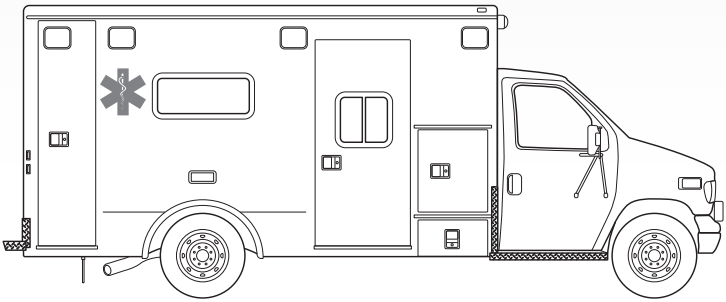
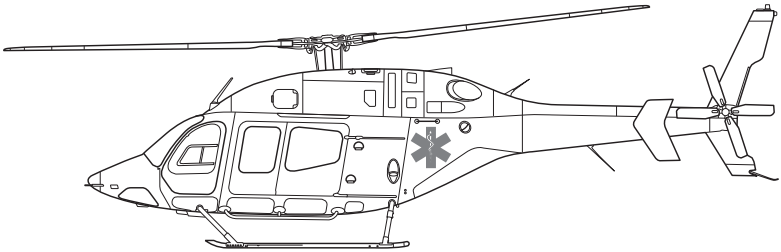
Patient Transport

with the Automated Impella® Controller





ABIOMED®

Recovering hearts. Saving lives.

TABLE OF CONTENTS

PURPOSE OF THESE INSTRUCTIONS

These instructions are designed for healthcare professionals to facilitate the safe transport of patients supported with the Automated Impella® Controller from one medical facility to another. This manual contains clinical and technical information to guide healthcare professionals before, during, and after transport.

INDICATION FOR USE

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

FAA ADVISORY

The Automated Impella® Controller has been subjected to, and passed the EMC/EMI tests as specified in IEC 60601-1-2 (General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests). Refer to the Electrical Safety Testing Appendix in this manual for more information.

The Automated Impella® Controller does not meet the requirements for conducted emissions of RTCA/DO-160G section 21.4 and has not been tested for radiated emissions per RTCA/DO-160G section 21.5. Abiomed recommends that air transport carriers follow the guidance FAA Advisory Circular AC No: 91-21.1B. Section 8-a of FAA Advisory Circular AC No: 91-21.1B states:

> "Equipment tested and found to exceed the section 21, Category M, emission levels are required to be evaluated in the operator's M-PED selected model aircraft for electromagnetic interference (EMI) and radio frequency interference (RFI). All navigation, communication, engine, and flight control systems will be operating in the selected aircraft during the evaluation."

ABOUT THE IMPELLA SYSTEM

The Impella® 2.5, 5.0, and LD are intravascular microaxial blood pumps that support a patient's circulatory system. The Impella® Catheter is inserted through the femoral or axillary artery into the left ventricle or, in the case of the LD, surgically via the ascending aorta. When properly positioned, the Impella® delivers blood from the inlet area, which sits inside the left ventricle, through the cannula, to the outlet opening in the ascending aorta. Users monitor the correct positioning and functioning of the Impella® on the display screen of the Automated Impella® Controller.

PATIENT TRANSPORT WITH THE IMPELLA SYSTEM

Patients are placed on the Automated Impella® Controller for either partial (Impella® 2.5) or full (Impella® 5.0/LD) circulatory support for periods up to 6 hours. If, during this time, a patient requires additional resources and specialized teams at another location (eg, a larger facility such as a transplant center), the patient may be transferred safely to such a location using the Automated Impella® Controller.

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

Abiomed encourages the establishment of a relationship between outlying centers (SPOKE facilities) and tertiary-care centers (HUB facilities). Criteria for accepting patients into a program should be determined between hospitals in advance of the need for a transfer.

Important 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. Abiomed recommends that air transport carriers follow the guidance FAA Advisory Circular AC No: 91-21.1B.
3. The Automated Impella® Controller should be fully charged prior to transport. Keep the controller connected to AC power (or an AC inverter) whenever possible.
4. 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.
5. Carefully monitor purge pressures during changes in altitude.
6. The controