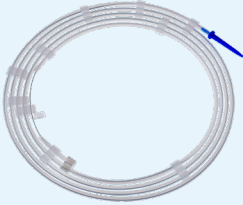
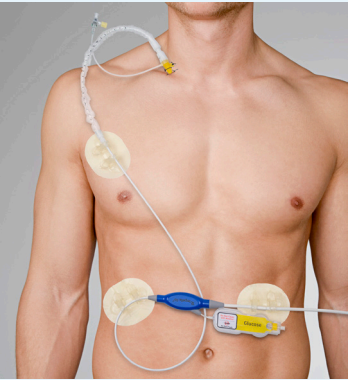
Component	Description
 Figure 3.6 <i>Introducer kit</i>	The introducer kit is used to place the Impella RP Flex with SmartAssist System Catheter. It contains: • 23 Fr peel-away introducer with dilator • 8 Fr, 12 Fr, 16 Fr, and 20 Fr supplemental dilators • 0.035 inch x 150 cm guidewire
 Figure 3.7 <i>Placement Guidewire</i>	The 0.027 inch, 260 cm placement guidewire is available for the placement of the Impella RP Flex with SmartAssist System Catheter.
 Figure 3.8 <i>3pt Fixation Accessory</i>	Catheter fixation accessory may be used to assist in 3-point external fixation of the pump catheter to the patient body. The catheter may be secured near the anchoring ring of the anticontamination sleeve and on either side of the blue plug. <i>*Note: Image shows a representative fixation piece.</i>
 Figure 3.9 <i>Sidearm Retainer</i>	The Impella Sidearm Retainer provides support to the Impella purge line assembly during procedures and patient transport. The retainer surrounds the components that make up the clear purge sidearm and aid in preventing potential mishandling of the assembly.

Table 3.3 Impella RP Flex with SmartAssist System Catheter and Automated Impella Controller Accessories (continued)

Component	Description
	Hospital Provided: Dextrose solution, typically 5% dextrose in water with: Heparin (25 or 50 IU/mL), OR If heparin is contraindicated, sodium bicarbonate (25 or 50 mEq/L) is used as the purge fluid through the Impella catheter. Do not add both heparin and sodium bicarbonate to the dextrose solution - only one should be used.
Figure 3.10 Dextrose Solution	The Automated Impella Controller cart holds the Automated Impella Controller. The cart has wheels for easy transport of the controller and a storage basket. (For more information, including assembly instructions, refer to the Automated Impella Controller cart instructions for use.)
	
Figure 3.11 Automated Impella Controller Cart	

4 USING THE AUTOMATED IMPELLA CONTROLLER™



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OVERVIEW

The Automated Impella Controller is the primary user control interface for the Impella RP Flex with SmartAssist™ System Catheter. It controls the Impella RP Flex with SmartAssist System Catheter performance and monitors the catheter for alarms. The controller can be powered by AC power or can operate on internal battery power for at least 60 minutes when fully charged.

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.

Selector Knob Function

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

Push the selector knob to confirm your selection.

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

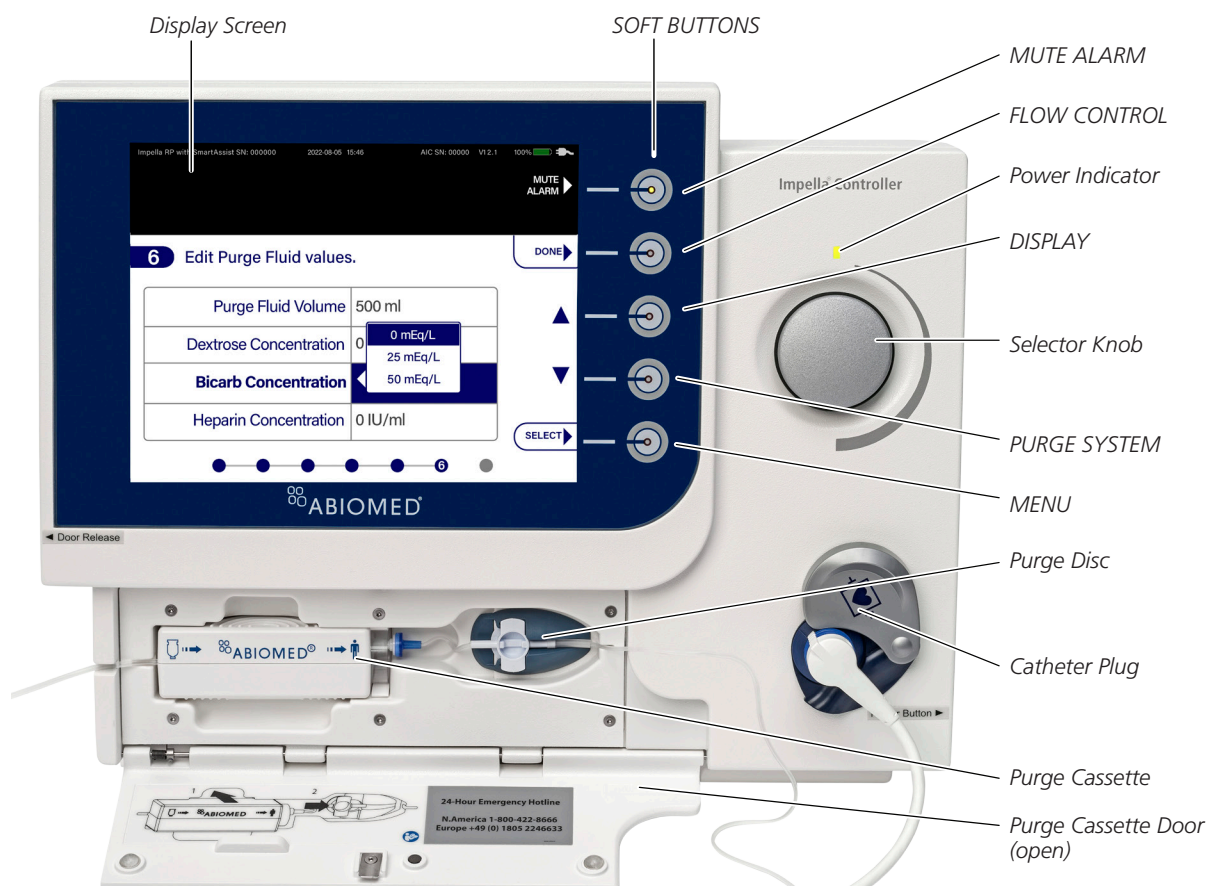


Figure 4.1 Automated Impella Controller Features – Front View

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 8 of this manual.

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	Display, open, and close menus. The function for each soft button is defined by labels adjacent to the button on the display screen; function changes depending on the screen. (Soft button functions are described in Table 4.3.) When the Impella RP Flex with SmartAssist System Catheter is running, the default soft button labels are as follows: • MUTE ALARM • FLOW CONTROL • DISPLAY • PURGE MENU • MENU
Power indicator	LED light above the selector knob; indicates the power status of the Automated Impella Controller. • Green light—controller is on and plugged into AC power or running on battery power • Amber light—controller is off but plugged into AC power • No light—controller is off and not plugged into AC power
Selector knob	Rotating push button; turn clockwise and counterclockwise to navigate through menu items; push to make a selection.
Purge Disc	A flexible diaphragm on the purge cassette tubing that applies pressure to the sensor in the controller so that purge pressure can be measured.
Catheter plug	Connection point on the controller for the connector cable that connects to the Impella RP Flex with SmartAssist System 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.

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.

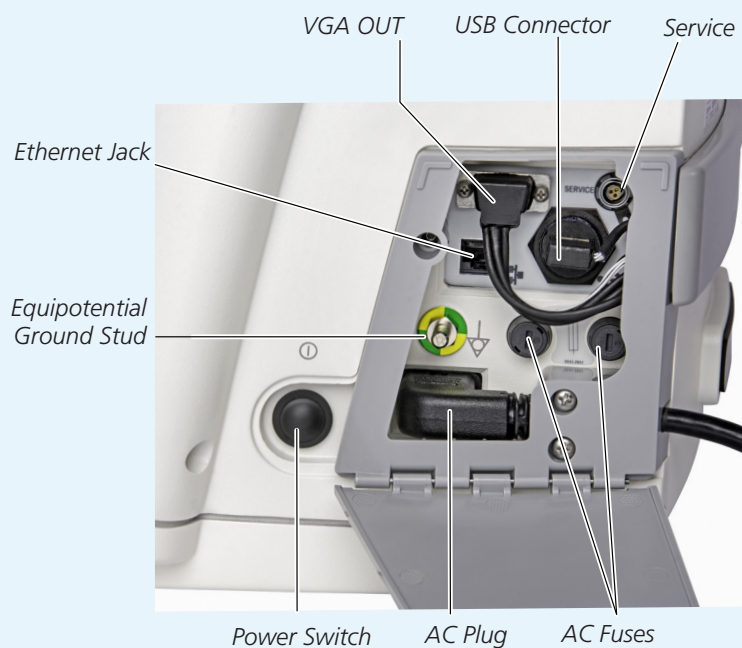
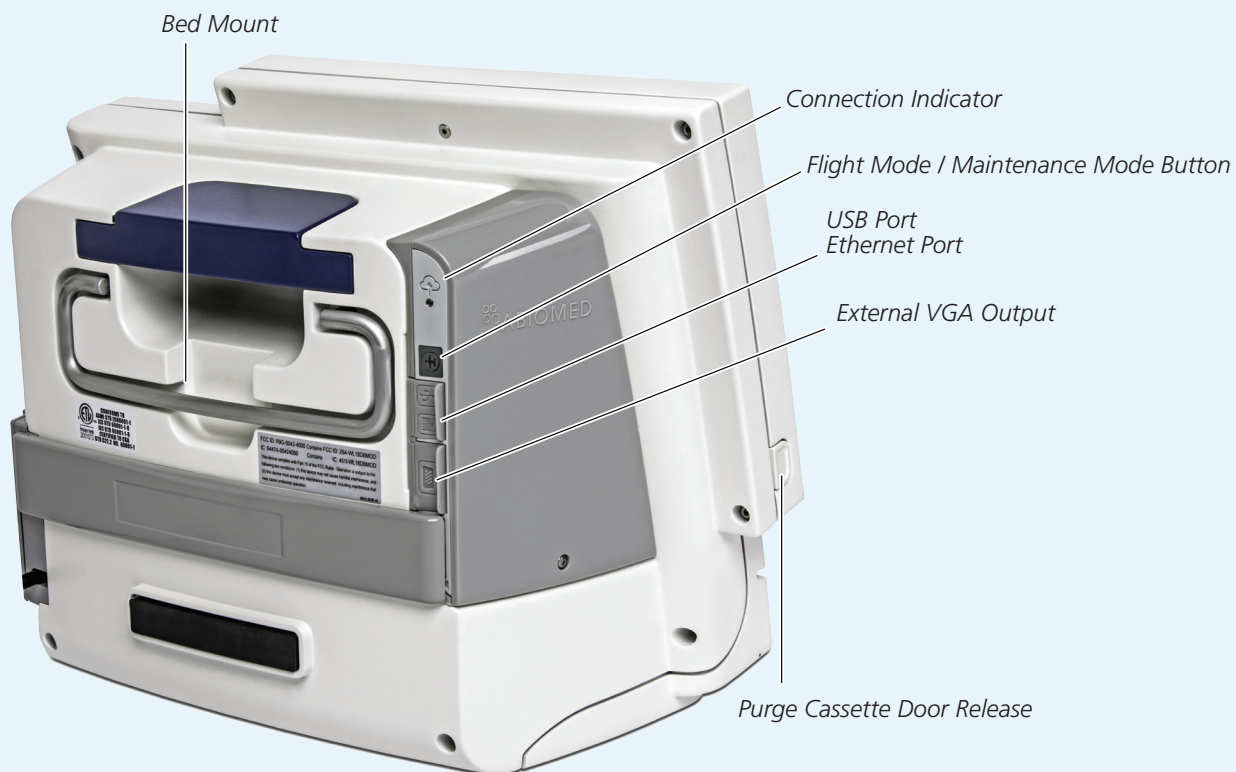


Figure 4.2 Automated Impella Controller Features – Side Views

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 / RS-232 jack	Interface for data transfer by Abiomed maintenance or service personnel; if equipped, this interface can also be used for connecting the controller to another monitor to slave the display
USB connector	Connection for data downloading by Abiomed maintenance or service personnel
AC fuses	Electrical safety device in the event of current overload
AC plug	Connection point on the controller for the AC power cord
Power switch	Button that turns the controller on or off • ON: Press and hold the power switch for 3 seconds • OFF: (1) Disconnect the Impella RP Flex with SmartAssist System 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 NOTE: Holding down the power switch for longer than 30 seconds during operation will cause the controller to initiate an emergency shutdown
Equipotential ground stud	Used to ground the Automated Impella Controller according to hospital procedures
Ethernet jack	Connection for downloading data or software upgrades during service use only, not for use during patient support
For consoles equipped with Impella Connect:	
Connection Indicator	Alerts user to connection Status
Flight Mode / Maintenance Mode Button	Allows user the ability to enter Flight Mode for air transport. It is also used to enter Maintenance Mode.
USB Port	Connection for data downloading by Abiomed maintenance or service personnel
Ethernet Port	Allows the Impella Connect to connect to the cloud.
External VGA Output	Connection for connecting the controller to another monitor to slave the display

AUTOMATED IMPELLA CONTROLLER™ DISPLAY

The Automated Impella Controller screens have several common display elements. Each element is shown in Figure 4.3 and described in Table 4.3.

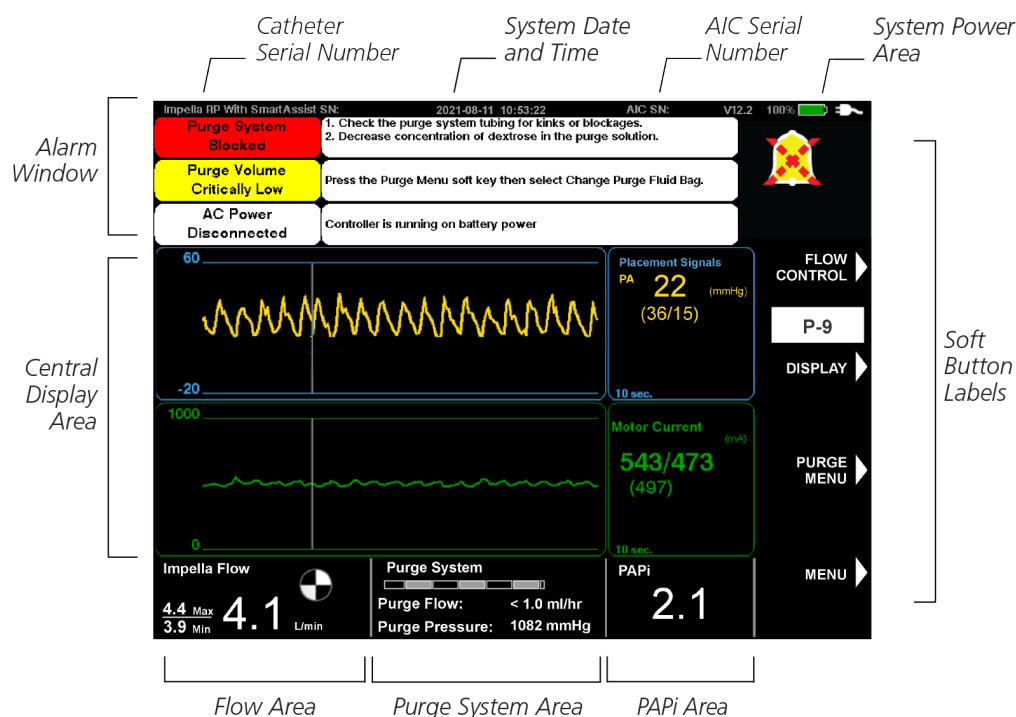


Figure 4.3 Automated Impella Controller Display Elements - Screen View

Table 4.3 Automated Impella Controller Display Elements

Display Element	Description
Alarm window	The alarm window displays up to 3 alarms simultaneously, in order of priority from top to bottom. For each alarm, the alarm window displays: - Alarm header – displayed in the left column; window is color-coded red for critical alarms, yellow for serious alarms, white for advisory notifications, gray for resolved alarms - Alarm subhead (if applicable) – further describes the alarm condition - Detailed text – up to 3 lines of instructions for resolving the alarm condition are displayed in the right column of the alarm window next to the alarm header and subhead information (See section 7 of this manual for further discussion of alarms.)
Catheter serial number	Displayed in the upper left of the display screen if a catheter is connected to the controller.
System date and time	The current date (YYYY-MM-DD) and time (24-hour format; HH:MM) are displayed in the upper center of the screen display. (In this example it is August 11, 2021 at 10:53 am.)
Automated Impella Controller Serial Number and SW version	The AIC serial number and the current SW version are shown in the upper right of the display screen
P-level Indicator	Displays current P-Level of Impella heart pump.

Purge System Stabilization

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

Table 4.3 Automated Impella Controller Display Elements (continued)

Display Element	Description
Mute alarm indicator	Displayed in place of the words “MUTE ALARM” when an alarm is silenced. (See section 7 of this manual for more information about the mute alarm function; Figure 7.1 illustrates the mute alarm indicator.) • Yellow bell with red X displayed when an alarm is muted • Not displayed when an alarm is active (but not muted) or when there are no active alarms
Soft button labels	The soft buttons on the 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 A in this manual for more details about the menu structure.) MUTE ALARM - Mutes (silences) active alarms FLOW CONTROL - Allows you to control the flow of the Impella Catheter DISPLAY - Brings up the Display menu for viewing waveforms and navigating to other screen displays PURGE MENU - Brings up the Purge Menu for changing the purge fluid, purge cassette and fluid or de-airing the purge system. MENU - Brings up a menu of options related to controller settings, alarm history and starting a case. Additional soft button functions may appear during specific controller procedures. START - Starts the specified procedure. NEXT - Advances to the next screen CANCEL - Exits out of the current menu. BACK - Returns to the previous screen EXIT - Exits the current procedure. DONE - Done completes the current step or procedure.
System power area	System power information is displayed to the right of the AIC Serial Number and software information at the top right of the display screen. Battery status – Bar within battery symbol indicates the overall remaining capacity of the batteries • Full green bar for fully charged battery • Partial green bar for battery that is at least 50% charged • Partial yellow bar for battery that is between 16% and 50% charged • Partial red bar for battery that is less than or equal to 15% charged • Moving gray bar for battery that is in charging mode • Numeric percentage of battery power remaining displayed below the battery icon AC plug indicator • Green plug indicates that the controller is running on AC power • Gray plug with a red X indicates no AC power detected and the controller is running on battery power

Table 4.3 Automated Impella Controller Display Elements (continued)

Display Element	Description
Purge system area	Information about the purge system is displayed to the right of the flow area at the bottom of the display screen. Purge system marquee—scrolls from left to right when purge system is operating • Slow scrolling represents normal purge flow rate • Fast scrolling represents bolus flow rate Purge flow • Current purge flow displayed in mL/hr below the purge system marquee if the purge flow is known • Not displayed when the purge system is stabilizing, when there is no purge cassette, or when the procedure has not yet started • Current purge pressure (pressure of the purge fluid delivered through the catheter to the motor) displayed in mmHg below the purge flow
Flow area	Information about Impella RP Flex with SmartAssist System Catheter flow is displayed in the lower left corner of the display screen. The Impella flow displays the flow rate based on the current performance level and the pressure signals measured from the differential pressure sensor. Table 5.4 P-Level Flow Rates should be relied on over the AIC displayed flow. However, displayed Impella flow and pump metrics should still be monitored and trended for monitoring pump performance and identifying sudden changes. Max/Min • Max/Min displays the range for the flow rate Current flow rate • Mean catheter flow displayed in liters per minute (L/min) • If the system is unable to calculate flow, a yellow triangular caution icon is displayed with the message “Flow Calculation Disabled” Catheter operation icon • The circular catheter operation icon rotates when the Impella RP Flex with SmartAssist System Catheter is running
PAPi area	The PAPi area displays the calculated pulmonary artery pulsatility index (PAPi) based on the pump’s Pulmonary Artery (PA) Placement Signal and the Central Venous Placement Signal
Central display area	On the placement screen, the central display area displays one waveform signal, described in the “Placement Screen” discussion below. On the placement screen, the central display area displays two waveform signals, described in the “Placement Screen” discussion below

Note: The pump metrics are for informational purposes only. Do not use for diagnostic purposes or patient monitoring. Independently verify all parameters are displayed with a cleared or approved diagnostic device.

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.

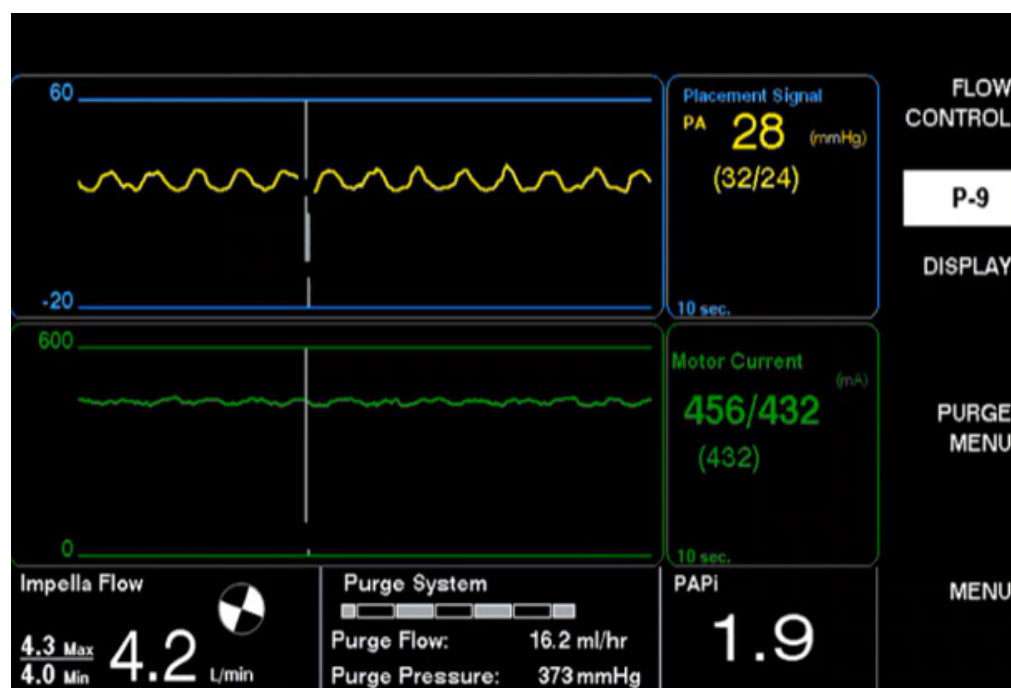


Figure 4.4 Placement Screen

Note: Do not use values as a clinical diagnostic tool, this is for informational purposes only.

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

- Pulmonary artery (PA) placement signal waveform
- Motor current waveform

MOTOR CURRENT WAVEFORM

Motor current is a measure of the energy intake of the Impella RP Flex with SmartAssist™ System Catheter motor. The energy intake varies with motor speed and the pressure difference between the inlet and outlet areas of the cannula.

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 RP Flex with SmartAssist System 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.

PULMONARY ARTERY (PA) PLACEMENT SIGNAL WAVEFORM

The Pulmonary Artery (PA) Placement Signal waveform displays the signal derived from pressures in the main pulmonary artery. The waveform is created based on the pressure signals measured from both the differential pressure sensor and the fiber-optic sensor. It is displayed on the 10-second time scale.

The scale for the PA Placement Signal waveform is displayed to the left of the waveform. The default scaling is -20-60 mmHg. The scale can be adjusted in increments of 10 mmHg, with a minimum difference between the upper and lower limits of 10 mmHg and a maximum difference of 400 mmHg.

To the right of the waveform is a display that labels the waveform, provides the units of measurement, and shows the minimum, maximum, and average value of the samples received.

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.

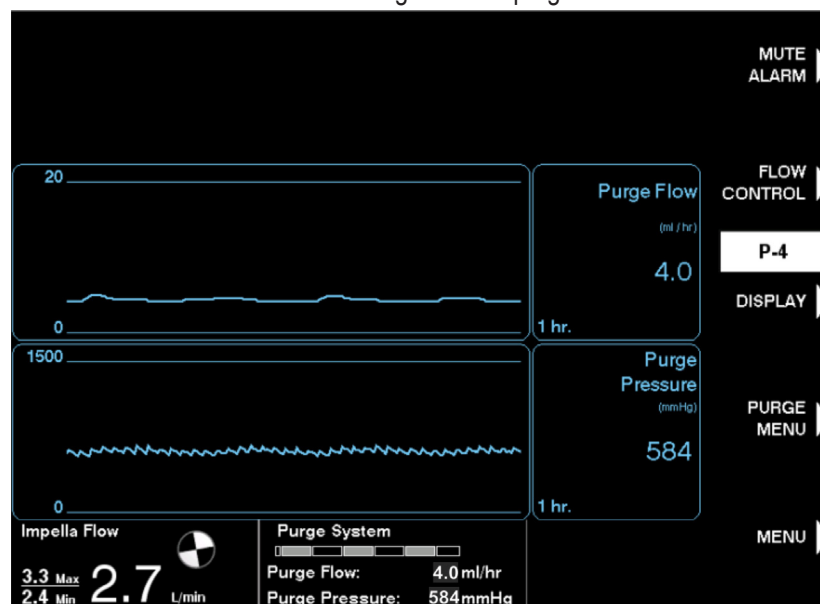


Figure 4.5 Purge Screen

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.

An Advisory Alarm can also be turned on via the **SETTINGS** menu.

PURGE PRESSURE

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.

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

PURGE INFUSION HISTORY

The Purge Infusion History screen displays the infusion volume as well as the amount of heparin, dextrose, and sodium bicarbonate infused each hour. The current time period is displayed at the top of the list. The calculations begin when the case start procedure is completed and Impella RP Flex with SmartAssist System Catheter flow rate is greater than 0 L/min. The Purge Infusion History screen updates after each milliliter of purge fluid is delivered and after each unit of heparin, dextrose, and sodium bicarbonate is delivered.

Use the **DISPLAY** soft button to navigate to the Purge Infusion History screen.

Figure 4.6 shows a sample Purge Infusion History screen.

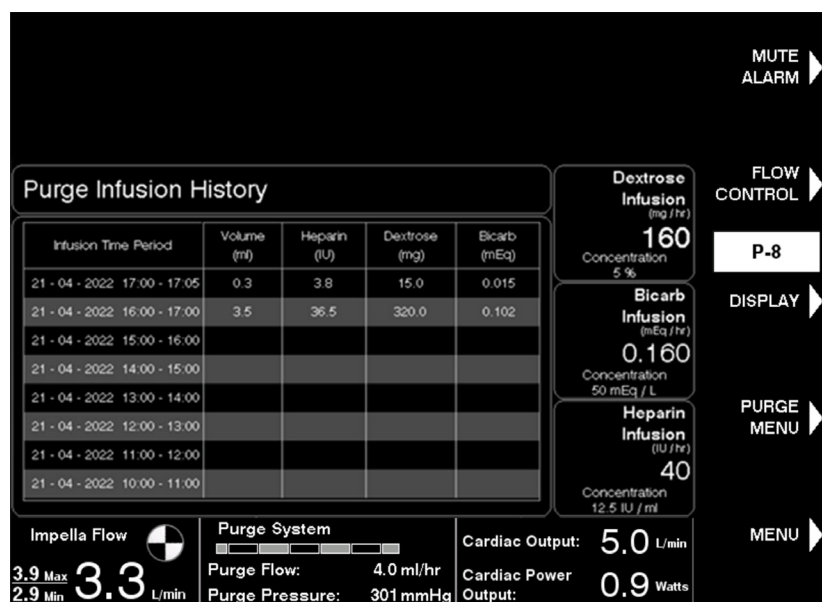


Figure 4.6 Purge Infusion History Screen

The heparin infused via the Impella purge system should be monitored and included in institutional anti-coagulation protocols. Failure to do so, may result in excessive heparin being infused, which may cause increased bleeding at the percutaneous and surgical access sites. Additional information on use of the heparin infusion for anti-coagulation can be found in Section 5 (see Anti-coagulation Therapy with Impella Heparin Infusion on page 5.4).

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 alarm 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.



5 USING THE AUTOMATED IMPELLA CONTROLLER™ WITH THE IMPELLA RP FLEX WITH SMARTASSIST™ SYSTEM CATHETER

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IMPELLA RP FLEX WITH SMARTASSIST PATIENT SELECTION



Benefits of Impella RP Flex with SmartAssist in salvage patients have not been proven.

The Impella RP Flex with SmartAssist patient indication and its contraindications are listed in Section 1 of this Impella RP Flex with SmartAssist IFU document. In order to guide Impella RP Flex with SmartAssist users to optimal patient outcomes, Impella RP Flex with SmartAssist patient selection guidance is an important element. Noted below, in the following figures, are definitions and a flow chart for enabling patient selection for Impella RP Flex with SmartAssist based on the premarket studies that will result in optimal outcomes.

Please note in Figure 5.2 that the “best practices pathway” is highlighted in green and is derived from PMA studies inclusion and exclusion criteria. Patients who follow the green pathway should have the best chance to benefit from Impella RP Flex with SmartAssist and the outcomes data for these patients can be found in Section 6 of this IFU. The alternate pathway (“the gray pathway”) represents patients who fall outside of the PMA studies guidelines, but still can be served with Impella RP Flex with SmartAssist. These patients are likely salvage patients and the benefit of Impella RP Flex with SmartAssist in these patients has not been proven.

The Table 5.1 “Checklist” is another useful tool for guiding optimal patient selection for Impella RP. Like the Figure 5.2, this list should be used to identify patients who are most likely to benefit from Impella RP Flex with SmartAssist and also to identify those who may not.

RIGHT VENTRICULAR FAILURE

Cardiac Index <2.2 L/min/m²
despite continuous High Dose Inotropes
(As defined in the RECOVER RIGHT Clinical Trial)

AND ANY OF THE FOLLOWING:

- CVP¹ >15 mmHg or
- CVP/PCWP¹ or LAP >0.63 or
- Moderate to severe global RV dysfunction on echo defined as one of the following¹:
 - Global RV hypokinesis or
 - TAPSE score of ≤ 14 mm or
 - RV diameter at base >42 mm or
 - RV short axis (or mid-cavity) diameter >35 mm

High Dose Inotropes defined as:

- Dobutamine of ≥ 10 µg/kg/min or equivalent for more than 15 minutes
- Milrinone >120 minutes
- Or administration of more than one inotrope/ vasopressor medication

Profound Cardiogenic Shock defined:

- SBP <75 mmHg
- CI <1.3 l/min/m² despite two or more high dose inotropes
- PH <7.1 not corrected by 100 mEq NaHCO₃
- DIC
- Anoxic brain Injury or CGS >24 hrs

Additional Measure for Early Identification of Right Ventricular Failure

$$PAPI^2 < 1.0$$

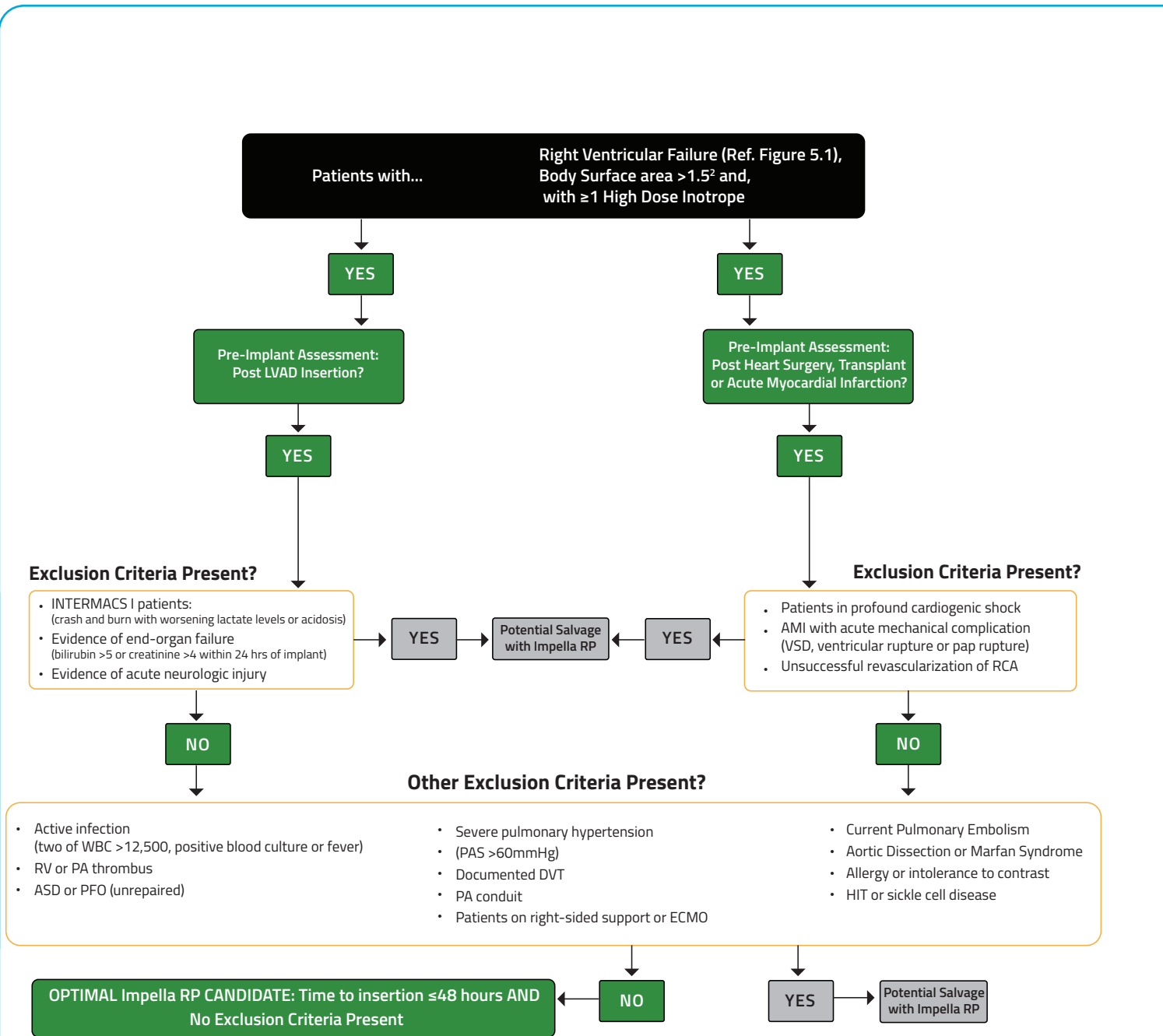
$$PAPI = \frac{PAS - PAD}{RA}$$

- PAPI = Pulmonary Artery Pulsatility Index
- PAS = Pulmonary Artery Systolic Pressure
- PAD = Pulmonary Artery Diastolic Pressure
- RA = Mean Right Arterial Pressure

1. Anderson MB, et al. J Heart Lung Transplant. 2015; 34(12):1549-1560

2. Korabathina, R et al. The Pulmonary Artery Pulsatility Index Identifies Severe Right Ventricle Dysfunction in Acute Inferior Myocardial Infarction. SCAI 2012; 80:593-600

Figure 5.1 Best Practices - Patient Selection Guidance with Right Ventricular Failure - Impella RP Flex with SmartAssist Heart Pump



Anderson MB, et al. J Heart Lung Transplant. 2015; 34(12):1549-1560

Figure 5.2 Impella RP Flex with SmartAssist Best Practice Selection Algorithm

Below you will find an Impella RP Patient Selection Criteria Checklist that can be used to optimize patient outcomes with Impella RP Flex with SmartAssist.

Treatment with the Impella RP Flex with SmartAssist System is appropriate for patients who develop signs of acute right ventricular failure:

1. Post-implantation of an approved surgical LVAD; or
2. Post-heart surgery, post-heart transplant or post-myocardial infarction

The checklists below are based on the exclusion criteria for the Impella RP pre-market clinical study. These checklists are provided to help you determine if Impella RP Flex with SmartAssist support is an appropriate treatment for your patient, and may predict whether your patient is likely to benefit from Impella RP Flex with SmartAssist support.

Table 5.1 Exclusion Criteria for the Impella RP Pre-Market Clinical Study

Pre-Implant Assessment: Post LVAD Insertion	Pre-Implant Assessment: Post Heart Surgery, Transplant or Acute Myocardial Infarction
☐ Time (hours) to insertion post LVAD implant _____hrs ☐ INTERMACS I patients (crash and burn with worsening lactate levels or acidosis) ☐ Evidence of end-organ failure (bilirubin >5 or creatinine >4 within 24 hours of implant) ☐ Evidence of acute neurologic injury ☐ Active infection defined as two of the following (WBC >12,500 or positive blood culture or fever) ☐ RA, RV or PA thrombus ☐ Prosthetic valves in the right heart ☐ Structural tricuspid disease ☐ ASD or PFO (unrepaired) ☐ Pulmonary valve stenosis or insufficiency ☐ Severe pulmonary hypertension (PAS>60mmHg) ☐ Documented DVT and/or presence of IVC filter ☐ Anatomic abnormalities precluding insertion ☐ PA conduit ☐ Patients on right-sided support or ECMO ☐ Current Pulmonary Embolism ☐ Aortic Dissection or Marfan Syndrome ☐ Allergy or intolerance to contrast ☐ HIT or sickle cell disease ☐ Existing congenital heart disease that would preclude placement	☐ Time (hours) to insertion post completion of Cardiac Surgery or Heart Transplant, or presentation with Acute Myocardial Infarction _____hrs ☐ Patients in profound cardiogenic shock ☐ AMI with acute mechanical complication (VSD, ventricular rupture or pap rupture) ☐ Unsuccessful revascularization of RCA ☐ Active infection defined as two of the following (WBC >12,500 or positive blood culture or fever) ☐ RA, RV or PA thrombus ☐ Prosthetic valves in the right heart ☐ Structural tricuspid disease ☐ ASD or PFO (unrepaired) ☐ Pulmonary valve stenosis or insufficiency ☐ Severe pulmonary hypertension (PAS>60mmHg) ☐ Documented DVT and/or presence of IVC filter ☐ Anatomic abnormalities precluding insertion ☐ PA conduit ☐ Patients on right-sided support or ECMO ☐ Current Pulmonary Embolism ☐ Aortic Dissection or Marfan Syndrome ☐ Allergy or intolerance to contrast ☐ HIT or sickle cell disease ☐ Existing congenital heart disease that would preclude placement
OPTIMAL CANDIDATE: Time to insertion ≤48 hours AND no boxes checked	OPTIMAL CANDIDATE: Time to insertion ≤48 hours AND no boxes checked

ANTI-COAGULATION THERAPY WITH IMPELLA HEPARIN INFUSION



Anti-coagulate patients as needed to maintain recommended ACT (160-180s), in particular when indwelling central venous lines or cannulas (i.e. hemodialysis, PA catheters, ECMO) are present. ACT below this level may increase the risk of thrombus formation or deposition. If either internal thrombus forms within or external thrombus deposits in the Impella RP Flex with SmartAssist, this may result in reduced flow, loss of support, or hemolysis.

To maximize reliability, Impella pump motors require a constant purge using a dextrose solution in water with heparin (25 or 50 IU/mL) or if heparin is contraindicated, sodium bicarbonate (25 or 50 mEq/L). In addition, Impella pumps are used in conjunction with heparin based anti-coagulation therapy. As a result, when heparin is used in the purge fluid, the heparin infused via the Impella purge system needs to be accounted for in institutional protocols, which include heparin for systemic anti-coagulation. Abiomed's recommendation on an optimal method to include Impella heparin infusion into an anti-coagulation protocol is provided below.

The section below is not applicable if sodium bicarbonate is used in the purge fluid when heparin is contraindicated. No heparin will be infused when sodium bicarbonate is used.

INCLUDING IMPELLA HEPARIN INFUSION IN HEPARIN ANTI-COAGULATION THERAPY

Anti-coagulation therapy protocols are extremely important for managing Impella pumps. These protocols usually include the use of heparin for systemic anti-coagulation, and careful monitoring of a patient's coagulation status using Activated Clotting Times (ACTs). During support with Impella pumps, the targeted ACT is 160-180 seconds. Depending on each patient's characteristics, different heparin doses are needed to maintain this ACT. This is accomplished by providing intravenous (IV) heparin infusions to maintain an optimal coagulation state, as monitored by ACT.

To optimize patient management on Impella support, anti-coagulation therapy utilizing heparin needs to account for the heparin delivered through the Impella purge system. Specifically, the heparin infused via the purge solution may provide a significant fraction of the heparin needed to maintain a patient's ACT. As a result, failure to account for the Impella heparin infusion can confound ACT maintenance, and potentially result in patients being in a hyper-coagulated state, leading to increased bleeding at the percutaneous and surgical access sites. A method to include Impella heparin infusion in an anti-coagulation protocol using heparin is described below. Overall, the total heparin to a patient is the sum of the Impella Delivered Heparin (Heparin source: Impella purge), and the IV Heparin (Heparin source: drip):

$$\text{Total Heparin} = \text{Impella Delivered Heparin} + \text{IV Heparin} \quad (1)$$

If your protocol does not include an allowance for heparin from the Impella purge, but calls out a specific total heparin, the IV Heparin can be calculated as:

$$\text{IV Heparin} = \text{Total Heparin} - \text{Impella Delivered Heparin} \quad (2)$$

As a sample patient case, if your protocol specifies to use heparin at 10 U/kg/hour to maintain an acceptable ACT, and you have a 100 kg patient, your total heparin would be 1,000 U/hour. If the Purge Infusion History Screen on the AIC (see Figure 4.6) shows that the Impella purge provides 150 U/hour (50 U/mL heparin at a purge rate of 3 mL/hour), using equation (2), the correct IV Heparin would be 850 U/hour of heparin or 8.5 mL/hour for a saline bag with 100 U/mL.

Table 5.2 provides additional clinical scenarios.

Table 5.2 Clinical scenarios for anti-coagulation therapy with the Impella purge system heparin (50 U/ml).

Scenario #1 – Total heparin = 8 U/kg/hour; IV Heparin Concentration = 100 U/mL		
Patient Weight (kg)	Impella Purge [^] Flow (mL/hour)	IV Heparin (mL/hour)
75	10	1
	15	-1.5†
	20	-4†
100	10	3
	15	0.5
	20	-2†
125	10	5
	15	2.5
	20	0*
Scenario #2 - Total heparin = 10 U/kg/hour; IV Heparin Concentration = 100 U/mL		
Patient Weight (kg)	Impella Purge [^] Flow (mL/hour)	IV Heparin (mL/hour)
75	10	2.5
	15	0*
	20	-2.5†
100	10	5
	15	2.5
	20	0*
125	10	7.5
	15	5
	20	2.5
Scenario #3- Total heparin = 12 U/kg/hour; IV Heparin Concentration = 100 U/mL		
Patient Weight (kg)	Impella Purge [^] Flow (mL/hour)	IV Heparin (mL/hour)
75	10	4
	15	1.5
	20	-1†
100	10	7
	15	4.5
	20	2
125	10	10
	15	7.5
	20	5
[^] Impella purge heparin = 50 U/mL * scenario where discontinuation of systemic heparin therapy should be assessed. † scenario where use of Impella purge heparin = 25 U/mL should be assessed.		

As noted in Table 5.2 (denoted with *), for some patients, the Impella purge system may provide a full heparin dose (IHD = THD). For these patients, systemic IV heparin therapy may not be needed. In addition, for other patients (denoted with †), the Impella purge system may provide too much heparin. For these patients, in order to maintain an optimal ACT, use of a purge fluid with a lower heparin concentration (25 U/mL) should be considered. Table 5.3 provides a corrected patient scenarios table for these cases.

Table 5.3 Patient scenarios for anti-coagulation therapy with the Impella purge system heparin (25 U/mL).

Scenario #1 – Total heparin = 8 U/kg/hour; IV Heparin Concentration = 100 U/mL		
Patient Weight (kg)	Impella Purge† Flow (mL/hour)	IV Heparin (mL/hour)
75	15	2.25
75	20	1
100	20	3
Scenario #2 – Total heparin = 10 U/kg/hour; IV Heparin Concentration= 100 U/mL		
Patient Weight (kg)	Impella Purge† Flow (mL/hour)	IV Heparin (mL/hour)
75	20	2.5
Scenario #2 - Total heparin = 10 U/kg/hour; IV Heparin Concentration = 100 U/mL		
Patient Weight (kg)	Impella Purge^ Flow (mL/hour)	IV Heparin (mL/hour)
75	20	4
† Impella purge heparin = 25 U/mL		

Please contact Abiomed's Clinical Support Center, 1-800-422-8666, if you have questions.

OPERATING THE IMPELLA CATHETER WITHOUT HEPARIN IN THE PURGE SOLUTION

The Impella Catheter is designed to be operated with a purge solution that contains heparin or if heparin is contraindicated, sodium bicarbonate, to maintain the patency of the Impella catheter's purge system. In the event that a patient is intolerant to heparin or in whom heparin is contraindicated (e.g., due to heparin-induced thrombocytopenia or bleeding), sodium bicarbonate (25 or 50 mEq/L) may be added to the purge solution instead of heparin as described in Table 3.3. The Impella catheter has not been tested with any other anticoagulants, such as direct thrombin inhibitors, in the purge solution. Therefore, avoid the use of any alternative anticoagulants in the purge solution to prevent damage to the Impella catheter.

STARTUP



Do **NOT** use an Impella RP Flex with SmartAssist™ System if any part of the system is damaged.



The sterile components of the Impella RP Flex with SmartAssist 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 RP Flex with SmartAssist System 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.



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.



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.



Have a backup Automated Impella Controller, purge cassette, and Impella RP Flex with SmartAssist System Catheter available in the unlikely event of a device failure.

SUPPLIES NEEDED

- Automated Impella Controller
- Impella RP Flex with SmartAssist System Catheter and accessories
- Balloon-tipped flow-directed catheter
- 500 cc bag of dextrose solution for purge solution in water (5% recommended; 5% to 20% acceptable) with 25 or 50 IU/mL heparin or if heparin is contraindicated, 25 or 50 mEq/L of sodium bicarbonate.

TURNING ON THE AUTOMATED IMPELLA CONTROLLER™

To turn the controller on:

1. Press and hold the power switch on the right side of the Automated Impella Controller for 3 seconds (see Figure 5.3).



Figure 5.3 Automated Impella Controller Power Switch

The Automated 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 5.4).

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

SYSTEM SELF CHECK FAILED.

CHANGE CONSOLE IMMEDIATELY.

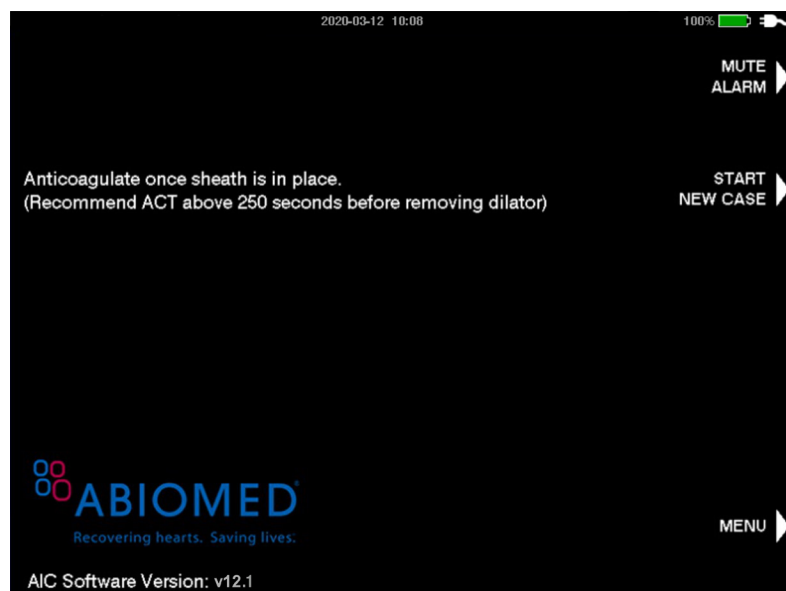
The controller displays the reason for the system test failure at the bottom of the screen.

Battery Switch

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

THE STARTUP SCREEN

The startup screen (see Figure 5.4) appears when you successfully turn on the Automated Impella Controller.



Check Date and Time

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

Figure 5.4 Automated Impella Controller Startup Screen

The startup screen displays the current version of the software that the Automated Impella Controller is running:

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

CASE START



To reduce the possibility of fibers being drawn into the Impella, customers should avoid exposing the inlet and cannula section of the Impella Heart Pumps to any surfaces or fluid baths where the device can come into contact with loose or floating fibers.



Fluoroscopy is required to guide placement of the Impella RP Flex with SmartAssist™ System Catheter. The small placement guidewire must be reliably observed at all times.



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



Avoid manual compression of the inlet, outlet, or sensor areas of the cannula assembly.



Do **NOT** remove the Impella RP Flex with SmartAssist System Catheter over the length of the placement guidewire.



Handle with care. The Impella RP Flex with SmartAssist System Catheter can be damaged during removal from packaging, preparation, insertion, and removal. Do **NOT** bend, pull, or place excess pressure on the catheter or mechanical components at any time.



Do **NOT** kink or clamp any part of the Impella RP Flex with SmartAssist System Catheter.

Sensitive Medical Device

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

To avoid fibers drawn into the Impella.

- Keep the Impella Heart Pump in its packaging tray until just before insertion.
- Do not attempt to run the pump in a basin of saline prior to insertion.
- Do not attempt to rinse and reinsert the device after initial insertion.
- Hold the surgical towel or 4 x 4 gauze pad away from the inflow and outflow windows, when controlling blood splatter during insertion of the Impella Heart Pump through the introducer.

INSPECT FOR TAMPERING BEFORE USE

Check the Automated Impella Controller for evidence of tampering before each use. Refer to Figure 5.5 for an Automated Impella Controller without evidence of tampering and Figure 5.6 for evidence of tampering. If tampered with, the tape adhering to the Automated Impella Controller or Impella Connect body will show a checkerboard pattern indicating the device may have been tampered with. In the event of suspected tampering, **do not use**. Use an alternate Automated Impella Controller, and contact your Abiomed Representative



Figure 5.5 Automated Impella Controllers without evidence of tampering



Figure 5.6 Automated Impella Controllers with evidence of tampering

In the event of suspected tampering, **do not use**. Use an alternate Automated Impella Controller, and contact your Abiomed Representative.

CASE START

1. Press the **START NEW CASE** soft button from the startup screen or plug in a new Impella Catheter. "Case Start" can also be selected by pressing the MENU soft key.
2. The controller displays the screen shown in Figure 5.7.

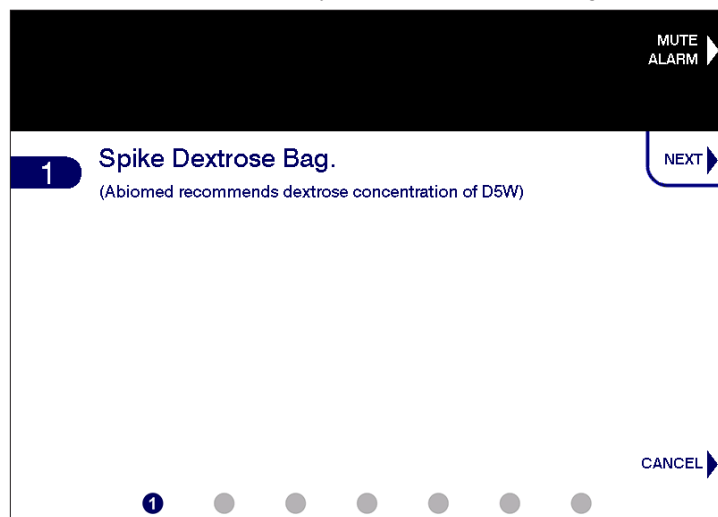


Figure 5.7 Initial Case Start Screen.

INSERT PURGE CASSETTE

1. Open the purge cassette package. Secure the YELLOW luer to the sterile field
2. Pass the purge cassette and spike off the sterile field.
3. Spike the fluid bag/bottle.
4. Press the **NEXT** soft button.
5. Open the purge cassette door by pressing the release on the left side of the controller. Insert the purge cassette into the Automated Impella Controller (as shown in Figure 5.8 and described in the steps that follow).

Shaded Steps

All shaded steps require sterile technique.



Figure 5.8 Inserting the Purge Cassette into the Automated Impella Controller

Connect Purge Disc Within 3 Seconds

The instructions for inserting the purge disc appear if it is not snapped into place within 3 seconds of inserting the purge cassette.

Purge Solution Bottles

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

Close Purge Cassette Door

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

6. 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.
7. Slide the purge disc into the slot to the right of the purge cassette until it snaps into place. The controller will automatically begin priming the purge cassette.
8. Align the left side of the purge tubing into the channel, no alignment is need on the right side to ensure sufficient room around the edges of the cassette door so it will not pinch the purge tubing as it exits.
9. Extend the purge tubing and close the cassette door.
10. The controller automatically begins priming the purge cassette after it is inserted. The progress bar shown in Figure 5.9 marks the progress of the purge cassette priming.

CONNECT THE IMPELLA™ CATHETER

1. Remove the Impella Catheter from its package using sterile technique and inspect the catheter for damage.
2. Inspect the cable for damage, including damage to the connector pins at the controller end.
3. Pass the sterile connector cable from the Impella Catheter off the sterile field.
4. Open the cover on blue connector plug by rotating clockwise. Line up the notch on the connector cable with the notch in the blue catheter plug on the front of the Automated Impella Controller and plug the cable into the controller. See Figure 5.9.

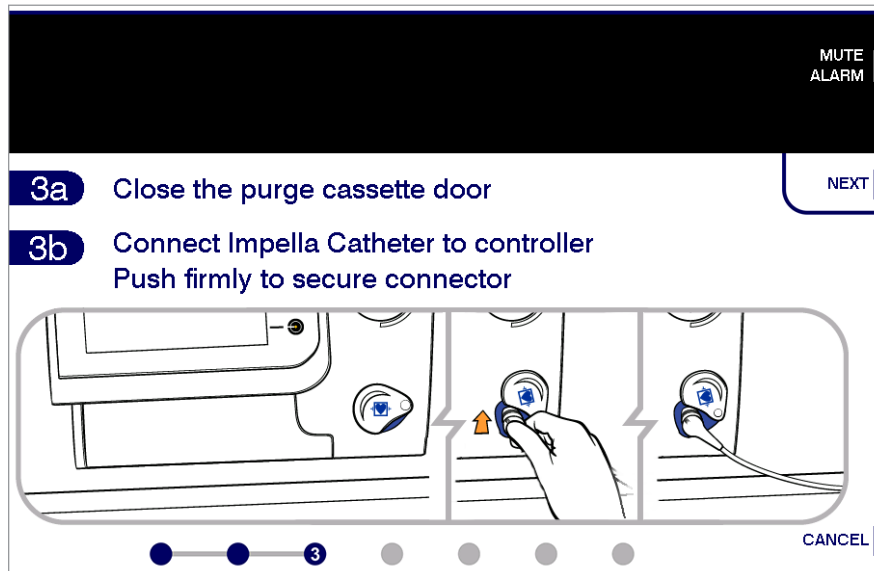


Figure 5.9 Connecting Impella Catheter

5. If not pre-attached, attach the sidearm retainer to the clear sidearm

6. Snap the purge clip (located on the pressure reservoir of the clear sidearm) to the connector cable as shown in Figure 5.10.

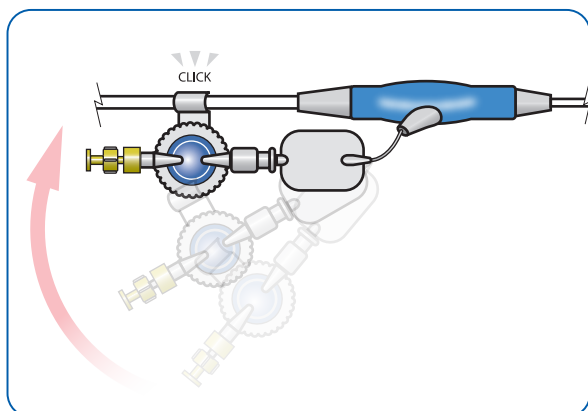


Figure 5.10 Snapping Purge Clip to Connector Cable

7. Once the purge cassette is primed and the controller detects that the connector cable is plugged in, it prompts you to connect the yellow luer to the Impella Catheter.

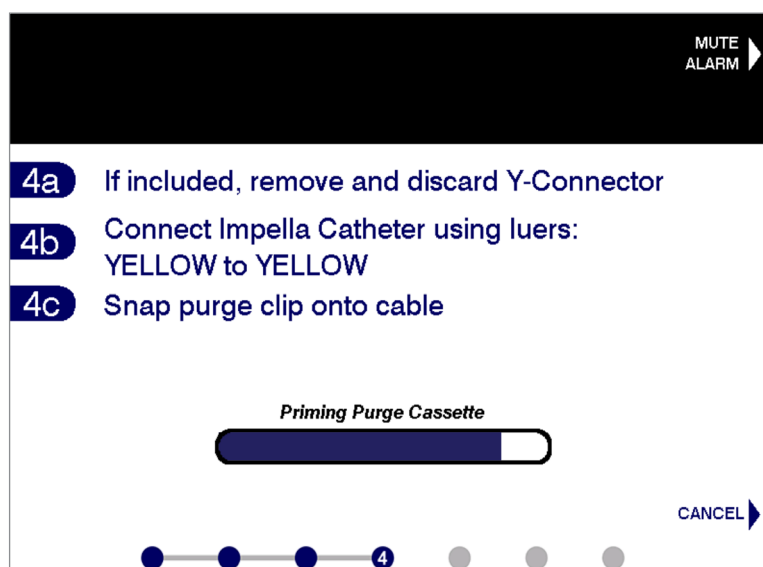


Figure 5.11 Connecting luer and priming Impella Catheter

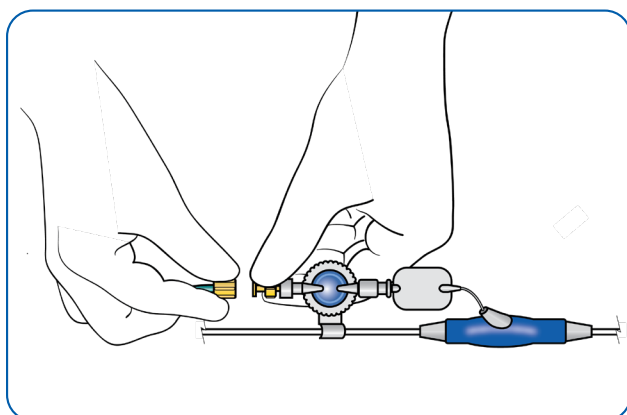


Figure 5.12 Connecting the Luer to the Impella RP Flex with SmartAssist System Catheter

Important Step

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

8. When the controller detects that the luer is connected, it automatically begins priming the purge lumen.
9. Once the purge cassette is primed and the luer is connected, the controller automatically advances to the next screen.
10. The first step on the next screen prompts you to enter the purge fluid information.

ENTER PURGE FLUID DATA

1. Enter the purge fluid information. The screen in Figure 5.13 shows a table of default values for the purge fluid. The default purge fluid values will be the purge fluid values from the last Case Start performed on a given Automated Impella Controller.

Purge Fluid Volume	500 ml
Dextrose Concentration	5 %
Bicarb Concentration	0 mEq/L
Heparin Concentration	0 IU/ml

Figure 5.13 Entering Purge Fluid Information

2. To select the default values displayed on the screen, press the **ACCEPT** soft button. This will select those values and automatically advance to the next screen. Note: The Automated Impella Controller will use the default values for the purge fluid unless changed.
3. To change the purge fluid information, press the **EDIT** soft button, scroll to the appropriate item and push the selector knob to select it or use the white soft arrow buttons. Then scroll through the values and push the selector knob to make a new selection. Press the **DONE** button to finish editing. The controller will use the default values if no other selections are made.
 - Purge fluid can be set to 50 mL, 100 mL, 250 mL, 500 mL, or 1000 mL.
 - Dextrose concentration can be set to 5%, 10% or 20%.
 - Heparin concentration can be set to 0, 5 IU/mL, 6.25 IU/mL, 10 IU/mL, 12.5 IU/mL, 15 IU/mL, 20 IU/mL, 25 IU/mL, 40 IU/mL or 50 IU/mL.
 - Bicarb concentration can be set to 0 mEq/L, 25 mEq/L, or 50 mEq/L.

MUTE
ALARM ▶

6

Edit Purge Fluid values.

DONE ▶

Purge Fluid Volume	500 ml	▲ ▼
Dextrose Concentration	0	
Bicarb Concentration	0 mEq/L 25 mEq/L 50 mEq/L	
Heparin Concentration	0 IU/ml	

6

SELECT ▶

Figure 5.14 Changing Purge Fluid Information

SECURE THE PURGE TUBING

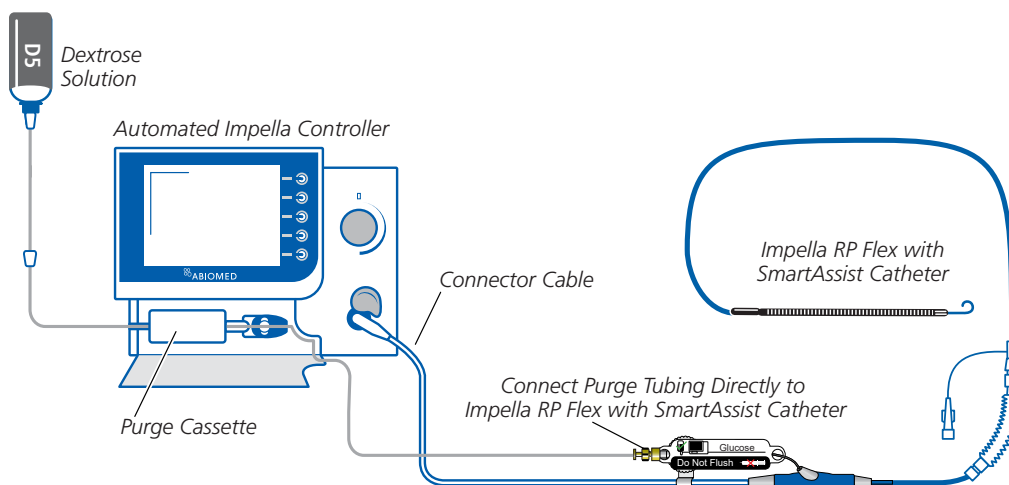
1. To complete the setup, connect the purge tubing to the white connector cable by pushing the purge tubing into the clips attached to the white connector cable as shown in Figure 5.15.



Figure 5.15 Connecting the Purge Tubing to the Connector Cable

IMPELLA RP FLEX WITH SMARTASSIST SYSTEM CONFIGURATION

Figure 5.16 illustrates the correct configuration of the Impella RP Flex with SmartAssist System.



Shaded Steps

All shaded steps require sterile technique.

Figure 5.16 Impella RP Flex with SmartAssist System Configuration

INSERTING THE IMPELLA RP FLEX WITH SMARTASSIST™ SYSTEM 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.



To reduce the possibility of fibers being drawn into the Impella, customers should avoid exposing the inlet and cannula section of the Impella Heart Pumps to any surfaces or fluid baths where the device can come into contact with loose or floating fibers.



To reduce the risk of cardiac or vascular injury (including perforation) when manipulating the heart during cardiac surgery, evaluate the position of the pump using imaging guidance prior to manipulating the heart, and monitor position.



To reduce the risk of cardiac or vascular injury (including ventricular perforation) physicians should exercise special care when inserting the Impella Catheter in patients with complex anatomy. This includes patients with known or suspected: decreased ventricular cavity size, ventricular aneurysms, thin-walled ventricles due to chronic dilation, congenital heart disease, or compromised cardiac tissue quality.



To reduce the risk of cardiac or vascular injury (including ventricular perforation) when advancing or torquing the Impella, adjustments should be performed under imaging guidance.



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, introducing the risk of cardiac or vascular injury (including ventricular perforation). Check that the pump is positioned correctly after CPR with chest x-ray guidance.



Thrombus formation or deposits on indwelling central venous lines or cannulas (i.e. hemodialysis catheters, PA catheters, ECMO) may break free and enter into the Impella RP Flex with SmartAssist inlet, resulting in reduced flow, loss of support, or hemolysis. Assess the risk for extraluminal thrombus on indwelling lines placed prior to initiation of support.



Fluoroscopy is required to guide placement of the Impella RP Flex with SmartAssist System Catheter. The small placement guidewire must be reliably observed at all times.



Avoid manual compression of the inlet, outlet, or sensor areas of the cannula assembly.



Do **NOT** kink or clamp any part of the Impella RP Flex with SmartAssist System Catheter.



Handle with care. The Impella RP Flex with SmartAssist System 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 Inlet or Outlet Areas

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

1. Confirm purge fluid is exiting the Impella Catheter.
2. Obtain access to the internal jugular or femoral vein using ultrasound guided micro-puncture technique.
3. Under fluoroscopic guidance, insert a 5–8 Fr introducer over the 0.035 inch guidewire (provided) to pre-dilate the vessel.
4. Place hemostatic stitch prior to removal of the 5-8Fr introducer but do not secure down
5. Remove the 5–8 Fr introducer over the 0.035 inch guidewire. Under fluoroscopic guidance, insert the 8 Fr, 12 Fr, 16 Fr, and 20 Fr dilators sequentially, as needed. Remove the 20 Fr dilator and insert the 23 Fr introducer with pre-loaded dilator. Under fluoroscopic guidance, while inserting the 23 Fr introducer, hold the shaft of the introducer to advance it into the vein.
6. Administer systemic anticoagulation. When ACT is at least 250 seconds. Remove the 23Fr dilator and the 0.035 inch guidewire.
7. Attach a flush syringe to the 23Fr introducer sidearm and aspirate and flush the 23 fr introducer.
8. Under fluoroscopic guidance, insert an 0.035" compatible flow-directed catheter into the 23 Fr introducer and advance it into the left or right pulmonary artery.
9. Form a curve or bend on the 0.027 inch, 260 cm placement guidewire and then insert it into the flow-directed catheter
10. Under fluoroscopic guidance, advance the placement guidewire deep into either PA branch until wire prolapses.
11. Utilize a fixed wire technique to remove the diagnostic or flow-directed catheter over the 0.027 inch guidewire, leaving the wire in the PA branch.

Patients should be assessed for femoral or internal jugular vein access site location to allow for optimal device position and hemodynamic support.

Shaping the 0.027" Placement Guidewire

Place the shaping tool just distal to the weld separating the shaping ribbon from the body of the placement guidewire. Bend the shaping ribbon against the tool, using minimal force. Do NOT use a shaping tool with a sharp tip or edge. Do NOT pull the shaping tool along the length of the shaping ribbon as this could strip the coil off the guidewire and cause it to unfurl and separate. Inspect the coil and guidewire for damage after shaping and before using.

Do NOT reinsert the EasyGuide lumen

Once you remove the EasyGuide lumen from the Impella Catheter, do not attempt to reinsert it. If necessary, follow instructions for backloading the catheter **without** the EasyGuide lumen.

To backload the catheter using the EasyGuide lumen

11. Insert the placement guidewire into the red EasyGuide lumen at the tip of the pigtail as shown in Figure 5.17. (If the red EasyGuide lumen has been removed, follow the procedure outlined in step 12.)
 - a. Wet the cannula with sterile water. Advance guide wire until it exits the EasyGuide lumen tip near the label.
 - b. Remove the EasyGuide lumen by gently pulling the label in line with the catheter shaft while holding the Impella™ Catheter as shown in Figure 5.17.
 - c. If you suspect that a portion of the EasyGuide lumen remains in the catheter, do **NOT** use the Impella Catheter. Measure EasyGuide lumen length using catheter markings (intact length is between 36 to 38 cm).
 - d. Skip to step 12 if the catheter is successfully backloaded on the guidewire.

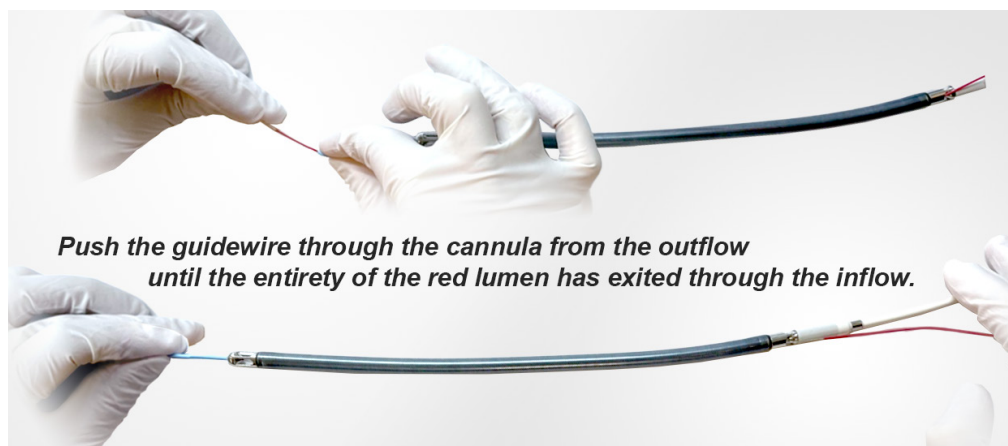


Figure 5.17 Loading the Catheter on the Guidewire using the EasyGuide Lumen

To backload the catheter without the EasyGuide lumen

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

One-person technique

- a. Advance the guidewire into the Impella Catheter through the distal tip of the pigtail and stabilize the cannula between the fingers. This prevents pinching of the outlet area. The guidewire must exit the inlet area out the window opposite the sensor face.

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 focus on advancing the guidewire.

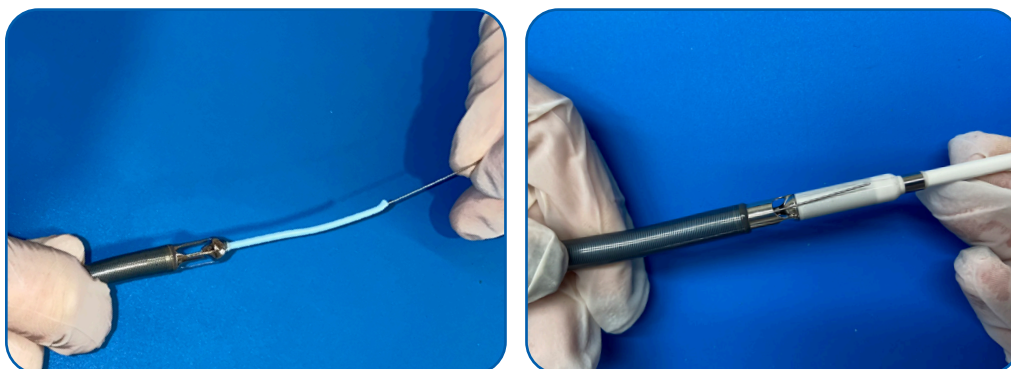


Figure 5.18 Loading the Catheter on the Guidewire without the EasyGuide Lumen and Aligning the Placement Guidewire



To reduce the risk of cardiac or vascular injury (including ventricular perforation) when advancing or torquing the Impella, adjustments should be performed under imaging guidance.



To reduce the risk of cardiac or vascular injury (including ventricular perforation) physicians should exercise special care when inserting the Impella Catheter in patients with complex anatomy. This includes patients with known or suspected: decreased ventricular cavity size, ventricular aneurysms, thin-walled ventricles due to chronic dilation, congenital heart disease, or compromised cardiac tissue quality.

13. While holding the 23Fr Introducer by the wings, advance the catheter through the hemostatic valve into the vein and along the placement guidewire using a fixed-wire technique. Bleed back through the inlet is expected until the entire catheter enters the introducer. Follow the catheter under fluoroscopy, at the level of the pulmonary artery bifurcation with the pigtail deviating. Position the outlet area of the cannula approximately 4 cm past the pulmonary valve annulus.
14. Slowly, remove the placement guidewire while monitoring pump positioning under fluoroscopic guidance.
15. Confirm position with fluoroscopy.



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

Use Fluoroscopy for Placement

Impella RP Flex with SmartAssist System Catheter 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 RP Flex with SmartAssist System Catheter after placement, TEE does not allow visualization of the entire catheter assembly and is inadequate for reliably placing the Impella RP Flex with SmartAssist System Catheter.

POSITIONING AND STARTING THE IMPELLA RP FLEX WITH SMARTASSIST™ SYSTEM CATHETER



Retrograde flow will occur from the pulmonary artery back into the vena cava or right atrium if the Impella RP Flex with SmartAssist System Catheter is set at performance level P-0.



To reduce the risk of cardiac or vascular injury (including ventricular perforation) when advancing or torquing the Impella, adjustments should be performed under imaging guidance

When the Impella RP Flex system is properly positioned across the pulmonary valve, but is not yet running, the PA placement signal waveform will be similar to a pulmonary arterial waveform. After starting the Impella RP Flex System, the amplitude of the placement signal may change, depending on the selected performance level.

1. Press the **START IMPELLA** soft button.
2. Turn the selector knob to increase P-level from P-0 to P-2.
3. Press the selector knob to select the new performance level.
4. The catheter operation icon in the lower left corner of the screen begins rotating when the Impella RP Flex with SmartAssist System Catheter begins to operate.
5. Increase P-level incrementally until desired P-level is reached to confirm correct and stable placement. Evaluate the catheter position and remove any excess slack if needed. The catheter inlet area should be in the vena cava or right atrium, and the outlet area in the pulmonary artery. Verify placement with fluoroscopy.

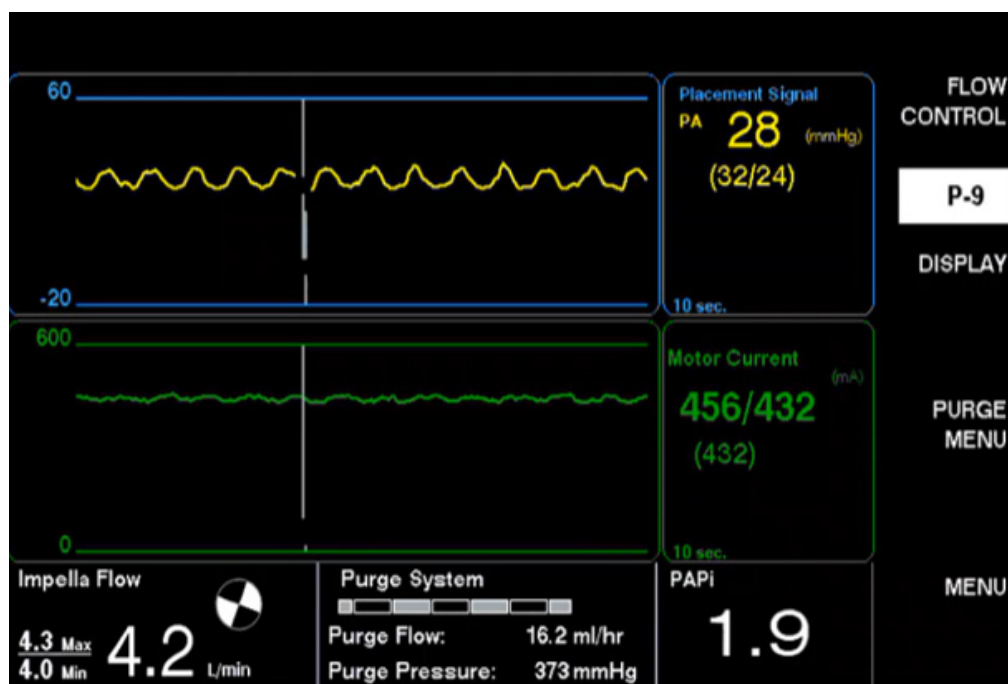


Figure 5.19 Maximum Performance Level

USE OF THE REPOSITIONING SHEATH AND THE 23 FR PEEL-AWAY INTRODUCER



To reduce the risk of cardiac or vascular injury (including ventricular perforation) when advancing or torquing the Impella, adjustments should be performed under imaging guidance

1. Confirm hemostatic stitch is in place.
2. Attach a Flush Syringe and flush the repositioning sheath prior to advancing the sheath.
3. Place two dead-end caps on the repositioning sheath 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.
4. Remove the 23 Fr peel-away introducer completely from the vein over the catheter shaft utilizing a pin and pull technique to ensure pump positioning is maintained. Once the sheath is out of the body, apply manual pressure at the venotomy.
5. Grasp the two wings of the 23 Fr Introducer and bend back until the valve assembly splits. To do this, first stretch then snap the flexible valve mechanism that temporarily holds the two wings together. Continue to peel the two wings until the introducer is completely separated from the catheter shaft. NOTE: Do NOT peel the 23 Fr peel-away introducer over the tip of the repositioning sheath.
6. Under fluoroscopic guidance, slide the repositioning sheath over the catheter shaft while securing the catheter to maintain pump position and advance it into the vein to the distal tip of the suture pad.
7. Secure the previously placed hemostatic stitch
8. Make sure there is no bleeding at the transition from the repositioning sheath to the vein.
9. Secure the repositioning sheath by suturing it to the skin using the suture ring on the sheath.
10. Verify placement with fluoroscopy, the position of the outlet area of the cannula should be at the level of the pulmonary artery bifurcation with the pigtail deviating towards the left or right pulmonary artery, approximately 4 cm past the pulmonary valve annulus.
11. Connect the Tuohy-Borst on the anticontamination sleeve to the repositioning sheath hub and turn the Tuohy-Borst clockwise to lock the T-lock in place. Secure the catheter shaft in place by holding both halves of the Tuohy-Borst and rotating the proximal side to tighten.
12. Carefully extend the anticontamination sleeve to maximum length and secure the end closest to the blue Impella plug by tightening the Tuohy-Borst at the proximal end of the anticontamination sleeve.
13. Dress the access site per hospital protocol.
14. Before leaving the procedural suite, when the pump access site is above the diaphragm, secure the catheter externally with a fixation point on either side of the blue plug. The catheter may be secured near the Tuohy-Borst of the anticontamination sleeve and on either side of the blue plug.

15. Reposition the catheter as necessary. During repositioning, turn the P-level down to P-2 prior to any manipulation and use imaging guidance, confirm pump positioning with imaging after returning to desired P-level.

To prevent contamination and subsequent infections, always use sterile technique on the insertion site. Follow institutional protocols for prophylaxis of infection for patients on ventricular assist devices and indwelling lines, as well as protocols for surveillance of such patients. If device-related infection occurs, consider each patient's clinical circumstances when deciding whether to continue Impella support.

P-LEVELS

You can select one of ten P-Levels (P-0 to P-9) as shown in Table 5.4. Flow rate is increased by approximately 10% with every additional performance level, but depends on preload and afterload and can vary due to suction or incorrect positioning. Flow rate may be reduced if thrombus is present in the inlet of the Impella catheter. Displayed Impella flow is the calculated flow rate based on current performance level and the pressure signals measured from the differential pressure sensor. Select the lowest performance level that will enable you to achieve the flow rate necessary for patient support.

Table 5.4 should be relied on over the AIC displayed flow. However, displayed Impella flow and pump metrics should still be monitored and trended for monitoring pump performance and identifying sudden changes. An abrupt change in flow or abrupt discrepancy from the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics.

Table 5.4 P-Level Flow Rates

P-Level	*Flow Rate (L/min)
P-0	0.0
P-1	0.0–0.9
P-2	0.0–1.3
P-3	0.0–1.8
P-4	0.7–2.3
P-5	1.3–2.6
P-6	2.0–3.0
P-7	2.7–3.4
P-8	3.2–3.7
P-9	3.7–4.2

**Flow rate depends on preload and afterload and can vary due to suction, incorrect positioning or presence of thrombus in the inlet.*

At P-levels between P-1 and P-6, the Impella RP Flex with SmartAssist™ System operates with a regularly recurring rapid speed pulse. This minimizes stasis and reduces the risk of thrombosis in the motor area.

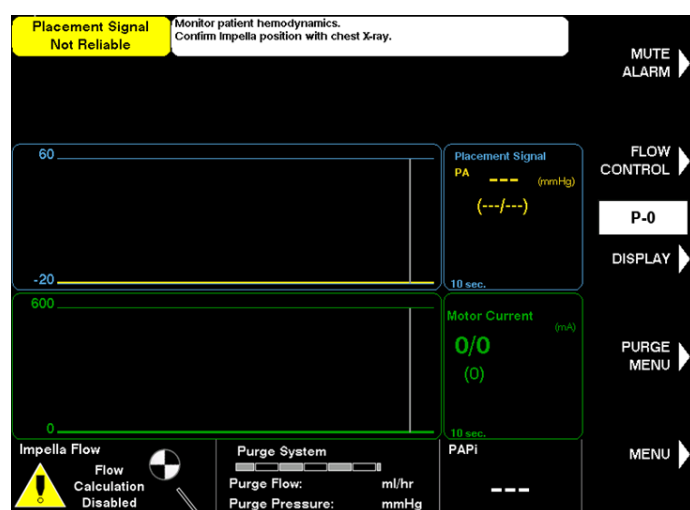
DIFFERENTIAL PRESSURE SENSOR AND EFFECTS ON FLOW CALCULATION

The differential pressure sensor is used to calculate Impella flow. Sensor signal may drift and become inaccurate due to sensor malfunction. Sensor accuracy can also be impacted by physical contact with the sensor and therefore contact should be avoided; this includes handling during insertion, presence of thrombus in the inlet, contact with concomitant lines or devices, or contact with patient anatomy.

Table 5.4 P-Level Flow Rates should be relied on over the AIC displayed flow. However, displayed Impella flow and pump metrics should still be monitored and trended for monitoring pump performance and identifying sudden changes. An abrupt change in flow or abrupt discrepancy from the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics. Monitor patient hemodynamics using cleared or approved diagnostic devices, and monitor Impella positioning with imaging. Monitor the motor current waveform and the circular catheter operation icon to monitor pump function. The circular catheter operation icon rotates when the Impella RP Flex with SmartAssist System Catheter is running.

When the differential pressure sensor signal exceeds the operating range for the sensor, a Placement Signal Not Reliable alarm will occur, the controller will no longer calculate the PA Placement Signal, the Central Venous Placement Signal, or the Impella flow rate, and the controller will display a yellow triangular caution icon with the message “Flow Calculation Disabled.” When this occurs, refer to Table 5.4 P-Level Flow Rates, and monitor the motor current waveform and the circular catheter operation icon to monitor pump function. Continue to monitor patient hemodynamics using cleared or approved diagnostic devices and continue to monitor Impella positioning with imaging.

Note: Placement Signal Not Reliable alarm may not occur in all instances of sensor drift



Circular catheter operation icon

Figure 5.20 Placement Signal Not Reliable Alarm with Yellow Triangular Caution Icon and “Flow Calculation Disabled” Message

SUCTION

If suction is an issue, the flow displayed on the controller may be higher than the actual Impella RP Flex with SmartAssist System flow rate. If the suction alarm appears on the controller when the Impella RP Flex with SmartAssist System is running at P-levels between P-7 and P-9, decrease P-level as needed to resolve suction.

INSERTION, MANIPULATION, OR REMOVAL OF CONCOMITANT DEVICES



Operating the pump at a high flow rate while inserting, manipulating, or removing guidewires, indwelling central venous lines or devices poses a risk of the device tip interacting with the pump inlet. This may cause damage to the pump sensors, damage to the interacting device, or loss of support. Reduce the P-level to P-2 and use imaging guidance during insertion, manipulation and removal of guidewires, indwelling central venous lines or devices.



Anti-coagulate patients as needed to maintain recommended ACT (160-180s), in particular when indwelling central venous lines or cannulas (i.e. hemodialysis, PA catheters, ECMO) are present. ACT below this level may increase the risk of thrombus formation or deposition. If either internal thrombus forms within or external thrombus deposits in the Impella RP with SmartAssist, this may result in reduced flow, loss of support, or hemolysis.



Thrombus formation or deposits on indwelling central venous lines or cannulas (i.e. hemodialysis catheters, PA catheters, ECMO) may break free and enter into the Impella RP Flex with SmartAssist inlet, resulting in reduced flow, loss of support, or hemolysis. Assess the risk for extraluminal thrombus on indwelling lines placed prior to initiation of support.

Guidewires, indwelling central venous lines, or devices have the potential to interact with the Impella RP Flex with SmartAssist inlet area during use. The following guidance is recommended:

- When inserting, manipulating, or removing guidewires, indwelling central venous lines, or devices, reduce the P-level to P-2 and use imaging guidance to limit the interaction between the distal tip of the device and the inlet area of the Impella RP Flex with SmartAssist.
- When manipulating or removing existing indwelling central venous lines or cannulas, thrombus formation or deposits on indwelling central venous lines or cannulas may break free. Reduce the P-level to P-2 during manipulation or removal to reduce the affinity of potential thrombus from entering the inlet area of the Impella RP Flex with SmartAssist.
- After insertion, manipulation, or removal is complete, return to previous P-level.

If the patient is maintained at a low flow rate (<1.5L/min) for a prolonged period of time, increase ACT to at least 250 seconds.

PULMONARY ARTERY PULSATILITY INDEX CALCULATIONS

If both the PA and Central Venous Placement Signals are calculated, the Automated Impella Controller can calculate the Pulmonary Artery Pulsatility Index (PAPi) using the following equation:

$$\text{PAPi} = (\text{Max PA Placement Signal} - \text{Min PA Placement Signal}) / \text{Mean Central Venous Placement Signal}$$

Note: Do not use values as a clinical diagnostic tool, this is for informational purposes only.

PURGE CASSETTE PROCEDURES



When replacing the purge cassette, the replacement process must be completed within 90 seconds after disconnecting luers. The Impella RP Flex with SmartAssist™ System Catheter may be damaged if replacement takes longer than 90 seconds.

There are three procedures for maintaining the Impella RP Flex with SmartAssist System Catheter purge system:

- Change Purge Cassette and Bag
- Change Purge Fluid Bag
- De-Air purge system

Each procedure can be accessed using the **PURGE MENU** soft button. This section describes each of these purge cassette procedures.

CHANGE CASSETTE AND BAG

Purge cassette change out may be required if extended use of the Impella Catheter and purge cassette is required. Follow these steps to change both the purge cassette and purge fluid:

1. Press **PURGE MENU** and select “Change Cassette and Bag” from the menu.
2. Select **START** to begin the cassette and fluid change process.



Figure 5.21 Purge Cassette

3. When prompted by the controller, disconnect the luer(s) from the Impella catheter.
4. Open the purge cassette door by pressing the button on the left side of the console. Remove and discard the old cassette and purge fluid bag.
5. Open the new purge cassette. Spike the new purge fluid bag with the new purge cassette tubing. Select **NEXT** to continue.

Purge Solution Bottles

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

Priming Purge Cassette Fluid

It may be helpful to flush the fluid from the purge cassette to ensure the tubing is primed with the new dextrose concentration when changing bags.

Disconnecting Luers

The system only prompts you to remove luers and prime and flush tubing if the purge fluid concentrations were changed or air was detected. You can only select **SKIP PRIME** if no air was detected.

De-air Procedure

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

6. Insert the new purge cassette into the controller. Be sure to slide the purge disc into place and extend the purge tubing through the gap in the purge cassette door when you close the door.
7. Confirm the luer(s) are disconnected. Press **NEXT** to proceed to prime the purge cassette.
8. Update the purge fluid information.
 - a. To select the default purge fluid values displayed on the screen, select **CONFIRM**.
 - b. To change the purge fluid information, select **EDIT**. Then use the soft keys to navigate selections and edit values. Select **DONE** to complete editing.
9. When purging is complete, connect the luer(s) from the new purge cassette to the Impella catheter.

CHANGE PURGE FLUID BAG

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

1. Press **PURGE MENU** and select "Change Purge Fluid Bag."
2. Select **START** to begin the purge fluid change process.
3. When prompted by the controller, remove the old purge bag and replace by spiking the new purge fluid bag. Select **NEXT** to advance to the next step.
4. Update the purge fluid information.
 - a. To select the default purge fluid values displayed on the screen, select **CONFIRM**.
 - b. To change the purge fluid information, select **EDIT**. Then use the soft keys to navigate selections and edit values. Select **DONE** to complete editing.
5. When prompted by the controller, disconnect the luer(s) from the Impella Catheter. The controller will automatically prime the tubing, which will flush the fluid from the last bag out of the purge cassette tubing. **Note:** the instructions to disconnect the luer(s) and to automatically prime the tubing only occurs if the user changed the purge fluid concentration
 - a. To skip the flush, select **SKIP PRIME**.
6. When prompted by the controller, connect the yellow luer from the purge cassette to the Impella catheter.

DE-AIR PURGE SYSTEM

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

1. Press **PURGE MENU** and select "De-Air Purge System."
2. Select **START** to begin the de-air process.
3. Make sure that the purge fluid bag is NOT empty or inverted and that the tubing is NOT kinked. Select **NEXT** to continue.
4. Disconnect the purge tubing from the Impella Catheter.
5. Confirm that no air remains in the purge tubing. If air remains, press **BACK** to repeat the air removal process.
6. Connect the purge tubing to the Impella Catheter to complete the de-air procedure.

AIR DETECTED ALERT

During any of the purge system processes above, the controller automatically monitors for air in the system. If air is detected in the system, the controller provides an alert to disconnect the luer(s) as shown in Figure 5.22. Once the luer(s) are disconnected, the controller automatically de-airs the purge system.

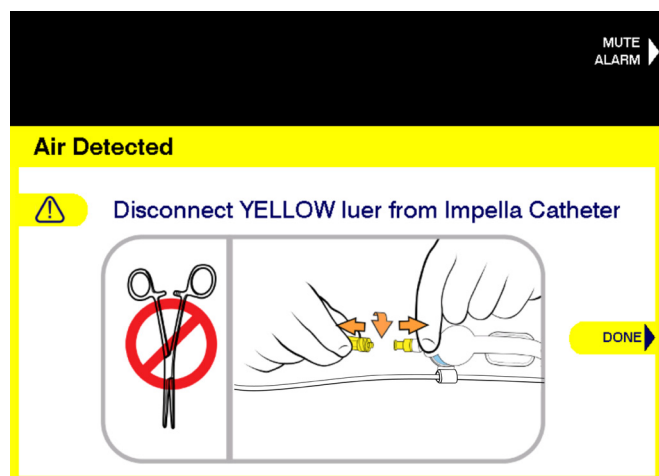


Figure 5.22 Air Detected Alert

TROUBLESHOOTING THE PURGE SYSTEM

Note: If Flight Mode is enabled, the purge cassette should not be changed. Follow the instructions displayed on the Automated Impella Controller.

PURGE PRESSURE LOW



If at any time during the course of support with the Impella RP Flex with SmartAssist™ System Catheter, the Automated Impella Controller alarms “Purge Pressure Low,” follow the instructions below.

1. Inspect the purge system for leaks.
2. If there are no leaks, change to a purge fluid with a higher dextrose concentration. To do this, open the **PURGE MENU** menu and select “Change Purge Fluid Bag.” Follow the instructions on the screen. (Refer to “Purge Cassette Procedures” earlier in this section of the manual.)
3. If the pressure stabilizes, no other action is required.
If the purge pressure is not stable, proceed to Step 4.
4. If the Purge Pressure Low alarm remains unresolved for more than 20 minutes, there may be a problem with the purge cassette. Replace the purge cassette. (Refer to “Change Cassette and Bag” instructions on the previous page.)

Purge Pressure

Optimal purge pressure is different for every Impella RP Flex with SmartAssist System Catheter. Purge pressure can range from 300 mmHg to 1100 mmHg. While purge pressure varies during operation, the Automated Impella Controller automatically maintains purge pressure within an acceptable range for each Impella RP Flex with SmartAssist System Catheter.

Purge System Open Alarm

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

Unresolved Purge Pressure High Alarm

If not resolved by the recommendations provided, high purge pressure—which triggers the “Purge Pressure High” alarm message—could be an indication of a kink in the Impella RP Flex with SmartAssist System Catheter. In this case, the motor is no longer being purged and may eventually stop. Monitor motor current and consider replacing the Impella RP Flex with SmartAssist System Catheter whenever a rise in motor current is seen.

Signs of Right Ventricular Recovery

As right-side support is slowly weaned, right ventricular recovery is indicated by preservation of the normal range of left-sided cardiac output as well as by a lack of severe elevation in CVP.

PURGE SYSTEM OPEN



If at any time during the course of support with the Impella RP Flex with SmartAssist™ System Catheter, the Automated Impella Controller alarms “Purge System Open,” follow the instructions below.

1. Inspect the purge system for leaks.
2. If no leaks are visible, there may be a problem with the purge cassette. Replace the purge cassette. (Refer to instructions earlier in this section of the manual.)

PURGE PRESSURE HIGH AND PURGE SYSTEM BLOCKED

If the purge pressure exceeds 1100 mmHg, the Automated Impella Controller displays the “Purge Pressure High” alarm. If the purge flow stops completely, the controller displays the “Purge System Blocked” alarm. For either event, follow these steps:

1. Inspect the purge system and check the Impella RP Flex with SmartAssist System Catheter for kinks in the tubing.
2. Check the dextrose concentration of the purge fluid. Decrease the concentration to 5% if current concentration is higher
3. Replace the purge cassette using the “Change Cassette and Bag” procedure earlier in this section.
4. Monitor Motor Current.

PATIENT WEANING

Weaning the patient from the Impella RP Flex with SmartAssist System Catheter is at the discretion of the physician. Weaning may occur when right ventricular recovery is suspected and/or the patient is approaching the maximum duration of use for the Impella RP Flex with SmartAssist System Catheter. It should be initiated in a step-wise manner, such as described below.

The following weaning protocol is provided as guidance only.

1. Initiate the weaning process by temporarily reducing the Impella RP Flex with SmartAssist System Catheter flow to about 2 L/min.
2. Assess right ventricular function. Small changes in right ventricular systolic function as measured by echocardiography may be accompanied by significant improvement in right side forward flow; therefore, it is important to evaluate both echocardiographic evidence of improvement as well as CVP from an appropriate diagnostic tool, flow rate, and overall perfusion.
3. Record available information regarding flow rate, CVP from an appropriate diagnostic tool, echo parameters, and systemic hemodynamics.
4. After 15–20 minutes at the reduced flow rate, if there are signs of right ventricular recovery and no adverse effects from reduction in flow rate, continue the weaning process by gradually reducing flow rate as tolerated to 0.5 L/min (P-1). At this flow rate there will no longer be any forward flow provided by the catheter across the right heart

If the patient is maintained at a low flow rate (<1.5 L/min) for a prolonged period, increase ACT to at least 250 seconds.

REMOVING THE IMPELLA RP FLEX WITH SMARTASSIST™ SYSTEM CATHETER

1. Wean the patient by following the steps in the previous section.
2. Leave the Impella RP Flex with SmartAssist System in the pulmonary artery at P-2 until ACT drops below 150 seconds.
3. When ACT is below 150 seconds and patient hemodynamics remain stable, remove initial hemostatic stitch and place new hemostatic stitch, but do not secure.
4. Gradually decrease performance level to P-1 and then stop the motor by reducing the performance level to P-0.
5. Remove the Impella RP Flex with SmartAssist System Catheter immediately after stopping the pump, allowing 10-15mL of back bleed.
6. Secure hemostatic stitch. Apply pressure until hemostasis is achieved.
7. Disconnect the patient cable from the Automated Impella Controller and turn the controller off by pressing the power switch on the side of the controller for 3 seconds.



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SUMMARY OF PRIMARY CLINICAL STUDY

Abiomed has collected clinical data to establish a reasonable assurance of safety and effectiveness of the Impella RP System in patients who developed acute right heart failure or decompensation and required temporary (≤ 14 days) right heart support. The clinical data supporting the PMA approval were pooled from the following three data sets:

- Impella RP System pivotal study: 30 patients
- Impella RP System continued access protocol (CAP) study: 4 patients
- Impella RP System post-approval study (PAS): 26 patients A summary of these clinical studies is presented below.

STUDY DESIGNS

IMPELLA RP SYSTEM PIVOTAL STUDY AND CAP STUDY

The Impella RP System pivotal study (also known as the “RECOVER RIGHT” study) and the Impella RP System CAP study had the same study design and were prospective, multi-center, non-randomized studies conducted under investigational device exemption (IDE) G120159. Patients in these two studies were treated between March 22, 2013 and January 19, 2015 at 9 investigational sites in the U.S.

The studies consisted of the following two cohorts:

- Cohort A: Patients who develop right heart failure within 48 hours post-implantation of an FDA approved implantable surgical left ventricular assist device (LVAD).
- Cohort B: Patients who developed cardiogenic shock involving right heart failure or dysfunction post cardiectomy within 48 hours post surgery or post myocardial infarction.

INCLUSION CRITERIA

The study population consisted of consented patients (≥ 18 years of age) who developed RVF either a) during or after durable LVAD implantation (Cohort A) or b) subsequent to post-cardiectomy cardiogenic shock or post myocardial infarction (Cohort B).

RVF was defined as:

- A CI < 2.2 l/min/m² despite continuous infusion of high dose of inotropes and any of the following:
- CVP > 15 mmHg or
- CVP/PCWP or LAP > 0.63 or
- Moderate to severe global RV dysfunction on echocardiography defined as one of the following criteria: global RV hypokinesis, a TAPSE score of ≤ 14 mm, right ventricular diameter at base > 42 mm, right ventricular short axis (or mid cavity) diameter > 35 mm)
- High dose of inotropes was defined as Dobutamine of ≥ 10 μ g/kg/min or equivalent for more than 15 minutes (120 minutes for milrinone) and/or administration of more than one inotrope/vasopressor medication

EXCLUSION CRITERIA

Specific to Cohort A:

1. INTERMACS 1 patients (Critical cardiogenic shock patient who is “crashing and burning,” has life-threatening hypotension and rapidly escalating inotropic or pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels)
2. End organ failure (defined as hepatic total bilirubin ≥ 5 mg/dL based on lab data within 24 hours prior to Impella RP System initiation, renal: creatinine ≥ 4 mg/dL based on lab data within the 24 hours prior to Impella RP System initiation)
3. Evidence of acute neurologic injury following LVAD implant

Specific to Cohort B:

1. Patient in profound cardiogenic shock defined as systolic blood pressure < 75 mmHg and CI < 1.3 l/min/m² despite 2 or more high dose of inotropes $\pm$ mechanical support or evidence of shock-related end-organ damage, metabolic acidosis (pH 7.1 or less) and not corrected by 100 ml NaHCO₃ (1mEq/ml), disseminated intravascular coagulation or clinical evidence of diffuse brain injury or in cardiogenic shock for > 24 hours.
2. AMI with mechanical complications (ventricular septal defect, myocardial rupture, papillary muscle rupture)
3. Unsuccessful revascularization of the RCA (TIMI 0.1 post PCI or post-CABG)

General – For Both Cohorts

1. Active infection, two of the following WBC $> 12,500$, positive blood culture, fever
2. RA, RV and/or PA thrombus
3. Prosthetic valves in the right heart (tricuspid or pulmonary valves)
4. Unrepaired atrial septal defect/ patent foramen ovale
5. Structural tricuspid valve disease
6. Severe pulmonary valve stenosis or insufficiency
7. Intolerance to anticoagulant or antiplatelet therapies
8. Severe pulmonary hypertension (PAP > 60 mmHg)
9. Documented DVT and/or presence of IVC filter
10. Anatomic conditions precluding insertion of the pump or safe use of the device such as severe anomaly of the inferior vena cava, calcification or other disorders of the pulmonary artery wall
11. Pulmonary artery conduit replacement
12. Patient on right side support device or extracorporeal membrane oxygenation
13. Current diagnosis of pulmonary embolism
14. Patient with anatomic anomalies or aortic diseases like aortic dissection, Marfan-Syndrome, Morbus Erdheim-Gsell or others
15. Allergy or intolerance to contrast media
16. Thrombolysis within the previous 30 days or known existing coagulopathy such as thrombocytopenia, heparin induced thrombocytopenia (HIT), hemoglobin diseases such as sickle cell anemia or thalassemia
17. Existing congenital heart disease precluding device insertion
18. Participation in any other clinical investigation that is likely to confound study results or affect study outcome

IMPELLA RP SYSTEM POST APPROVAL STUDY (PAS)

The Impella RP System PAS was a prospective, multi-center, non-randomized study conducted as a condition of approval for the original HDE. Patients in the study were treated in the commercial setting between May 27, 2015 and September 24, 2016 at 8 investigational sites in the U.S.

INCLUSION CRITERIA

Enrollment in the Impella RP System PAS was limited to patients who met the approved indication of the device under the HDE and who were not contraindicated.

FOLLOW-UP SCHEDULE (SAME FOR BOTH STUDIES)

All patients were scheduled to return for follow-up examinations at 30- and 180-days post device explant.

STUDY ENDPOINTS (SAME FOR BOTH STUDIES)

The primary endpoint was the survival rate at 30 days post device explant or hospital discharge (whichever is longer), or at induction of anesthesia for a longer term therapy, including heart transplant or implantation of a surgical right ventricular assist device (RVAD; as a bridge-to-recovery or bridge-to-transplant).

The secondary safety endpoints were determined by the rates of the following adverse events at 30 days or discharge (whichever is longer), or at induction of anesthesia for a longer-term therapy:

- Major bleeding
- Hemolysis
- Pulmonary embolism
- Tricuspid/pulmonary valve dysfunction (defined as tricuspid/pulmonic valve injury resulting in increased valve regurgitation versus baseline)

The secondary effectiveness endpoints included the following:

- Central venous pressure (CVP) and cardiac index (CI) improvement post initiation of Impella RP System support
- Decreased use of inotropes during support
- Improvement in left ventricular assist device (LVAD) flow or left ventricle pumping function secondary to the increased venous return by the Impella RP System within 48 hours post implant

ANALYSIS

The three data sets listed above were pooled and analyzed descriptively. The success criterion was based on clinical judgment.

ACCOUNTABILITY OF COHORT

A total of 60 subjects were treated in the 3 prospective studies, including 31 subjects (52%) enrolled in Cohort A and 29 subjects (48%) enrolled in Cohort B, as shown in Figure 6.1.

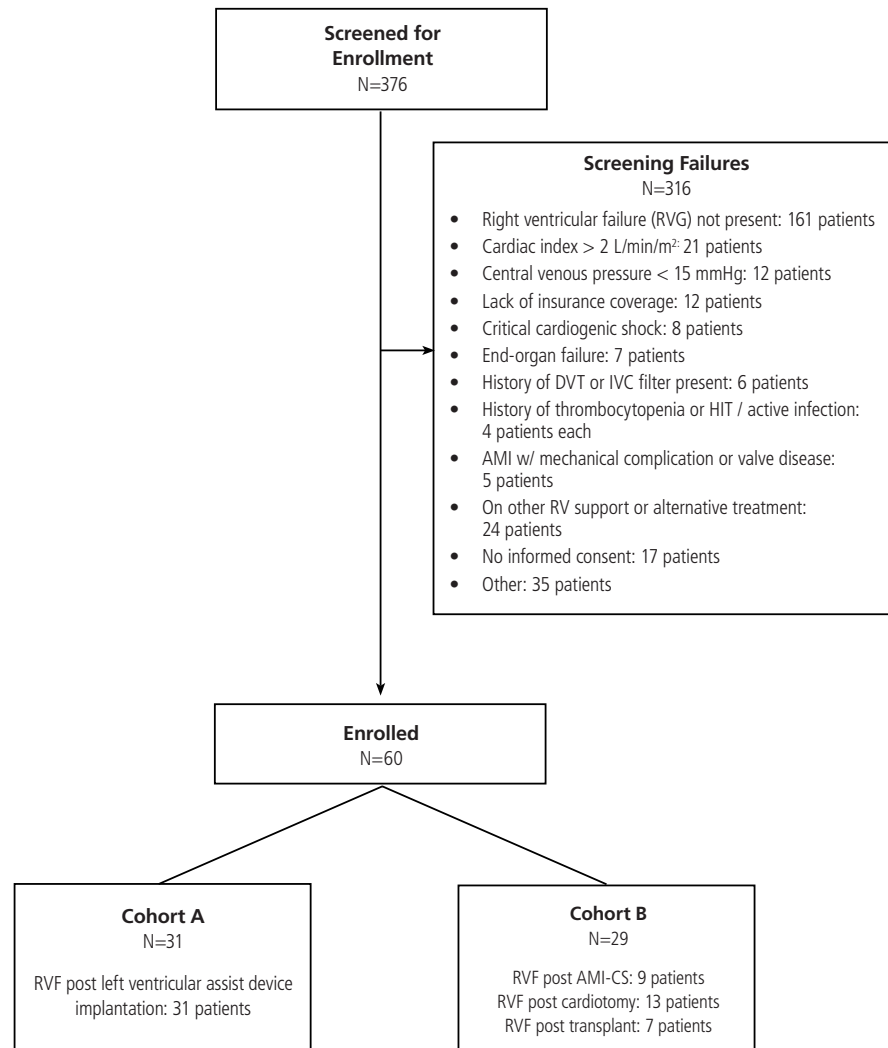


Figure 6.1 Study Flow Schematic

STUDY POPULATION DEMOGRAPHICS AND BASELINE CHARACTERISTICS

The patient baseline characteristics are summarized in Table 6.1. The overall age was 59±15 years old. Among all patients, 88.5% presented with congestive heart failure (CHF), 60% had history of arrhythmia, 57% had ICD or pacemaker implanted, 53% had diabetes, 37.5% had chronic kidney disease, and 20% had prior CVA. Of note, 60% of the patients had received blood products and 78.6% were in NYHA Class IV prior to device implant.

Table 6.1 Patient Characteristics

Patient Characteristics	Summary Statistics*		
	Cohort A (N=31)	Cohort b (N=29)	All patients (N=60)
Age	54.5±14.9 (31)	62.9±14.3 (29)	58.6±15.1 (60)
Gender			
Male	80.6% (25/31)	55.2% (16/29)	68.3% (41/60)
Female	19.4% (6/31)	44.9% (13/29)	31.7% (19/60)
Race			
White	54.8% (17/31)	44.8% (13/29)	50.0% (30/60)
Black or African American	41.9% (13/31)	44.8% (13/29)	43.3% (26/60)
Asian	3.2% (1/31)	6.9% (2/29)	5.0% (3/60)
Body Surface Area (m²)	2.0±0.2 (31)	1.9±0.2 (29)	1.9±0.2 (60)
Hypertension	77.4% (24/31)	86.2% (25/29)	81.7% (49/60)
Coronary Artery Disease	60.0% (18/30)	57.1% (16/28)	58.6% (34/58)
Congenital Heart Disease	7.7% (2/26)	8.0% (2/25)	7.8% (4/51)
Congestive Heart Failure	96.8% (30/31)	66.7% (16/24)	83.6% (46/55)
New York Heart Association (NYHA) Classification			
I	0.0% (0/29)	5.0% (1/20)	2.0% (1/49)
II	3.4% (1/29)	5.0% (1/20)	4.1% (2/49)
III	10.3% (3/29)	15.0% (3/20)	12.2% (6/49)
IV	86.2% (25/29)	75.0% (15/20)	81.6% (40/49)
Myocardial Infarction	46.4% (13/28)	52.0% (13/25)	49.1% (26/53)
PCI	41.9% (13/31)	32.1% (9/28)	37.3% (22/59)
CABG	9.7% (3/31)	17.2% (5/29)	13.3% (8/60)
Arrhythmia	79.3% (23/29)	73.1% (19/26)	76.4% (42/55)
Cerebrovascular Accident	10.7% (3/28)	28.0% (7/25)	18.9% (10/53)
Stroke	7.1% (2/28)	4.0% (1/25)	5.7% (3/53)
TIA	0.0% (0/28)	24.0% (6/25)	11.3% (6/53)
Other	3.6% (1/28)	0.0% (0/25)	1.9% (1/53)
Smoking	46.7% (14/30)	51.7% (15/29)	49.2% (29/59)
Chronic Obstructive Pulmonary Disease	20.7% (6/29)	7.7% (2/26)	14.5% (8/55)
Diabetes	51.6% (16/31)	41.4% (12/29)	46.7% (28/60)
Chronic Kidney Disease	37.9% (11/29)	32.0% (8/25)	35.2% (19/54)
Valve Replacement/Repair	12.9% (4/31)	17.2% (5/29)	15.0% (9/60)
ICD/Pacemaker Implanted	64.5% (20/31)	24.1% (7/29)	45.0% (27/60)
LVEF (%)	13.8±6.0 (28)	46.5±5.9 (25)	29.2±20.2 (53)
TAPSE (mm)	13.9±6.5 (14)	11.7±4.8 (14)	12.8±5.7 (28)

* Categorical data: % (n/total no.); variable data: mean±SD (n)

The baseline laboratory parameters are provided in Table 6.2. Both kidney and liver functions were reflective of poor end-organ perfusion prior to device insertion.

Table 6.2 Baseline Laboratory Parameters

Baseline Characteristics	Summary Statistics*		
	Cohort A (N=31)	Cohort B (N=29)	All patients (N=60)
White blood cell (WBC) count (10^3)	12.1±6.8 (31)	14.4±9.5 (29)	13.2±8.2 (60)
Platelets count (10^3)	208.1±92.3 (31)	230.4±133.4 (29)	218.9±113.6 (60)
Hemoglobin (g/dL)	10.1±2.0 (31)	10.9±2.0 (29)	10.5±2.0 (60)
Hematocrit (%) (N)	30.9±6.2 (31)	33.3±5.9 (29)	32.1±6.1 (60)
Plasma free hemoglobin (mg/dL)	13.6±11.8 (16)	39.0±59.1 (12)	24.5±40.8 (28)
Blood urea nitrogen (BUN; mg/dL)	27.3±17.2 (31)	31.5±16.6 (29)	29.4±16.9 (60)
Serum creatinine (mg/dL)	1.5±0.6 (31)	1.5±0.7 (29)	1.5±0.6 (60)
Creatinine clearance (mL/min)	76.8±55.1 (23)	68.9±55.2 (22)	73.0±54.7 (45)
Total bilirubin (mg/dL)	1.6±1.1 (29)	1.1±0.6 (29)	1.4±0.9 (58)
Lactate dehydrogenase (LDH; U/L)	539.5±345.9 (24)	715.0±553.6 (14)	604.1±435.2 (38)
* Mean±SD (n)			

WBC: White Blood Cells; BUN: Blood Urea Nitrogen; LDH: Lactate Dehydrogenase; BNP: B-type natriuretic peptide

The baseline support and hemodynamic characteristics are summarized in Table 6.3. All patients enrolled presented with right ventricular failure and poor hemodynamics at the time of implant, despite high dose of inotropes/pressors.

Table 6.3 Baseline Support and Hemodynamic Characteristics

Support and Hemodynamic Characteristics	Summary Statistics*		
	Cohort A (N=31)	Cohort B (N=29)	All patients (N=60)
Number of inotropes/pressors (prior to device insertion)	3.6±.2 (31)	3.1±1.3 (28)	3.4±1.2 (59)
Hemodynamics (prior to device insertion)			
Cardiac index (L/min/m ²)	1.8±0.5 (31)	1.9±0.6 (28)	1.9±0.5 (59)
Cardiac output (L/min)	3.9±1.4 (31)	3.8±1.3 (28)	3.9±1.3 (59)
Pulmonary Capillary Wedge pressure/left arterial pressure (mmHg)	14.5±4.6 (8)	20.4±8.5 (8)	17.4±7.3 (16)
Right arterial pressure/central venous pressure (mmHg)	18.42±4.79 (31)	19.84±5.83 (29)	19.1±5.3 (60)
Pulmonary artery pressure: Systolic (mmHg)	39.4±12.1 (29)	39.8±10.3 (26)	39.6±11.1 (55)
Pulmonary artery pressure: Diastolic (mmHg)	23.9±11.6 (31)	21.2±7.8 (27)	22.5±9.9 (58)
Mean arterial Pressure (mmHg)	75.6±12.4 (24)	65.9±16.3 (24)	70.7±15.1 (48)
Heart rate (BPM)	91.9±19.7 (28)	86.1±18.0 (28)	89.0±18.9 (56)
LVAD flow (L/min; Cohort A only)	4.0±0.7 (19)	N/A	4.0±0.7 (19)
* Mean±SD (n)			

SAFETY AND EFFECTIVENESS RESULTS

PRIMARY ENDPOINT

The primary endpoint of survival at 30 days or discharge post device removal (whichever is longer), or at induction of anesthesia for the next longer-term therapy (i.e., heart transplant or implantation of a surgical RVAD) was achieved in 73.3% of the patients, with 77.4% in cohort A and 69.0% in cohort B, as shown in Table 6.4. It is important to note that all patients discharged from the hospital (70% of all patients) recovered their right heart function and were discharged without any right ventricular mechanical support.

Table 6.4 Patient Survival Outcomes

Event	Summary Statistics*		
	Cohort A (N=31)	Cohort B (N=29)	All patients (N=60)
Alive at 30 days/discharge/next therapy	77.4% (24/31)	69.0% (20/29)	73.3% (44/60)
Alive at next longer-term therapy	16.1% (5/31)	6.9% (2/29)	11.7% (7/60)
Alive at 30 days	77.4% (24/31)	65.5% (19/29)	71.7% (43/60)
Alive at discharge	71.0% (22/31)	69.0% (20/29)	70.0% (42/60)
Right ventricle recovered (discharged without RVAD)	100% (22/22)	100% (20/20)	100% (42/42)

SECONDARY ENDPOINTS

Safety Endpoints

The secondary safety endpoint results are summarized in Table 6.5, which were measured at hospital discharge or to induction of anesthesia to a longer-term therapy.

Table 6.5 Secondary Safety Endpoints Results

Event	Summary Statistics*		
	Cohort A (N=31)	Cohort B (N=29)	All patients (N=60)
Major bleeding	54.8% (17/31)	41.4% (12/29)	48.3% (29/60)
Hemolysis	29.0% (9/31)	24.1% (7/29)	26.7% (16/60)
Pulmonary embolism	0.0% (0/31)	0.0% (0/29)	0.0% (0/60)
*% (n/total no.)			

Effectiveness Endpoints

Central venous pressure and cardiac index:

The central venous pressure and cardiac index changes over time are shown in Figures 6.2 and 6.3, respectively. The central venous pressure decreased from 19 ± 0.8 to 13 ± 1 mmHg post support; the cardiac index increased from 1.9 ± 0.1 to 3.1 ± 0.2 L/min/m² post support. In addition, both the central venous pressure and the cardiac index remained stable post- explant of the Impella RP System.

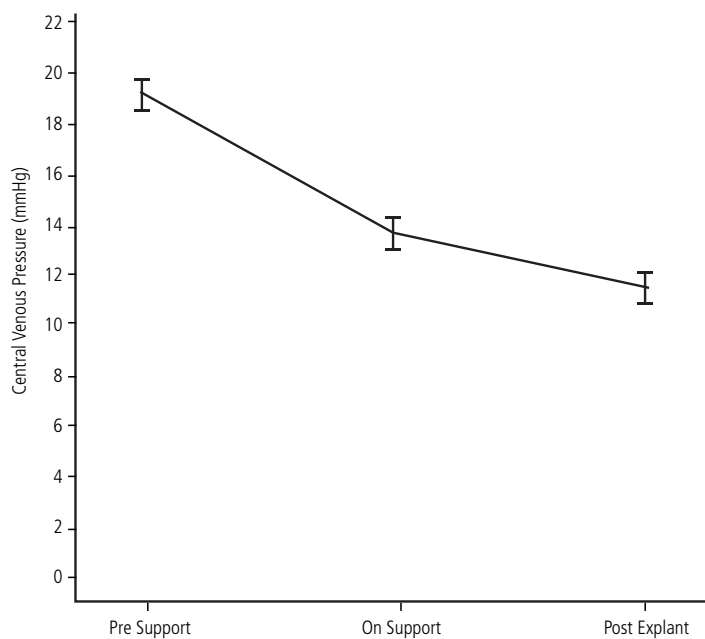


Figure 6.2: Central Venous Pressure Change Over Time

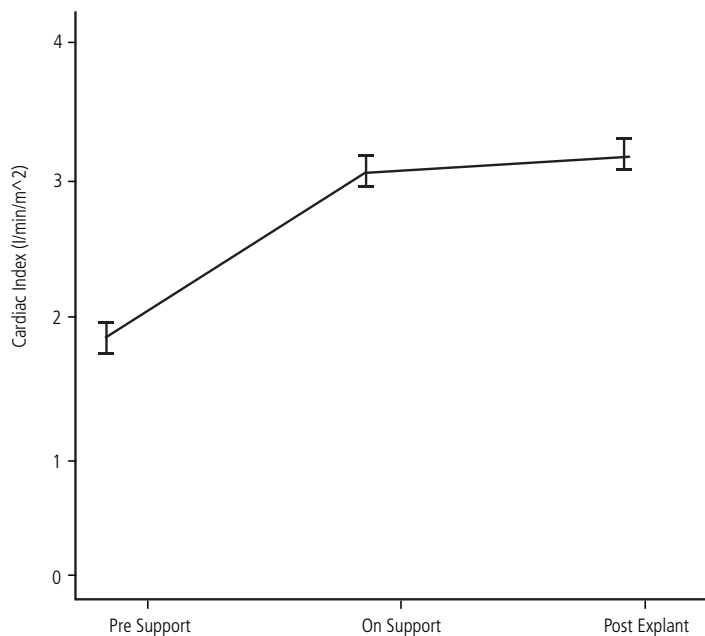


Figure 6.3: Cardiac Index Change Over Time

LVAD flow:

The LVAD flow in Cohort A patients is shown in Figure 6.4. The flow increased from 4.0 ± 0.2 L/min to 4.6 ± 0.1 L/min post support.

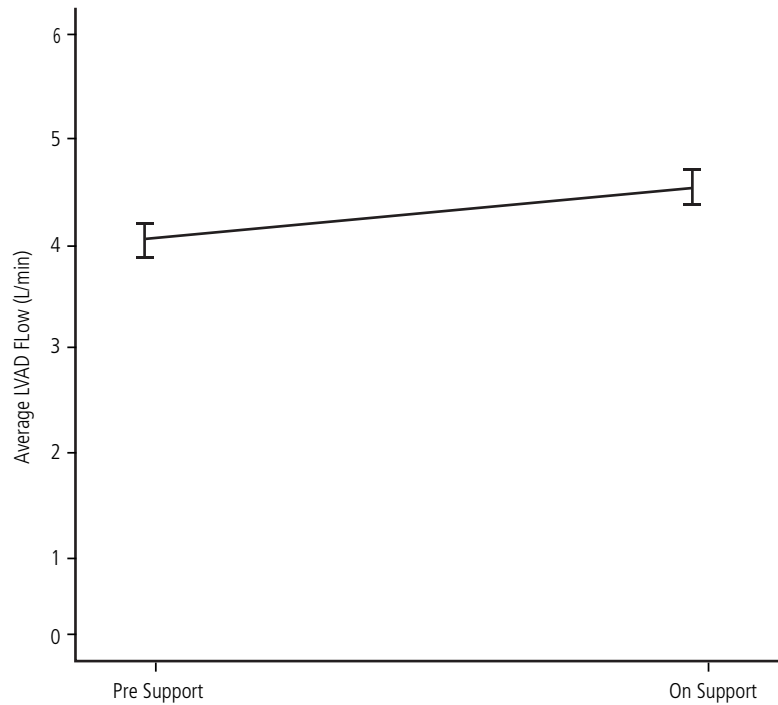


Figure 6.4: LVAD Flow Change from Baseline to On support

Inotrope and pressor uses during support:

The inotrope and pressor uses during support are shown in Figure 6.5. A rapid decrease of such uses were seen post initiation of Impella RP System support.

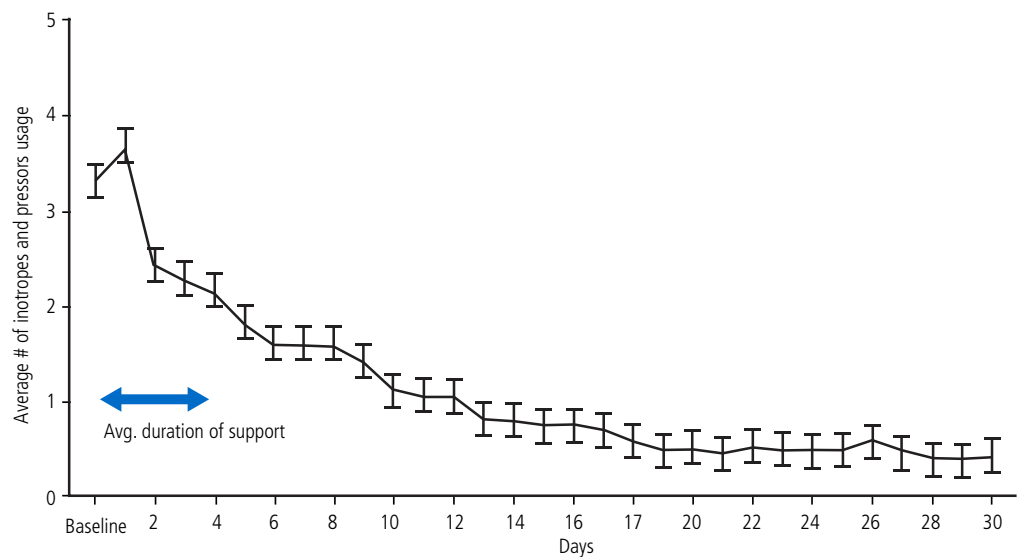


Figure 6.5: Inotrope and Pressor Uses during Support

OTHER RESULTS

PROCEDURAL PARAMETERS

The procedural parameters are summarized in Table 6.6.

Table 6.6 Procedural Parameters

Procedural Parameters	Summary Statistics*		
	Cohort A (N=31)	Cohort B (N=29)	All patients (N=60)
Side of implantation			
Left femoral vein	0.0% (0/31)	6.9% (2/29)	3.3% (2/60)
Right femoral vein	100.0% (31/31)	93.1% (27/29)	96.7% (58/60)
Estimated blood loss during introducer insertion			
<25 mL	86.4% (19/22)	88.5% (23/26)	87.5% (42/48)
25-50 mL	9.1% (2/22)	7.7% (2/26)	8.3% (4/48)
>100 mL	4.5% (1/22)	3.8% (1/26)	4.2% (2/48)
Estimated blood loss during catheter placement			
<25 mL	66.7% (14/21)	46.2% (12/26)	55.3% (26/47)
25-50 mL	28.6% (6/21)	38.5% (10/26)	34.0% (16/47)
>100 mL	4.8% (1/21)	7.7% (2/26)	6.4% (3/47)
Duration of support (hours)	101.2±66.0 (21)	81.9±49.1 (29)	90.0±57.0 (50)
Average device flow (L/min)	3.2±0.4 (23)	3.2±0.4 (27)	3.2±0.4 (50)
Categorical data: % (n/total no.); variable data: mean±SD (n)			

SUBGROUP ANALYSIS

Gender Analysis

The outcomes by gender were also examined. A trend towards higher mortality was observed in female patients; the rate of the other adverse events appeared comparable between genders. However, the small sample size and the multiple cohorts studied prevent any conclusions based on gender.

IMPELLA RP SYSTEM PEDIATRIC POST-APPROVAL STUDY (PAS)

SUMMARY OF THE POST-APPROVAL STUDY METHODS

Study Objective

The study objective was to monitor post-market approval safety and outcomes trends of the Impella RP device in pediatric patients with right ventricular failure deemed to require hemodynamic support.

Study Design

The study was designed as a retrospective, single arm, multi-center post approval surveillance.

Study Population

The study population consisted of pediatric patients that developed right ventricular failure and were supported with Impella RP. The retrospective data collected in the post approval study was based on institutional standards of care for this patient population.

Up to 15 consecutive pediatric patients or all pediatric patients supported with the Impella RP over a 5 year time period (whichever came first) were to be enrolled in the study at the participating clinical centers.

Inclusion Criteria:

- Patients that develop right ventricular failure post left ventricular assist device (LVAD) implantation, post myocardial infarction, post heart transplant or open heart surgery
- Age 15-17 years old and body surface area (BSA) ≥ 1.5 m²

Data Source

The Global cVAD Study was used as a support to collect the data for the PAS. All qualifying subjects treated at cVAD Study sites were to be enrolled in the PAS. Additionally, Abiomed's commercial database was monitored to identify qualifying subjects treated at non-cVAD sites. Global cVAD Study case report forms (CRFs) were to be used to collect all available data on subjects treated at non-cVAD sites, subject to Institutional Review Board (IRB) approval at each site.

Key Study Endpoints

The primary endpoint was the survival rate at 30 days post device explant or hospital discharge (whichever is longer), or to induction of anesthesia to a longer term therapy, which included a heart transplant or an implant of a surgical right ventricular assist device (RVAD).

The secondary endpoints were adverse event rates (death, major bleeding, hemolysis, and pulmonary embolism) at hospital discharge or to induction of anesthesia to a longer term therapy, which included a heart transplant or an implant of a surgical RVAD; and improvement in hemodynamic parameters (central venous pressure (CVP), cardiac index, and LVAD flow) after the initiation of Impella RP support.

Technical success at exit from the operating room (defined as successful device implant and positioning for hemodynamic support, and patient alive for transport from the operating room or catheterization lab), and patient success (defined as survival at 30 days post device explant or hospital discharge (whichever is longer), or to induction of anesthesia to a longer term therapy, which included a heart transplant or an implant of a surgical RVAD), were also collected.

Follow-Up Schedule

Survival status was assessed at 30 days (+/- 10 days) and 180 days (+/- 30 days).

Total Number of Enrolled Study Sites and Subjects

Between January 23, 2015 and January 23, 2020, 5 patients under age 18 were supported with the Impella RP at US sites (Figure 6.6). One of the five patients was supported for right ventricular failure post LVAD implantation, and qualified for the study. Four of the patients were supported for reasons other than right ventricular failure post LVAD implantation, post myocardial infarction, post heart transplant or open heart surgery, and therefore did not qualify for the study.

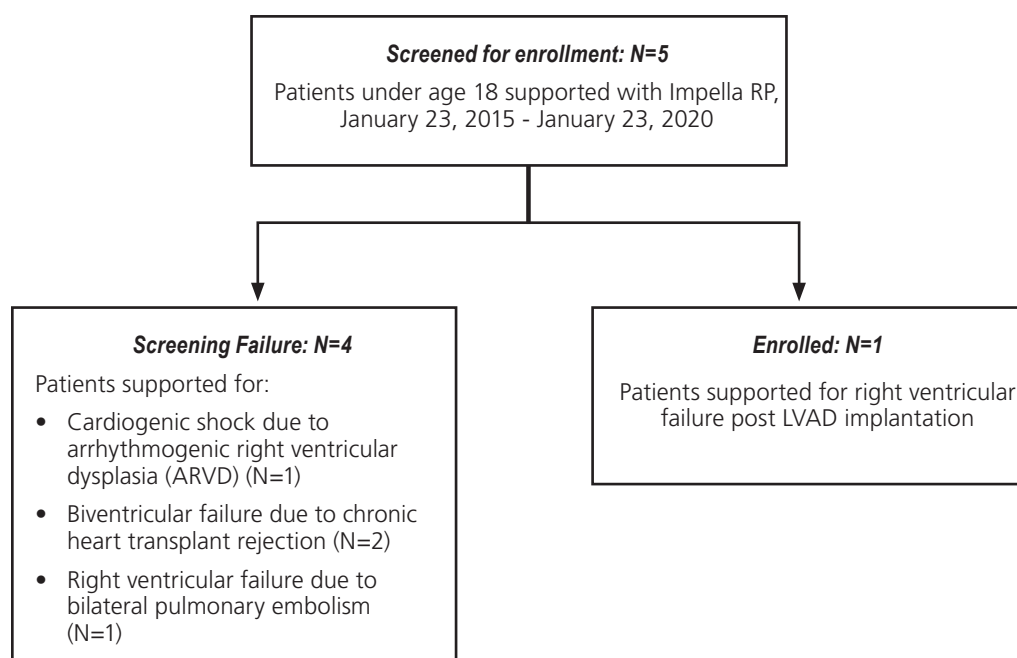


Figure 6.6: Study Flow Schematic

The one enrolled patient was treated at a non-Global cVAD Study site in the United States. The patient was 14 years old at the time of treatment, and was enrolled under a protocol deviation (due to age below 15 years old). Abiomed was unable to obtain IRB approval at the site for retrospective data collection per this protocol. Abiomed included all information known about the patient per entry into Abiomed's commercial database (which contains limited data entered by Abiomed's field clinical personnel, covering the time period from Impella insertion through Impella removal).

Subject Accountability

The one enrolled patient survived to induction of anesthesia to a longer term therapy. The patient was lost to follow-up at discharge, 30 days post device explant, and 180 days post device explant.

Summary of the Post-Approval Study Results

A 14 year-old male patient with history of dilated cardiomyopathy presented with worsening right ventricular function four days post LVAD implant. The patient was placed on Impella RP support. The patient's CVP decreased from 28 mmHg to 19 mmHg on Impella RP support. After approximately three days of support, the Impella RP was removed and the patient received a surgical RVAD for bridge to transplant.

Primary Endpoint

The patient survived to induction of anesthesia to a longer term therapy (surgical RVAD), and therefore met the primary endpoint.

Secondary Endpoints

No adverse events (death, major bleeding, hemolysis, and pulmonary embolism) were reported for the patient, to induction of anesthesia to a longer term therapy. The patient's CVP decreased from 28 mmHg to 19 mmHg on Impella RP support. Improvements in cardiac index and LVAD flow after the initiation of Impella RP support were not reported.

Other Endpoints

The patient achieved technical success at exit from the operating room (defined as successful device implant and positioning for hemodynamic support, and patient alive for transport from the operating room or catheterization lab), and patient success (defined as survival at 30 days post device explant or hospital discharge (whichever is longer), or to induction of anesthesia to a longer term therapy, which included a heart transplant or an implant of a surgical RVAD).

Survival status at 30 days (+/- 10 days) and 180 days (+/- 30 days) was unknown.

Study Limitations

This study was limited by the low enrollment (N=1) and limited dataset available.

IMPELLA RP POST-APPROVAL STUDY

SUMMARY OF THE POST APPROVAL STUDY METHODS

Study Objective

The objective of this post-approval study was to monitor safety and efficacy trends of the commercial use (post-PMA) of the Impella RP System to treat patients suffering from right ventricular (RV) failure.

Study Design

The study was designed as an observational, prospective, multicenter, single cohort clinical investigation that enrolled patients with RV dysfunction who were implanted with an Impella RP device after approval of the PMA post approval study. The Global cVAD Registry was used to collect the data for the PAS.

A minimum of 60 subjects were to be evaluated to benchmark the survival rate at 30 days or discharge (whichever was longer), or to induction of anesthesia to a longer-term therapy, to that in the pre-market Impella RP studies. The study subjects were divided into the following groups:

- Checklist Group – A minimum enrollment of 30 subjects who would have met inclusion/exclusion criteria for the premarket clinical studies, which included at least 10 Cohort A (post-LVAD) subjects and at least 10 Cohort B (post-myocardial infarction [MI] or post-open-heart surgery) subjects.
- Salvage Group – A minimum enrollment of 30 “all-comers” subjects who would not have met inclusion/exclusion criteria for the premarket studies

Patient status, major adverse cardiac and cerebrovascular events (MACCE), and cardiac-related re-admissions were collected at 30 days, 90 days, and 1-year post-Impella implant.

Study Population

The study population consisted of patients age ≥ 18 years old, supported with Impella RP devices for the approved indication after approval of the PMA study, at U.S. sites participating in the cVAD Registry.

Inclusion Criteria

Prior to primary endpoint analysis, each subject captured in the cVAD Registry was evaluated retrospectively for meeting the inclusion/exclusion criteria for the premarket studies. Subjects who satisfied the inclusion/exclusion criteria for the RP pre-market study were included in the Checklist Group, while subjects who did not meet the inclusion/exclusion criteria for premarket studies were included in the Salvage Group.

Exclusion Criteria

Patients enrolled in the cVAD Registry for other indications were excluded from this study.

Data Source

The Global CVAD Registry was used to collect data to support the post approval study. This summary includes data on qualifying subjects treated between September 20, 2017 (PMA approval date) and November 24, 2020. The date of database closure for the report was May 10, 2022.

Key Study Endpoints

The primary study endpoint was survival rate at 30 days post-device explant or hospital discharge (whichever was longer), or to induction of anesthesia to a longer-term therapy, which includes a heart transplant or an implant of a surgical ventricular assist device (VAD).

The secondary endpoint included site-reported outcomes and adverse event rates (death, bleeding, hemolysis, and pulmonary embolism) at 30 days or discharge (whichever was longer). In addition, the secondary endpoints of device malfunction, central venous pressure (CVP), cardiac index, and left ventricular assist device (LVAD) flow during device support through explant, were evaluated.

MACCE events and device malfunctions were also recorded.

Total Number of Enrolled Study Sites and Subjects, Follow-up Rate

Twenty-nine (29) sites contributed to the enrollment in this study. Of the overall one hundred ten (110) subjects in the study, the Checklist Group comprised the thirty-seven (37) subjects who would have met inclusion/exclusion criteria for the Impella RP premarket clinical studies, and the Salvage Group comprised the seventy-three (73) subjects who would not have met inclusion/exclusion criteria for the premarket studies. There were seven (7) subjects in Cohort A and thirty (30) in Cohort B for the Checklist Group, and sixteen (16) in Cohort A and fifty-seven (57) in Cohort B for the Salvage Group.

Of the thirty-seven (37) subjects in the Checklist Group and seventy-three (73) subjects in the Salvage Group, thirty-three (33) and seventy (70) were available for the primary endpoint analysis (evaluable subjects). The overall follow-up rate was 93.6% (103/110) based on the primary endpoint.

Study Visits and length of follow-up

The length of follow-up was one year. During the study, there were follow-up visits at 30 and 90 days and one year.

Summary of the Post Approval Study Results

Baseline characteristics represented a contemporary subject profile regarding sex, race, and basic risk factor distribution, as shown in Table 6.7.

Table 6.7 Baseline Characteristics

	Checklist Group			Salvage Group			Total Subjects (N=110)
	Cohort A (N=7)	Cohort B (N=30)	Total (N=37)	Cohort A (N=16)	Cohort B (N=57)	Total (N=73)	
Age							
Mean ± SD (n)	55.7 ± 14.35 (7)	63.5 ± 11.80 (30)	62.0 ± 12.49 (37)	59.8 ± 12.56 (16)	66.1 ± 10.54 (57)	64.7 ± 11.23 (73)	63.8 ± 11.68 (110)
Median (min, max)	61.0 (28.0, 70.0)	62.5 (27.0, 83.0)	62.0 (27.0, 83.0)	62.5 (28.0, 76.0)	67.0 (42.0, 85.0)	66.0 (28.0, 85.0)	64.0 (27.0, 85.0)
Sex (Male), %	100.0 (7/7)	53.3 (16/30)	62.2 (23/37)	87.5 (14/16)	64.9 (37/57)	69.9 (51/73)	67.3 (74/110)
Race, %							
Asian	0 (0/7)	3.8 (1/26)	3.0 (1/33)	0 (0/16)	0 (0/50)	0 (0/66)	1.0 (1/99)
Black or African American	28.6 (2/7)	15.4 (4/26)	18.2 (6/33)	18.8 (3/16)	10.0 (5/50)	12.1 (8/66)	14.1 (14/99)
Native Hawaiian or Other Pacific Islander	0 (0/7)	0 (0/26)	0 (0/33)	6.3 (1/16)	0 (0/50)	1.5 (1/66)	1.0 (1/99)
Other	14.3 (1/7)	7.7 (2/26)	9.1 (3/33)	0 (0/16)	6.0 (3/50)	4.5 (3/66)	6.1 (6/99)
White	57.1 (4/7)	73.1 (19/26)	69.7 (23/33)	75.0 (12/16)	84.0 (42/50)	81.8 (54/66)	77.8 (77/99)
BSA (m2)							
Mean ± SD (n)	2.1 ± 0.43 (7)	2.0 ± 0.32 (30)	2.0 ± 0.34 (37)	2.2 ± 0.32 (16)	1.9 ± 0.27 (56)	2.0 ± 0.29 (72)	2.0 ± 0.31 (109)
Median (min, max)	2.1 (1.6, 3.0)	2.0 (1.5, 2.5)	2.0 (1.5, 3.0)	2.1 (1.8, 3.1)	1.9 (1.4, 2.5)	2.0 (1.4, 3.1)	2.0 (1.4, 3.1)
Hypertension, %	85.7 (6/7)	70.0 (21/30)	73.0 (27/37)	50.0 (8/16)	70.9 (39/55)	66.2 (47/71)	68.5 (74/108)
Coronary Artery Disease, %	57.1 (4/7)	50.0 (15/30)	51.4 (19/37)	66.7 (10/15)	46.4 (26/56)	50.7 (36/71)	50.9 (55/108)
NYHA III/IV, %	100.0 (4/4)	87.5 (7/8)	91.7 (11/12)	100.0 (7/7)	100.0 (10/10)	100.0 (17/17)	96.6 (28/29)
Myocardial infarction, %	57.1 (4/7)	20.7 (6/29)	27.8 (10/36)	37.5 (6/16)	23.1 (12/52)	26.5 (18/68)	26.9 (28/104)
Prior percutaneous coronary intervention (PCI), %	28.6 (2/7)	33.3 (10/30)	32.4 (12/37)	50.0 (8/16)	32.1 (17/53)	36.2 (25/69)	34.9 (37/106)
Prior coronary artery bypass grafting (CABG), %	28.6 (2/7)	23.3 (7/30)	24.3 (9/37)	37.5 (6/16)	11.3 (6/53)	17.4 (12/69)	19.8 (21/106)
Arrhythmia, %	75.0 (3/4)	24.0 (6/25)	31.0 (9/29)	60.0 (6/10)	29.3 (12/41)	35.3 (18/51)	33.8 (27/80)
Prior stroke/TIA, %	42.9 (3/7)	13.8 (4/29)	19.4 (7/36)	18.8 (3/16)	11.5 (6/52)	13.2 (9/68)	15.4 (16/104)
Smoking, %	85.7 (6/7)	55.2 (16/29)	61.1 (22/36)	62.5 (10/16)	55.8 (29/52)	57.4 (39/68)	58.7 (61/104)
Chronic pulmonary disease, %	28.6 (2/7)	6.7 (2/30)	10.8 (4/37)	18.8 (3/16)	20.8 (11/53)	20.3 (14/69)	17.0 (18/106)
Diabetes, %	42.9 (3/7)	44.8 (13/29)	44.4 (16/36)	56.3 (9/16)	45.3 (24/53)	47.8 (33/69)	46.7 (49/105)
Renal insufficiency, %	42.9 (3/7)	14.3 (4/28)	20.0 (7/35)	50.0 (8/16)	29.6 (16/54)	34.3 (24/70)	29.5 (31/105)
Implantable cardioverter defibrillator (ICD), %	75.0 (3/4)	4.0 (1/25)	13.8 (4/29)	90.9 (10/11)	7.7 (3/39)	26.0 (13/50)	21.5 (17/79)
Pacemaker, %	50.0 (2/4)	8.0 (2/25)	13.8 (4/29)	18.2 (2/11)	2.6 (1/39)	6.0 (3/50)	8.9 (7/79)
Left ventricular ejection (LVEF), %							
Mean ± SD (n)	12.0 ± 5.93 (6)	39.6 ± 18.15 (16)	32.1 ± 20.06 (22)	14.6 ± 7.34 (11)	36.4 ± 17.34 (41)	31.8 ± 18.08 (52)	31.9 ± 18.55 (74)
Median (min, max)	10.0 (8.0, 24.0)	35.0 (15.0, 75.0)	30.0 (8.0, 75.0)	10.0 (10.0, 29.0)	35.0 (5.0, 70.0)	29.5 (5.0, 70.0)	30.0 (5.0, 75.0)

Between groups, however, the Salvage Group showed higher rates of historic chronic pulmonary disease, renal insufficiency, and ICD (Implantable Cardioverter Defibrillator), indicating advanced signs of multi-organ dysfunction, as compared to the Checklist Group. The admission and procedural characteristics of subjects in the Salvage Group were also more frequently associated with parameters of delayed support, such as transfer-from-other-hospital, in- and out-of-hospital cardiac arrest, active ACLS protocol, shock-to-support duration >24hrs, pre-Impella RP use of IABP and ECMO, and prevalence of hypoxic-ischemic brain injury, versus the Checklist Group. These data may suggest that Impella RP was implemented as a last resort in many Salvage Group subjects.

Final Safety Findings (Key Endpoints)

Results for key safety endpoints are presented in the Table 6.8 below.

Table 6.8 Secondary Safety Endpoints - Death, Hemolysis, Bleeding and Pulmonary Embolism Rates at 30 Days Post-Device Explant or Hospital Discharge (Whichever is Longer)

	Checklist Group			Salvage Group			Total Subjects
	Cohort A (N=7)	Cohort B (N=30)	Total (N=37)	Cohort A (N=16)	Cohort B (N=57)	Total (N=73)	
Subjects with at least one adverse event, %	71.4 (5/7)	53.3 (16/30)	56.8 (21/37)	81.3 (13/16)	86.0 (49/57)	84.9 (62/73)	75.5 (83/110)
Death, %	28.6 (2/7)	33.3 (10/30)	32.4 (12/37)	81.3 (13/16)	80.7 (46/57)	80.8 (59/73)	64.5 (71/110)
Bleeding considered life-threatening, disabling, or major (≥BARC 3a), %	28.6 (2/7)	26.7 (8/30)	27.0 (10/37)	12.5 (2/16)	15.8 (9/57)	15.1 (11/73)	19.1 (21/110)
Hemolysis, %	28.6 (2/7)	6.7 (2/30)	10.8 (4/37)	18.8 (3/16)	8.8 (5/57)	11.0 (8/73)	10.9 (12/110)
Pulmonary embolism, %	0 (0/7)	0 (0/30)	0 (0/37)	0 (0/16)	0 (0/57)	0 (0/73)	0 (0/110)

The incidence of device malfunction was 8.1% in the Checklist Group and 2.7% in the Salvage Group.

Follow-up data regarding MACCE events are summarized in Table 6.9.

Table 6.9 Site-Reported MACCE to 30 Days, 90 Days, and 1-Year Post-Device Explant (Subject-Based)

	Checklist Group			Salvage Group			Total Subjects
	Cohort A (N=7)	Cohort B (N=30)	Total (N=37)	Cohort A (N=16)	Cohort B (N=57)	Total (N=73)	
To 30 days post-device explant ¹ ,%							
MACCE	14.3 (1/7)	44.4 (12/27)	38.2 (13/34)	62.5 (10/16)	85.5 (47/55)	80.3 (57/71)	66.7 (70/105)
Death	14.3 (1/7)	37.0 (10/27)	32.4 (11/34)	62.5 (10/16)	83.6 (46/55)	78.9 (56/71)	63.8 (67/105)
Myocardial Infarction	0 (0/7)	0 (0/27)	0 (0/34)	0 (0/16)	0 (0/55)	0 (0/71)	0 (0/105)
CVA/Stroke/TIA	0 (0/7)	7.4 (2/27)	5.9 (2/34)	6.3 (1/16)	1.8 (1/55)	2.8 (2/71)	3.8 (4/105)
Revascularization (Coronary)/ Emergent CABG	0 (0/7)	0 (0/27)	0 (0/34)	0 (0/16)	0 (0/55)	0 (0/71)	0 (0/105)
To 90 days post-device explant ² ,%							
MACCE	28.6 (2/7)	54.5 (12/22)	48.3 (14/29)	75.0 (12/16)	90.6 (48/53)	87.0 (60/69)	75.5 (74/98)
Death	28.6 (2/7)	50.0 (11/22)	44.8 (13/29)	68.8 (11/16)	86.8 (46/53)	82.6 (57/69)	71.4 (70/98)
Myocardial Infarction	0 (0/7)	0 (0/22)	0 (0/29)	0 (0/16)	0 (0/53)	0 (0/69)	0 (0/98)
CVA/Stroke/TIA	0 (0/7)	9.1 (2/22)	6.9 (2/29)	12.5 (2/16)	1.9 (1/53)	4.4 (3/69)	5.1 (5/98)
Revascularization (Coronary)/ Emergent CABG	0 (0/7)	0 (0/22)	0 (0/29)	0 (0/16)	1.9 (1/53)	1.5 (1/69)	1.0 (1/98)
To 1-year post-device explant ³ ,%							
MACCE	33.3 (2/6)	60.0 (12/20)	53.9 (14/26)	93.3 (14/15)	92.5 (49/53)	92.7 (63/68)	81.9 (77/94)
Death	33.3 (2/6)	55.0 (11/20)	50.0 (13/26)	86.7 (13/15)	88.7 (47/53)	88.2 (60/68)	77.7 (73/94)
Myocardial Infarction	0 (0/6)	0 (0/20)	0 (0/26)	0 (0/15)	0 (0/53)	0 (0/68)	0 (0/94)
CVA/Stroke/TIA	0 (0/6)	10.0 (2/20)	7.7 (2/26)	13.3 (2/15)	1.9 (1/53)	4.4 (3/68)	5.3 (5/94)
Revascularization (Coronary)/ Emergent CABG	0 (0/6)	0 (0/20)	0 (0/26)	0 (0/15)	1.9 (1/53)	1.5 (1/68)	1.1 (1/94)
1 Denominators indicate the number of subjects who had any MACCE within 30 days post device explant, or no MACCE with at least 20 days of follow-up post device explant.							
2 Denominators indicate the number of subjects who had any MACCE within 90 days post device explant, or no MACCE with at least 60 days of follow-up post device explant.							
3 Denominators indicate the number of subjects who had any MACCE within 360 days post device explant, or no MACCE with at least 330 days of follow-up post device explant.							

Adjudication of death, stroke, and revascularization events by independent clinical events committee (CEC) found that 81.3% (61/75) of the MACCE were either not related, or only remotely likely to be related to the Impella RP device, with no single MACCE event determined to be related to the Impella RP.

Final Effectiveness Finding (Key Endpoints)

The survival, per primary endpoint, was 69.7% among the evaluable subjects in the Checklist Group and 18.6% among the evaluable subjects in the Salvage Group, as shown in Table 6.10.

Table 6.10 Primary Endpoint: Survival at 30 Days Post-Device Explant or Hospital Discharge (Whichever is Longer), or to Induction of Anesthesia to a Longer-Term Therapy

	Checklist Group			Salvage Group			Total Subjects
	Cohort A (N=7)	Cohort B (N=30)	Total (N=37)	Cohort A (N=16)	Cohort B (N=57)	Total (N=73)	
Primary endpoint—Survival based on evaluable subjects ¹ , %	85.7 (6/7)	65.4 (17/26)	69.7 (23/33)	31.3 (5/16)	14.8 (8/54)	18.6 (13/70)	35.0 (36/103)
Survival at 30 Days Post-Device Explant or Hospital Discharge (Whichever is Longer), %	71.4 (5/7)	61.5 (16/26)	63.6 (21/33)	18.8 (3/16)	14.8 (8/54)	15.7 (11/70)	31.1 (32/103)
Survival to Induction of Anesthesia to a Longer-Term Therapy ⁴ %	14.3 (1/7)	3.8 (1/26)	6.1 (2/33)	12.5 (2/16)	0 (0/54)	2.9 (2/70)	3.9 (4/103)
Primary endpoint—Survival at best-case scenario ² , %	85.7 (6/7)	70.0 (21/30)	73.0 (27/37)	31.3 (5/16)	19.3 (11/57)	21.9 (16/73)	39.1 (43/110)
Primary endpoint—Survival at worst-case scenario ³ , %	85.7 (6/7)	56.7 (17/30)	62.2 (23/37)	31.3 (5/16)	14.0 (8/57)	17.8 (13/73)	32.7 (36/110)
1 Denominators indicate the number of (evaluable) subjects with known status at discharge or follow-up to 30 days post-device explant (whichever is longer), or alive to induction of anesthesia to a longer-term therapy. Seven (7) subjects with missing status are not considered as evaluable. 2 Subjects who were discharged alive, but without follow-up to 30 days post-explant or alive to induction of anesthesia to a longer-term therapy, assumed alive at 30 days post-explant. 3 Subjects who were discharged alive, but without follow-up to 30 days post-explant or alive to induction of anesthesia to a longer-term therapy, assumed expired at 30 days post-explant. 4 "Induction of Anesthesia to a Longer-Term Therapy," which includes a heart transplant or an implant of a surgical RVAD							

Study Strength and Weaknesses

The study's main strengths were its representation of the real-world experience and its size in patient cohort, which was nearly twice the size of the clinical data set used to support the PMA approval. The study's main weaknesses were the missing data associated with unconfirmed status for the primary endpoint evaluation in 4 patients in the Checklist Group and in 3 patients in the Real-World Use Group as well as the missing of the minimum enrollment target of 10 patients (7 enrolled) for Cohort A (patients who develop right heart failure within 48 hours post-implantation of an FDA approved implantable surgical left ventricular assist device) in the Checklist Group largely due to slow enrollment associated with changes in clinical practice patterns.

SODIUM BICARBONATE POST-APPROVAL STUDY (PAS)

SUMMARY OF THE POST APPROVAL STUDY METHODS

Study Objective

The study objective was to demonstrate the safety of a bicarbonate-based purge solution in patients who received an Impella device.

Study Design

The study was designed as a multicenter observational real-world study of patients who received an Impella device in which a bicarbonate-based purge solution was used.

Study Population

The study population included patients who received commercially-available Abiomed hemodynamic support devices (Impella) while receiving sodium bicarbonate in the purge. Patients were enrolled at participating US sites in the Long-Term Outcome and Quality Indicator (LOQI) registry. In this real world observational registry, the Impella devices consisted of left-sided and right-sided devices.

Inclusion Criteria

All patients with left-sided devices (Impella 2.5 System, Impella CP System, Impella CP with SmartAssist System, Impella 5.0 System and Impella 5.5 with SmartAssist System) with sodium bicarbonate in the purge solution.

All patients with right-sided devices (Impella RP System, Impella RP with SmartAssist System, Impella RP Flex System) with sodium bicarbonate in the purge solution.

Exclusion Criteria

Patients with known left ventricular (LV) thrombus for left-sided Impella patients.

Patients with known pulmonary thromboemboli (PT) or deep vein thrombosis (DVT) in the right-sided Impella patients.

Data Source

The Bicarb PAS consisted of a sub-set of the Abiomed Long-Term Outcome and Quality Indicator (LOQI) Impella Registry, which is an ongoing multi-center, observational, records review study of routine clinical care and outcomes. The data were captured through review of the medical records and entered into electronic case report forms (eCRFs) by trained clinical staff at the participating sites.

Key Study Endpoints

The goal of the analysis was to represent real world usage of sodium bicarbonate, including across patients receiving left- or right- sided support. Since the access and utilization for left- and right-sided support are different, the study had separate primary endpoints for left- and right-sided support; and common descriptive endpoints.

Table 6.11 Bicarb PAS Endpoints by Left- or Right-Sided Devices

	Left-Sided Devices	Right-Sided Devices
Primary Endpoint	Composite of stroke, transient ischemic attack (TIA), and LV thrombus through hospital discharge	Composite of PT and DVT through hospital discharge
Descriptive Endpoints	Thrombotic events excluding LV thrombus, stroke, and TIA through hospital discharge	Thrombotic events excluding PT and DVT through hospital discharge
Common Descriptive Endpoints	Bleeding Academic Research Consortium (BARC) ≥ 3 bleeding events through hospital discharge	

Total Number of Enrolled Study Sites and Subjects, Follow-Up Rate

This study included 312 patients; 300 patients in the left-sided cohort and 20 patients in the right-sided cohort from 20 clinical centers. Any patient receiving at least one left-sided device or at least one right-sided device was included in the respective left-sided or right-sided cohort. Two hundred ninety-two (292) patients received at least one left-sided device with sodium bicarbonate in the purge, but no right-sided device with sodium bicarbonate in the purge. Eight patients received both an Impella left-sided device and a right-sided Impella, and twelve patients received at least one right-sided device (with two out of those receiving two right-sided devices) with sodium bicarbonate in the purge.

In this observational study, all patients were followed through discharge or death, whichever occurred sooner.

Study Visits and Length of Follow-Up

This study included data on qualifying patients treated between April 19, 2022 (PMA approval date) and February 22, 2024. The date of final data extraction was May 15, 2024, to enable corresponding patient data entry.

The observational study data collection was limited to the hospital admission – beginning at enrollment and ending at discharge or death, whichever occurred earlier. Adverse events were collected for the full admission duration.

SUMMARY OF THE POST-APPROVAL STUDY RESULTS

Baseline Characteristics, Left-Sided Support Population

Overall mean age was 62.1 ± 13.4 years with 69.3% male patients. Patients presented with multiple comorbidities, including hypertension (68.9%), coronary artery disease (52.5%), diabetes (37.7%), prior myocardial infarction (MI) (28.4%), chronic kidney disease (CKD) (27.4%), history of heart failure (HF) (49.8%), history of cardiac valve stenosis (11.0%), history of stroke/cerebrovascular accident (CVA) (9.7%), history of bleeding disorder (5.7%), and prior percutaneous coronary intervention (PCI) (21.7%) or prior coronary artery bypass grafting (11.4%).

In the left-sided cohort, 46.3% of patients were admitted through the emergency department, 14.3% experienced out of hospital cardiac arrest (OHCA), and 25.3% patients had pulseless electrical activity (PEA) or refractory ventricular tachycardia/ventricular fibrillation before Impella support was used. The mean left ventricular ejection fraction (LVEF) was 27.8%. Over one third (36.7%) of patients were on mechanical ventilation prior to Impella insertion, 31.0% had signs of right heart failure (RHF), and 3.0% had anoxic brain injury before Impella implantation. Inotrope use was present in 12.2% of patients at admission, 16.5% were on vasodilators and 57.1% on diuretics. In the left-sided cohort, 27.0% of patients were on anti-arrhythmic medications, and 52.7% were on anticoagulation/antiplatelet medication prior to admission. The mean lactate was 4.9 ± 4.9 mmol/dL, and mean creatinine level was 1.7 ± 1.4 mg/dL.

Prior to their first Impella insertion, 29.7% of patients received other mechanical circulatory support (MCS) – primarily consisting of extracorporeal membrane oxygenation (ECMO) or an intra-aortic balloon pump (IABP).

Baseline Characteristics, Right-Sided Support Population

Overall mean age was 59.4 ± 18.5 years with 50.0% male patients. Comorbidities included hypertension (70.0%), coronary artery disease, diabetes, prior MI, and CKD (25.0% each), and history of HF (45.0%), out of which 77.8% patients had reduced EF. Additionally, 15.0% of patients had a prior history of stroke/CVA. Most (85.0%) patients had evidence of RHF before admission, 45.0% were admitted through the ER, 35.0% were on mechanical ventilation prior to Impella insertion, 60.0% were on diuretics, and 25.0% received ECMO, IABP or a left ventricular assist device before the first Impella insertion.

Patients had a mean lactate of 6.0 ± 5.8 mmol/dL and a mean creatinine level of 2.3 ± 2.1 mg/dL. Sixty percent of the patients were on antiplatelet/anticoagulant medication, 60.0% were on diuretics, 20.0% on inotropes, and 13.3% on anti-arrhythmic medication at admission.

The baseline characteristics confirm an overall high-acuity population.

Impella Procedure Characteristics

A total of 345 Impella devices were placed in the overall (both left-sided and right-sided) cohort of 312 patients.

Impella support was provided for cardiogenic shock (CS) indication in 77.4% of the patients in the left-sided cohort, and for 81.8% of patients in the right-sided cohort.

In the left-sided cohort, the Impella device used was distributed between Impella CP and Impella 5.5, at 47.7% and 51.4%, respectively. Forty-two (41.8%) percent of patients received the Impella via the femoral artery, 40.3% via axillary artery and 9.3% directly via aorta.

In the left-sided cohort, the time from admission to Impella support was 5.8 ± 8.1 days, and the support duration was 8.7 ± 10.5 days. In the right-sided cohort, time from admission to Impella support was 15.5 ± 23.3 days and the support duration was 6.0 ± 8.6 days. The hospital length of stay for the left-sided cohort was 26.4 ± 24.9 days and 27.8 ± 23.5 days for right-sided support patients. Heparin (outside the purge solution, for systemic anticoagulation) was administered for 92.5% of Impella support in the left-sided cohort and 77.8% of Impella support in the right-sided cohort.

Context of Sodium Bicarbonate Purge Usage

In the left-sided support cohort, the reasons for the use of sodium bicarbonate in the purge fluid were listed as: 67.1% due to physician's preference, 13.0% for high bleeding risk, 3.7% for heparin-induced thrombocytopenia (HIT) and 16.2% for 'other' reasons. In the right-sided cohort, the reasons for bicarbonate use were listed as: 72.7% due to physician preference, 4.6% for high bleeding risk, 13.6% for HIT and 9.1% for 'other' reasons.

Device Deficiencies

During the PAS, there were no device deficiencies found to be related to the use of sodium bicarbonate in the purge fluid.

Seven Impella devices (out of 345) did not provide intended circulatory support and were removed (three Impella CP devices and four Impella RP devices) and replaced if deemed appropriate by the attending physician. There is no evidence that any of the failures were related to the use of sodium bicarbonate in the purge fluid.

- Impella CP: Three Impella CP devices experienced pump stops and were removed after 15, 19, or 21 days of support (respectively), exceeding the approved duration of use (4 days). The devices were not returned for investigation and the root cause for the failures could not be determined, but there was no evidence that the use of sodium bicarbonate in the purge fluid contributed to the failures.
- Impella RP: Four Impella RP devices failed to produce the intended circulatory support (three demonstrated lower than expected flow, one experienced a pump stop) and were removed. Although this 20% rate of device failure (4 of 20 right-sided Impella subjects) is higher than expected, there is no evidence that the device failures were related to the use of sodium bicarbonate in the purge fluid. In three cases, the root cause was sudden biological material ingestion into the Impella RP device which is unrelated to the use of sodium bicarbonate in the purge fluid. This is a known risk that is included in the Impella RP System Instructions for Use, along with instructions for mitigating this risk by maintaining adequate systemic anticoagulation and assessing the risk for extraluminal thrombus on indwelling lines placed prior to initiation of support. In the fourth case, the root cause could not be determined but there was no evidence that the use of sodium bicarbonate in the purge fluid contributed to the failure.

Six additional patients experienced a device deficiency that was not a failure to provide intended circulatory support, and none of those device deficiencies were found to be related to the use of sodium bicarbonate in the purge fluid.

Final Safety Findings (Key Endpoints)

The primary endpoint for left-sided Impella devices (Impella 2.5 System, Impella CP System, Impella LD System, Impella 5.0 System and Impella 5.5 System) was a composite of stroke, transient ischemic attack (TIA), left ventricular (LV) thrombus evaluated at discharge. Event data included all events during index hospitalization, including prior to, during and after Impella support. The composite event rate of 7.7% during the entirety of the index hospitalization (Table 6.12) fell within the expected event rate of the Impella device usage for the studied patient population.

The key contributor to the composite endpoint was stroke, with 22 of the 23 composite endpoint events being stroke events (22/300; 7.33%). The remaining event was one event of left ventricular thrombus. The observed rate of stroke (7.33%) fell within the expected stroke rate derived from literature reports. Recent large studies of similar patient populations reported stroke rates ranging from 3.20% - 9.70% for any stroke and 2.70% - 6.50% for ischemic stroke in various sub-groups of STEMI (ST segment elevation myocardial infarction) cardiogenic shock (CS) utilizing a temporary mechanical circulatory support (MCS) device¹; and 8.50% for ischemic stroke in non-ischemic CS subjects with an MCS device². Another large study with two-thirds acute myocardial infarction CS (AMICS) subjects and one third non-AMICS subjects reported an in-hospital stroke rate of 6.40%³. Lastly, an independent multicenter analysis of Impella 5.0/5.5 support for 754 CS subjects from the Cardiogenic Shock Working Group (CSWG) registry reported a stroke rate of 6.8% in the total CSWG cohort⁴.

Additional descriptive endpoints included 1) BARC ≥ 3 bleeding events through hospital discharge; 2) For left-sided devices, thrombotic events excluding LV thrombus, stroke, and TIA through hospital discharge; and 3) For right-sided devices, thrombotic events excluding pulmonary thromboemboli and DVT through hospital discharge.

Table 6.12 Primary and Descriptive Endpoints to Discharge – Left-Sided

Endpoints	Left-Sided ¹ (N = 300)
Primary Endpoint	
Composite of Stroke/TIA/LV Thrombus	7.67% (23/300)
Stroke	7.33% (22/300)
TIA	0% (0/300)
Left Ventricular(LV) Thrombus	0.33% (1/300)
Descriptive Endpoint	
Bleeding (BARC ≥ 3)	21.00% (63/300)
Thrombotic events excluding LV Thrombus, Stroke/TIA	3.67% (11/300)
¹ Left-sided patients = 292 left-sided only + 8 left- and right-sided = 300 patients	

When patients were grouped by Impella-only patients and Impella patients with other MCS (Impella + MCS) (Table 6.13), the endpoint rates were considerably lower in the Impella-only group. Specifically, the composite endpoint rate of stroke/TIA/LV thrombus was 3.1% in the Impella-only group versus 13.5% in the Impella + MCS group. Fourteen (14) out of 23 primary endpoints were reported to be unlikely or not related to the device (Table 6.14), only two primary endpoints were found to be probably related to the device, four possibly related to the device, and relatedness of two other primary endpoints was classified as unknown. Similar to the finding seen with the primary endpoints, there is an appreciable difference in descriptive endpoint rates between Impella only and Impella + MCS sub-groups, with lower BARC ≥ 3 bleeding event rates (15.4% versus 29.4%) and thrombotic event rates (3.1% versus 4.8%) seen in Impella only sub-group, with majority of the endpoints reported to be unlikely or not related to the device.

Table 6.13 Primary and Descriptive Endpoints to Discharge – Left-Sided; Stratified by Impella Used Alone; and Impella Preceded by or Used with MCS

Endpoints	Impella Only ¹ (N = 162)	Impella + MCS ² (N = 126)
Primary Endpoint		
Composite of Stroke/TIA/LV Thrombus ³	3.09% (5/162)	13.49% (17/126)
Stroke	2.47% (4/162)	13.49% (17/126)
TIA	0% (0/162)	0% (0/126)
Left Ventricular(LV) Thrombus	0.62% (1/162)	0% (0/126)
Descriptive Endpoint		
Bleeding (BARC ≥ 3)	15.43% (25/162)	29.37% (37/126)
Thrombotic events excluding LV Thrombus, Stroke/TIA	3.09% (5/162)	4.76% (6/126)
¹ Impella only consists of patients who did not use a mechanical circulatory support (MCS) prior to Impella implant or during Impella support.		
² Impella + MCS consists of patients who used a MCS prior to Impella implant and/or during Impella support.		
³ Twelve patients had missing data for prior MCS or concurrent ECMO use. One patient had stroke in that cohort.		

Table 6.14 Site-Reported Primary Endpoint by Device Relatedness – Left-Sided¹

Primary and Descriptive Endpoint	Left-Sided, All (N=300)						Total
	Definitely	Probably	Possibly	Remote (Unlikely)	None (Not-related)	Unknown	
Primary Endpoint Composite of Stroke/TIA/LV Thrombus							23
Stroke	0	2	4	0	14	2	22
TIA	0	0	0	0	0	0	0
LV Thrombus	0	0	1	0	0	0	1
Descriptive Endpoint							
Bleeding (BARC ≥3)	4	0	17	8	32	2	63
Thrombotic events excluding LV Thrombus, Stroke/TIA	0	0	3	4	4	0	11

TIA=Transient Ischemic Attack; BARC= Bleeding Academic Research Consortium
¹In case of multiple similar endpoints, the endpoint event nearest to (but before) the left-sided device utilizing bicarbonate was selected.

The primary endpoint for right-sided Impella devices was a composite of pulmonary thromboemboli and DVT evaluated at discharge. No patients met the primary endpoint in the right-sided cohort (Table 6.15). No right-sided cohort patient experienced the descriptive endpoint of thrombotic events, while BARC ≥ 3 bleeding was seen in 15.0% of the patients. None of the BARC ≥ 3 bleeding in the right-sided cohort was reported to be definitely or probably related to the device (Table 6.16).

Table 6.15 Primary and Descriptive Endpoints to Discharge – Right-Sided

Endpoints	Right-Sided ¹ (N = 20)
Primary Endpoint	
Composite of Pulmonary Thromboemboli and Deep Vein Thrombosis	0% (0/20)
Pulmonary Thromboemboli	0% (0/20)
Deep Vein Thrombosis (DVT)	0% (0/20)
Descriptive Endpoint	
Bleeding (BARC ≥3)	15.00% (3/20)
Thrombotic events excluding PT and DVT	0% (0/20)

¹ Right-sided patients = 12 right-sided only + 8 left- and right-sided = 20 patients.

Table 6.16 Site-Reported Primary Endpoint by Device Relatedness – Right-Sided

Primary and Descriptive Endpoint	Right-Sided, All (N=20)						
	Definitely	Probably	Possibly	Remote (Unlikely)	None (Not-related)	Unknown	Total
Primary Endpoint							
Composite of Pulmonary Thromboemboli and Deep Vein Thrombosis	0	0	0	0	0	0	0
Pulmonary Thromboemboli (PT)	0	0	0	0	0	0	0
Deep Vein Thrombosis (DVT)	0	0	0	0	0	0	0
Descriptive Endpoint							
Bleeding (BARC ≥3)	0	0	1	0	1	1	3
Thrombotic events excluding PT and DVT	0	0	0	0	0	0	0
BARC= Bleeding Academic Research Consortium							

Final Effectiveness Findings (Key Endpoints)

The primary and descriptive endpoints of the study are described above in the “Final Safety Findings” section.

Study Strengths and Weaknesses

The study’s main strength was its representation of the real-world experience, representing physician preference for the use of sodium bicarbonate in the purge fluid during Impella support for a variety of challenging clinical scenarios, indications, and procedural characteristics. The study provided rigorous data on this real-world cohort.

The study’s main weaknesses were its lack of data to identify timing of the purge administration with respect to the timing of the endpoints, and lack of data to directly compare outcomes between bicarbonate and other purge fluids.

References

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7 AUTOMATED IMPELLA CONTROLLER ALARMS



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ALARMS OVERVIEW

The Automated Impella Controller™ monitors various functions to determine whether specific operational parameters are within expected limits. When a parameter goes outside of its specified limits, the Automated Impella Controller sounds an alarm tone and displays an alarm message that can be viewed on the display screen on the front of the controller. The alarm tone indicates the severity of the alarm. The alarm message on the display screen is color-coded for severity and provides details on the cause of the alarm and how to resolve the alarm. After muting an alarm, if another alarm occurs it will only be heard and displayed if it is a higher priority alarm than the one that was muted.

ALARM LEVELS

Alarms are divided into three levels of severity:

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

Table 7.1 Alarm Levels

Category	Description	Audible Indicator*	Visual Indicator
Advisory	Notification	1 beep every 5 minutes	Alarm header on white background
Serious	Abnormal situation. Prompt action needed.	3 beeps every 15 seconds	Alarm header on yellow background
Critical	High priority. Immediate action needed.	10 beeps every 6.7 seconds	Alarm header on red background

* Sound pressure of audible alarm indicators is 60-80 dBA at a measured range of 1 m

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

ALARM DISPLAY

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



Figure 7.1 Alarm Window

Alarms That Resolve On Their Own

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

MUTE ALARM FUNCTION

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

ALARM HISTORY SCREEN

The alarm history screen may be accessed through the **MENU**. This screen contains a log of the alarms that occurred during the case. This log is maintained when the Automated Impella Controller is powered down or after a power failure. The controller does maintain a long-term log that is saved after the Automated Impella Controller is powered down or after a power failure and this information may be downloaded by Abiomed personnel.

ALARM MESSAGE SUMMARY

Table 7.2 briefly describes all of the alarm messages that may appear on the Automated Impella Controller when used with the Impella RP Flex with SmartAssist™ System Catheter.

Table 7.2 Automated Impella Controller Alarm Messages

Severity	Alarm Header	Action	Cause
Critical Alarms	Air in Purge System	The purge system has stopped. Press the PURGE MENU soft key then select De-Air Purge System.	There is air in the purge tubing.
	Battery Critically Low	Plug controller into AC power.	Battery power has 15% remaining capacity.
	Battery Failure	Plug controller into AC power.	One of the batteries has failed.
	Battery Failure	1. Plug controller into AC power. 2. Press switch located on the underside of the controller. 3. Switch to backup controller.	A battery switch is turned off or there is a malfunction of the switch.
	Battery Temperature High	Switch to backup controller.	Battery temperature is greater than 60°C.
	Complete Procedure	1. Follow the steps on the screen or 2. Exit the procedure	The Complete Procedure serious alarm (yellow; see <i>next page</i>) is active and the user has not responded for an additional 2 minutes.
	Controller Failure	The purge system has stopped. Switch to backup controller.	The controller has detected a purge pressure sensor defect and has stopped the purge system.
	Controller Failure	Switch to backup controller.	There is a problem with the controller electronics.
	Emergency Shutdown Imminent	Release ON/OFF push button.	Power switch pressed for 15 seconds while Impella RP Flex with SmartAssist System Catheter still connected.
	Impella Disconnected	1. Check cable connection to console. 2. Check Impella connection to cable.	Running Impella RP Flex with SmartAssist System Catheter disconnected.
	Impella Failure	Replace Impella.	There is a problem with the Impella RP Flex with SmartAssist System Catheter motor.
	Impella Stopped	1. Replace white connector cable. 2. Switch to backup controller. 3. Replace Impella pump.	There is a problem with the electronics.
	Impella Stopped	1. Restart Impella. 2. Replace Impella after 3rd unsuccessful restart attempt	There may be a mechanical or electrical problem in the Impella RP Flex with SmartAssist System Catheter.
	Impella Stopped Controller Failure	Switch to backup controller.	There is a problem with the controller electronics.

Table 7.2 Automated Impella Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Critical Alarms	Impella Stopped Motor Current High	1. Restart Impella. 2. Replace Impella after 3rd unsuccessful restart attempt.	There is a problem with the Impella RP Flex with SmartAssist System Catheter motor.
	Impella Stopped Retrograde Flow	To prevent retrograde flow, restart Impella by turning P-level up or withdraw pump from pulmonary artery.	Impella RP Flex with SmartAssist System Catheter is not running; possible retrograde flow through Impella RP Flex with SmartAssist System Catheter.
	Purge Disc Not Detected	Re-insert Purge Disc	The controller is not detecting that the purge disc is clicked into the front of the controller.
	Purge Pressure High	Decrease concentration of dextrose in the purge solution.	Purge pressure is ≥ 1100 mmHg with the purge flow < 2 mL/hr.
	Purge Pressure Low	1. Check purge system tubing for leaks. 2. Increase concentration of dextrose in the purge solution. 3. Replace purge cassette.	Purge pressure has dropped below 300 mmHg with the purge flow 30 mL/hr for 30 seconds or longer.
	Purge Pressure Low (when Flight Mode enabled)	1. Check the purge system tubing for leaks. 2. Upon arrival at receiving hospital, notify managing team to address alarm condition once Flight Mode is disabled.	Purge pressure has dropped below 300 mmHg with the purge flow ≥ 30 mL/hr for 30 seconds or longer.
	Purge System Blocked	1. Check all purge system tubing for kinks or blockages. 2. Decrease concentration of dextrose in the purge solution.	Purge flow has dropped below 1 mL/hr. Kinked or blocked purge connecting tube. Kinked or blocked purge lumen in Impella RP Flex with SmartAssist System Catheter.
	Purge System Failure	1. Replace purge cassette. 2. Switch to backup controller.	There is a problem with the purge cassette or the purge unit driver.
	Purge System Failure (when Flight Mode enabled)	Upon arrival at receiving hospital, notify managing team to address alarm condition once Flight Mode is disabled.	There is a problem with the purge cassette or purge unit driver.
	Purge System Open	1. Check the purge system tubing for open connections or leaks. 2. Replace purge cassette.	Purge pressure has dropped below 100 mmHg for 20 seconds or longer.
	Purge System Open (when Flight Mode enabled)	1. Check the purge system tubing for open connections or leaks. 2. Upon arrival at receiving hospital, notify managing team to address alarm condition once Flight Mode is disabled.	Purge pressure has dropped below 100 mmHg for 20 seconds or longer.
	Retrograde Flow	Check for high afterload pressure.	Reverse flow detected at high motor speed.

Table 7.2 Automated Impella Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Serious Alarms	Battery Comm. Failure	Plug controller into AC power.	Loss of communication to the battery.
	Battery Level Low	Plug controller into AC power.	Battery power has 50% remaining capacity.
	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.
	Complete Procedure	1. Follow the steps on the screen or 2. Exit the procedure	User has not responded to a de-air or purge procedure screen for more than 1 minute or a transfer to standard configuration screen for more than 5 minutes.
	Controller Error	Switch to backup controller.	There is a problem with the controller electronics.
	Impella Catheter Not Supported	1. Replace Impella with supported catheter. 2. Contact Abiomed Service to upgrade Impella Controller.	The Impella Catheter is not supported to operate with the current version of controller software and/or hardware.
	Impella Defective	Do not use Impella. Replace Impella.	There is a problem with the Impella RP Flex with SmartAssist System Catheter electronics.
	Impella Stopped Controller Failure	Locate Back-up Controller	Attempting to restart catheter. Catheter expected to start within 30 seconds.
	Placement Signal Not Reliable	Monitor patient hemodynamics. Confirm Impella position with chest X-ray.	There is a problem with the Impella Catheter fiber-optic sensor signal, Impella flow will still be calculated. .
	Placement Signal Not Reliable	Monitor patient hemodynamics. Confirm Impella position with chest X-ray.	There is a problem with the Impella Catheter differential pressure sensor, a yellow triangular caution icon is displayed with the message "Flow Calculation Disabled."
	Purge Volume Critically Low	1. Open PURGE MENU and select Change Purge Fluid Bag. 2. Follow the instructions to change the purge fluid.	There are 15 mL (in addition to 5% of the starting bag volume) or fewer remaining in the purge fluid bag.
	Reinstall Software	Software installation was unsuccessful.	Reinstall software. Software was not installed successfully.
	Suction	1. Check filling and volume status. 2. Check Impella position. 3. Reduce P-Level.	Suction is detected.

Table 7.2 Automated Impella Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Advisory Alarms	AC Power Disconnected	Controller is running on battery power.	AC power was disconnected.
	Audio Off	The audio for the following alarms has been disabled. <Alarms will be listed here>	User has disabled audio for one or more of the following alarms: • Purge Pressure High • Purge System Blocked • Suction • Placement Signal Not Reliable
	Flight Mode Enabled	1. Connect controller to ground during air transport. 2. If equipped with Impella Connect, enable Flight Mode on module. 3. Upon arrival at receiving hospital, disable Flight Mode under MENU .	Flight mode has been enabled for transport.
	Preventing Retrograde Flow	Impella P-level has increased to prevent retrograde flow. 1. Consider increasing target P-level. 2. For weaning, disable Retrograde Flow Control through MENU soft key.	Retrograde flow has been detected and minimum motor speed has been increased to more than target P-level.
	Purge Cassette Incompatible	Contact Abiomed Service to update Impella Controller.	Incompatible purge cassette RFID version.
	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.
	Purge Flow Increased	The purge flow has increased by 2.5 mL/hr or more. This is a notification only; no action is required.	Purge flow has increased by ≥ 2.5 mL/hr.
	Purge Volume Low	1. Open PURGE MENU and select Change Purge Fluid Bag. 2. Follow the instructions to change the purge fluid.	There are 30 mL (in addition to 5% of the starting bag volume) or fewer remaining in the purge fluid bag.
	Surgical Mode Enabled	Impella pump stopped. Purge system running. 'Impella Stopped' alarm disabled. To exit this mode, start Impella pump.	Surgical Mode has been enabled to silence 'Impella Stopped' alarm at P-0.
	Unexpected Controller Shutdown	Switch to back-up Controller if condition persists.	Unexpected restart of controller due to software or hardware failures



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TERMINOLOGY, ABBREVIATIONS, AND SYMBOLS

Table 8.1 Terminology and Abbreviations

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

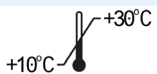
	Caution; follow instructions for use
	Defibrillator-proof type CF equipment
	Keep dry
	Storage temperature (eg, 10°C to 30°C)
	Declares conformity with directive 93/42/EEC for medical devices
 2014-10-01	Date of manufacture (e.g., October 1, 2014)
	Protect from sunlight
	Symbol for lot designation; the manufacturer's lot designation must be stated after the LOT symbol

Table 8.2 Symbols (continued)

 123456	Abiomed part number (e.g., part number 123456)
 123456	Manufacturer's serial number (e.g., serial number 123456)
Non Sterile!	The product is not sterile
 2016-06-01	Use-by date (e.g., use before June 1, 2016)
	Do not reuse
	Sterilized using ethylene oxide
	Electric scrap; must be disposed of separately. Must not be disposed of as domestic waste.
	Protective Earth
	ON / OFF
	Alternating current (AC) only
	Equipotentiality
	Fuse
	Non-ionizing electromagnetic radiation
	USB port
	CAT 5 Port (Ethernet)
	MR Unsafe
 Do Not Flush	Do Not Flush
 Glucose	Glucose
DO NOT REMOVE	Do not remove tamper tape. Inspect Automated Impella Controller for evidence of tampering before each use.

AUTOMATED IMPELLA CONTROLLER™ MECHANICAL SPECIFICATIONS

Table 8.3 Mechanical specifications for the Automated Impella Controller

Parameter	Specification
Temperature	Operating: 10°C to 40°C (50°F to 104°F)
	Storage: –15°C to 50°C (5°F to 122°F)
Relative Humidity	Operating: 95%
	Storage: 95%
Atmospheric Pressure	Operating: 8000 ft (750 hPa) to –1000 ft (1050 hPa)
	Storage: 18,000 ft (500 hPa) to –1000 ft (1050 hPa)
Dimensions	Height: 351 mm (13.8 in)
	Width: 443 mm (17.4 in)
	Depth: 236 mm (9.3 in)
Dimensions – Packaged	Height: 508 mm (20.0 in)
	Width: 559 mm (22.0 in)
	Depth: 406 mm (15.0 in)
Weight	Maximum: 12.2 kg (26.8 lbs)
Weight – Packaged	Maximum: 14.3 kg (31.5 lbs)
Maintenance and repair interval	12 months (Work must be performed by technicians authorized by Abiomed)
Model Number	0042-0000-US
	0042-0010-US (Optical Console)
	0042-0040-US (Optical Console with Impella Connect)

AUTOMATED IMPELLA CONTROLLER ELECTRICAL SPECIFICATIONS

Table 8.4 Electrical specifications for the Automated Impella Controller

AC operation	100-240 V AC; 2A; 50-60 Hz
Internal battery operation	14.4 V DC (nominal); lithium ion
Characteristic values	
Max. power consumption under load	200 VA
9.7 fuses	2 Amp. 250 V. 5 mm x 20 mm, slow-blow fuses
Running time without AC power with fully charged batteries	At least 60 minutes (charging duration of at least 5 hours)
Electrical system	Installation in accordance with pertinent regulations is required for use in medical facilities (e.g., IEC stipulations).

EQUIPMENT DESIGN

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

- IEC 60601-1: 2012 Edition 3.1 *Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance*
- CSA C22.2#60601-1 (2014) Ed:3 *Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance*
- AAMI ES60601-1:2005 +C1:A2 *Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2:2014 Edition 4, *Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- IEC 60601-1-6:2010, AMD1:2013 *Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability*
- IEC 60601-1-8:2006, AM1:2012 *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 62304:2015 *Medical Device Software - Software Life-cycle processes*
- RTCA DO160G *Environmental Conditions and Test Procedures for Airborne Equipment*
- AIM 7351731 *Medical Electrical Equipment and System Electromagnetic Immunity test for Exposure to Radio Frequency Identification Readers*

EQUIPMENT CLASSIFICATIONS

Table 8.5 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 Automated 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.

NOTE: "Harmful interference" is defined by the FCC as follows: Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

ELECTROMAGNETIC COMPATIBILITY



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



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



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



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



The Automated Impella Controller (AIC) performs as intended when exposed to radiofrequency (RF) disturbances below 20 V/m. During transport, the AIC may be exposed to RF disturbances above 20 V/m, which could cause minor problems, such as intermittent displays of soft button menu selections, which have no effect on the operating parameters of the Impella support system and will resolve readily once the disturbance ends. It could also potentially result in loss of support. Patients must be closely monitored at all times during transport.



Do not transport an Impella patient via commercial aircraft. Loss of support may occur aboard a commercial aircraft due to exposure to radiofrequency (RF) disturbances above the compliance level (<20 V/m) of the Automated Impella Controller.

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. For the electromagnetic testing (detailed in the following tables), the AIC Essential Performance was specified as: during the entire test period, the AIC continues to provide support to the patient.

Table 8.6 Guidance and manufacturer's declaration - emissions, all equipment and systems

The Automated Impella Controller is intended for use in the electromagnetic environment specified below. The customer or user of the Automated 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 Automated 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.
	Class A	The Automated Impella Controller is suitable for use in all locations other than those located in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	
RTCA DO-160G Section 21.4, conducted emissions	Category M	
RTCA DO-160G Section 21.5, radiated emissions	Category B	

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 8.7 Guidance and manufacturer's Declaration - Immunity

The Automated Impella Controller is intended for use in the electromagnetic environment specified below. The customer or user of the Automated 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	The relative humidity should be at least 5%.
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 Automated Impella Controller requires continued operation during power mains interruptions, it is recommended that the Automated Impella Controller be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.

Table 8.8 Guidance and manufacturer's declaration - emissions, equipment and systems that are life-supporting

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

Immunity Test	IEC 60601	Compliance Level	Electromagnetic Environment – Guidance
			Except as indicated in Table 8.11, portable and mobile RF communications equipment should be separated from the Automated Impella Controller by no less than the recommended separation distances calculated/listed below:
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	10 Vrms	$d = 0.35\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	$d = 0.6\sqrt{P}$ 80 to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum power rating in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey ^(a) , should be less than the compliance level in each frequency range. ^(b) Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

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

Table 8.8 Guidance and manufacturer's declaration - emissions, equipment and systems that are life-supporting

Immunity Test	Compliance Level
Avionics RTCA DO-160G	
Conducted RF Section 20.4	Category R 10 MHz - 400 MHz
Radiated RF Section 20.5	Category T (c) 100 MHz - 8 GHz
(c) the AIC will not maintain its essential performance when subjected to Category R Levels (radiated RF at a field strength of 150 V/m).	

Immunity Test		
RFID AIM 7351731:2017		
RFID Specification	Frequency	Test Level (RMS)
ISO 14223	134.2kHz	65 A/m
ISO/IEC 14443-3 (Type A)	13.56 MHz	7.5 A/m
ISO/IEC 14443-4 (Type B)	13.56 MHz	7.5 A/m
ISO/IEC 15693 (ISO 18000-3 Mode 1)	13.56 MHz	5 A/m
ISO/IEC 15693 (ISO 18000-3 Mode 3)	13.56 MHz	12 A/m
ISO/IEC 18000-7	433 MHz	3 V/m
ISO/IEC 18000-63 Type Ca	890-960 MHz	54 V/m
ISO/IEC 18000-4 Mode 1	2.45 GHz	54 V/m

Table 8.9 Recommended separation distances between portable and mobile RF communications equipment and the Automated Impella Controller, equipment and systems that are life-supporting

The Automated Impella Controller is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Automated Impella Controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Automated Impella Controller as recommended below, according to the maximum output power of the communications equipment, except as indicated in Table 8.11.

Rated Maximum Output Output Power of Transmitter (Watts)	Recommended Separation Distances for the Automated Impella Controller (m)		
	150 KHz to 80 MHz $d = 0.35\sqrt{P}$	80 to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0.01	0.04	0.06	0.12
0.1	0.11	0.19	0.38
1	0.35	0.6	1.2
10	1.11	1.9	3.8
100	3.5	6.0	12

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

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

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

Table 8.10 RFID transmitter / receiver specifications

RFID Transmitter / Receiver Specifications	
Frequency	13.56 MHz
Receiver bandwidth	14 kHz
Effective radiated power	30 nW
Modulation	ASK

Table 8.11 Testing for immunity to portable and mobile RF transmitters, for which the recommended separation distance is 30 cm (12 inches)

Test frequency (MHz)	Band (MHz)	Service	Compliance level (V/m)
385	380 - 390	TETRA 400	27
450	430 - 470	GMRS 460, FRS 460	28
710	704 - 787	LTE Band 13, 17	9
745			
780			
810			
870	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28
930	1,700 - 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28
1,720			
1,845			
1,970			
2,450	2,400 - 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28
5,240	5,100 - 5,800	WLAN 802.11 a/n	9
5,500			
5,785			

Table 8.12 Impella Connect™ Wi-Fi transmitter / receiver specifications

IEEE Protocols		802.11a, 802.11b, 802.11g, and 802.11n		
Receiver bandwidth		120 MHz/ 40 MHz		
Effective radiated power		<0.071 watts		
Frequency Bands		2412 MHz to 2462 MHz US 2412 MHz to 2472 MHz EU 2412 MHz to 2684 MHz JP 5180 MHz to 5825 MHz US 5180 MHz to 5700 MHz EU 5180 MHz to 5700 MHz JP		

IEEE	802.11a	802.11b	802.11g	802.11n
Modulation	OFDM	DSSS	OFDM	MxMO OFMD

Video Frame Rate		20 fps (Maximum)		
Data Rate		512 Kbps (Average)		

Certified Wi-Fi Module	
Manufacturer:	Texas Instruments
Part number:	WL18MODGI
FCC ID:	Z64-WL18DBMOD

TRANSPORT BETWEEN HOSPITALS



The Automated Impella Controller (AIC) performs as intended when exposed to radiofrequency (RF) disturbances below 20 V/m. During transport, the AIC may be exposed to RF disturbances above 20 V/m, which could cause minor problems, such as intermittent displays of soft button menu selections, which have no effect on the operating parameters of the Impella support system, and will resolve readily once the disturbance ends. It could also potentially result in loss of support. Patients must be closely monitored at all times during transport.



Do not transport an Impella patient via commercial aircraft. Loss of support may occur aboard a commercial aircraft due to exposure to radiofrequency (RF) disturbances above the compliance level (<20 V/m) of the Automated Impella Controller.

GUIDELINES FOR PATIENT TRANSPORT

Intra-hospital transport may be required if a patient requires additional resources and specialized teams located at another hospital. The patient may be transferred to such a location using the Automated Impella Controller for hospital-to-hospital transport via ambulance, or helicopter, or fixed-wing aircraft specially outfitted and equipped for transport of critically ill patients. Do not transport the patient via commercial aircraft. Loss of support may occur aboard a commercial aircraft due to exposure to extreme radiofrequency (RF) disturbances.

Patients must be closely monitored at all times during transport. Maintaining optimal patient hemodynamic status and correct Impella Catheter position are two key factors in managing patients supported with the Impella Ventricular Support Systems during transport. Steps should be taken to eliminate or minimize any aspect of the transport that might adversely affect these factors.

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

IMPORTANT TRANSPORT CONSIDERATIONS

1. Planning is critical to success. Abiomed representatives can help with planning for transport. They can be contacted 24 hours a day at 1-800-422-8666.
2. The Automated Impella Controller should be fully charged prior to transport. Keep the Automated Impella Controller connected to AC power (or an AC inverter) whenever possible.
3. Do not stress the connector cable from the controller to the Impella Catheter. Such tension could move the catheter out of correct position and compromise patient circulatory support.
4. Carefully monitor purge pressures during changes in altitude.
5. The Automated Impella Controller should be positioned to allow easy access to the display screen and soft buttons to view alarms and make any necessary changes.
6. Maintain ACTs between 160 and 180 or at the level recommended by the physician responsible for the patient.

GROUND THE AUTOMATED IMPELLA CONTROLLER FOR AIR TRANSPORT

If the patient is being transported by helicopter or fixed-wing aircraft, the Automated Impella Controller should be grounded using a cable with the specifications below. Connect the cable to the Automated Impella Controller's equipotential ground stud (see Figure 4.2) and the aircraft's chassis ground.

Table 8.13 Specifications for Grounding Cable

Specifications for Grounding Cable	
Wire Material	New England Wire Tech N30-36T-7000-45UL, or equivalent
Length	≤ 900 mm
Termination to interface the Automated Impella Controller's equipotential ground stud	Staubi Electrical Connectors 55.3225-20, or equivalent
Termination to interface the aircraft's chassis ground	Mueller Electric BU-21APN, NTE Electronics 72-113, or equivalent
End-to-End resistance	<10 mOhms

ENABLE FLIGHT MODE FOR AIR TRANSPORT

Flight Mode is available for use during air transport. When active, Flight Mode disables the purge cassette RFID transmitter. The purge cassette continues to function and deliver purge fluid to the pump.

Enable Flight Mode by selecting **MENU** > Settings/Service > **Enable Flight Mode**. When Flight Mode is active, the white alarm (notification) below is displayed. Upon arrival at the receiving hospital, disable flight mode by selecting **MENU** > Disable Flight Mode.

Flight Mode Enabled	1. Connect controller to ground during air transport. 2. If equipped with Impella Connect, enable Flight Mode on module. 3. Upon arrival at receiving hospital, disable Flight Mode under MENU.
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EMISSIONS TESTING FOR AIR TRANSPORT

The Automated Impella Controller has been subjected to, and passed, the EMC/EMI tests as specified in IEC 60601-1-2:2014 (General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances—Requirements and tests). The Automated Impella Controller also meets the requirements for conducted emissions per RTCA DO-160G section 21.4, Category M, and for radiated emissions per RTCA DO-160G section 21.5, Category B.

TRANSPORT WITHIN THE HOSPITAL

Patients supported with the Impella System may require transport within the hospital.

Considerations for transport within the hospital:

- The Automated Impella Controller and Impella Catheter are designed to operate on battery power for at least 1 hour.
- Confirm that the battery capacity displayed on the controller is 100%.
- If transport time might be longer than 1 hour, bring an extension cord or confirm that you will be able to connect the controller to AC power once you arrive at your destination.
- When rolling the Automated Impella Controller cart across a threshold, firmly grasp the cart handle and pull it over the threshold.
- Pay close attention to all system components and connections when rolling the Automated Impella Controller cart over thresholds and through elevator doors.
- Do not stress the connector cable from the controller to the Impella Catheter.

VGA MONITOR CONNECTION

The Automated Impella Controller, which is equipped with a VGA output connector, which can be connected to a remote monitor to display the information from the controller to another screen at a resolution of 800 x 600 pixels. The connection between the controller and the monitor can be made using a cable up to 20 feet in length. If the AIC has the optional Impella Connect MDDS attached, the VGA Output connector is located on the back of the Impella Connect. The Impella Connect, can be used to transfer the video stream from the AIC, to a remote viewing location (via the internet).

The communication between the Impella Connect and the AIC is one-way. The streamed video data is limited to Impella device operating parameters and alarms messages. There is no patient identifiable information on any of the AIC screens. The Impella Connect will have to be configured by the hospital's IT department to access approved wireless networks. The video stream displayed via the Impella Connect web app enables remote patient monitoring by providing authorized users with passive viewing of the AIC's display which includes information on alarms and hemodynamic data useful for troubleshooting and managing Impella devices to aid in patient management.



During use with the Impella Connect, a Medical Device Data System (MDDS), if the Automated Impella Controller is exposed to strong electromagnetic disturbances, the Impella Connect may either restart or shut down. Operators should be aware that, under these conditions, the Automated Impella Controller operating parameters are not affected.



Do not insert any unauthorized devices into the USB port. This includes chargers, memory sticks, wireless dongles and other unauthorized devices.

ALARM DELAY INFORMATION

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

Table 8.14 Alarm Delay Information

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

PATIENT ENVIRONMENT

The Automated Impella Controller and the components of the Impella RP Flex with SmartAssist System are approved for use within the patient environment defined in IEC 60601-1: 3rd edition and in the figure below.

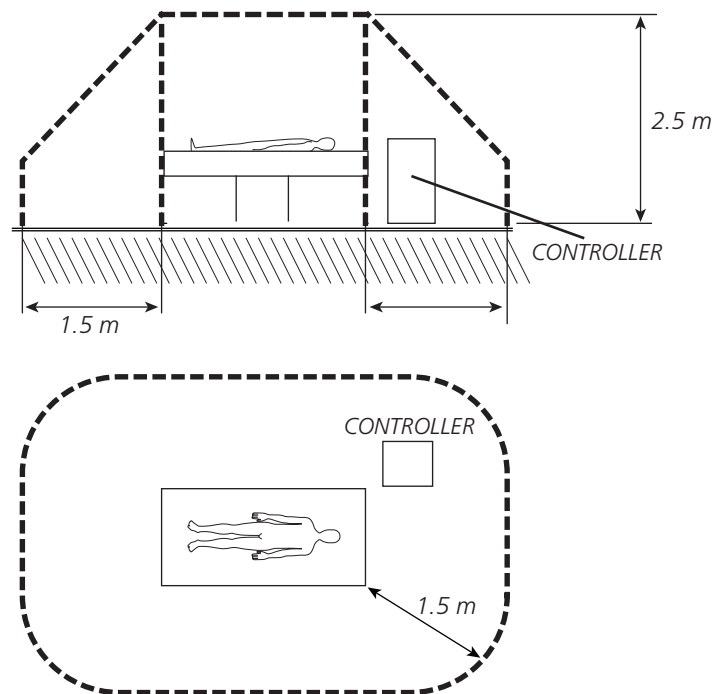


Figure 8.1 Automated Impella Controller Patient Environment

USE ENVIRONMENT

The Automated Impella Controller system is suitable for use in hospital and transport environments. For additional detail, please refer to section 2.1 and section 8.

IMPELLA RP FLEX WITH SMARTASSIST CATHETER PARAMETERS

Table 8.15 Impella Catheter Parameters

Speed range	0 to 33,000 rpm
Power consumption	Less than 23 W
Voltage	Max. 20 V DC
Flow-Maximum	4.0 L/min
Purging the Impella RP Flex with SmartAssist System Catheter	
Recommended purge fluid	5% glucose solution with heparin (25 or 50 IU per mL) or if heparin is contraindicated, sodium bicarbonate (25 or 50 mEq/L)
Dextrose concentration	5% to 20%
Purge pressure	300 to 1100 mmHg
Purge flow	2 to 30 mL/hr
Maximum duration of use	
US	Up to 14 days
Dimensions of Impella RP Flex with SmartAssist System Catheter	
Length of invasive portion (without catheter)	Approx 299 mm
Diameter	Max. 7.6 mm
Classification per DIN EN 60601-1	Protection class I, degree of protection: CF (Automated Impella Controller and Impella RP Flex with SmartAssist System Catheter)
Classification per directive 93/42/EEC	Class III
Latex content	Not made with natural rubber latex

Latex

The Automated Impella Controller and Impella RP Flex with SmartAssist System Catheter, including all accessories, are not made with natural rubber latex.

PUMP METRICS SPECIFICATIONS

Table 8.16 Pump Metrics Specifications

Frequency	Range	Accuracy*
Central Venous Placement Signal	0 to 25 mmHg	3.1 mmHg
PA Placement Signal	0 to 70 mmHg	5.6 mmHg
PAPi**	0-5	0.4
*the measured root mean square error (of multiple benchtop measurements)		
** PAPi is unitless		

Alcohol Warning

Do NOT clean the Impella Catheter infusion filter or pressure reservoir with alcohol and AVOID exposing these components to products containing alcohol.

Storing the Controller

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

CLEANING

- Clean the Automated Impella Controller keypad and display with either 70% isopropyl alcohol or soap and water. (NOTE: Be aware that soft buttons may be activated when you spray or wipe the display.)
- Clean the Automated Impella Controller housing with mild detergent.
- Do not allow any fluids to enter the connector sockets.
- Do NOT clean with or expose any part of the clear sidearm of the Impella Catheter (e.g., infusion filter, pressure reservoir) to alcohol. Alcohol has been shown to cause cracks and leaks in these components. Carefully read labels on common skin preps and lotions to avoid using any alcohol-containing products in the area of the infusion filter or pressure reservoir.

STORING THE AUTOMATED IMPELLA CONTROLLER



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

- Place the Automated 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 Automated Impella Controller is stored with a depleted battery.

RETURNING AN IMPELLA RP FLEX WITH SMARTASSIST SYSTEM CATHETER TO ABIOMED (UNITED STATES)

To return an Impella RP Flex with SmartAssist System Catheter to Abiomed, contact your local Clinical Consultant for an Abiomed-approved return kit.* The kit includes instructions for returning the Impella RP Flex with SmartAssist System Catheter to Abiomed.

** Only available in the United States*

DISPOSAL OF IMPELLA CATHETER AND ACCESSORIES

The Impella Catheter is a disposable item that must be disposed of in accordance with hospital regulations for blood contaminated materials.

The Automated Impella Controller is considered electric scrap and must be disposed of separately. Devices sold within the US can be returned to Abiomed US for correct disposal.

To return Abiomed products, contact the local Clinical Consultant for an Abiomed approved return kit. The return kit includes instructions for returning products to Abiomed.



APPENDIX A: ABIOMED-APPROVED INTRODUCERS A.1

APPENDIX B: AUTOMATED IMPELLA CONTROLLER MENU STRUCTURE B.1

 OverviewB.1

 Mute AlarmB.1

 Flow ControlB.1

 Display B.2

 Purge Menu B.2

 Menu B.3

APPENDIX A: ABIOMED-APPROVED INTRODUCERS

COMPATIBLE INTRODUCER SHEATHS

Abiomed has developed and qualified introducer kits for use with the Impella RP Flex with SmartAssist Catheters. These kits were specifically designed for use with the Impella RP Flex with SmartAssist Catheters and take into account several technical parameters, such as:

- Size of the sheath (internal diameter)
- Force required to pass the device through the hemostatic valve.

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

Table A.1 lists the introducer sheaths that have been qualified for use with the Impella RP Flex

Table A.1 Compatible Introducer Sheaths

Manufacture	Supplied/Alternative	FR	Length	Catalog Number
Abiomed, Inc	Supplied	23	11cm	2000342
Abiomed, Inc	Alternative	23	30 cm	0052-3069

If the patient has a tortuous iliac vein, consider using the available 30cm sheath for insertion of the Impella RP Flex with SmartAssist Catheter.

APPENDIX B: AUTOMATED IMPELLA CONTROLLER™ MENU STRUCTURE

OVERVIEW

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

- **MUTE ALARM**
- **FLOW CONTROL**
- **DISPLAY**
- **PURGE MENU**
- **MENU**

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

MUTE ALARM

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

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

FLOW CONTROL

The **FLOW CONTROL** soft button opens the performance level icon enabling you to select the desired performance level. The procedure for setting performance level is described in "Positioning and Starting the Impella RP Flex with SmartAssist System 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 PA Placement signal waveform and the Motor Current waveform
- **Center**—automatically centers the motor current waveform and adjusts the range accordingly.
- **Purge Infusion History**—opens the Purge Infusion History screen. The Purge Infusion History screen, which is discussed in section 4 of this manual, shows the volume and the amount of heparin, dextrose, and sodium bicarbonate delivered. The top entry in the table shows the volume and amount of heparin, dextrose, and sodium bicarbonate infused from the top of the hour through the current time.
- **Purge**—displays the purge system waveforms and pressure and flow values.
- **Placement**—displays the placement signal screen which includes the placement signal, PA, and the Motor Current Waveform (described in section 4 under “Placement Screen”).
- **Display Speed Pulse**— allows you to see the speed pulses in the Placement Signal as well as the Motor Current Waveform.
- **Trend** — displays trends of the Impella RP Flex with SmartAssist pump metric trend: Central Venous Placement Signal, PA Placement Signal, PAPi, and Impella Flow.

PURGE MENU

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

- **Change Purge Fluid Bag**—starts the procedure to change the purge fluid
- **Change Cassette and Bag**—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 5 of this manual.

MENU

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

- **Settings / Service**

- Service**

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

- Set Date/Time.** Displays the menu for changing the date and time

- USB Data Download.** When no pump is connected, this display appears for downloading data logs to a USB device

- Service Timers.** Displays the Service Timers menu. Console operating time and purge motor operating time are displayed in hours.

- 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.** When the software supports multi-language, this opens the Language selection box. 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.

- Disable (Enable) Retrograde Flow Control.**

- Disable (Enable) Audio – Placement Signal not Reliable.** Allows you to enable or disable audio for the Impella Placement Signal not Reliable alarm. This selection is available only if an Impella Placement Signal not Reliable alarm is active or the audio has been disabled for this alarm.

- Disable (Enable) Audio – Purge Pressure High / System Blocked.** Allows you to enable or disable audio for the Purge Pressure High or Purge System Blocked alarms. This selection is only available if one of these two alarms is active or the audio has been disabled for one of these alarms.

- Disable (Enable) Audio - Suction.** Allows you to enable or disable audio for Suction alarms. This selection is available only if a Suction alarm is active or the audio has been disabled for this alarm.

- Enable (Disable) Purge Flow Change Notifications.** Allows you to enable or disable the purge flow notification white alarms ("Purge Flow Increased" and "Purge Flow Decreased").

- Enable (Disable) Surgical Mode.** Allows you to enable or disable Surgical Mode. If Surgical Mode is enabled, the "Impella Stopped" alarm is silenced at P-0.

- Enable (Disable) Flight Mode.** Allows you to enable or disable Flight Mode. When active, Flight Mode disables the purge cassette RFID transmitter so that the controller cannot detect the purge cassette. If any purge system alarms are triggered during transport, the transport team should inform the managing hospital upon arrival.

- **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.
- **Start Data Snapshot**—starts the timed data recording function to save real-time operating data for later analysis.
- **Start Manual Zero**—opens the procedure for manually zeroing the differential pressure sensor.
- **Case Start**—begins the case procedure. Case Start is described in section 5 of this manual under “Case Start.”



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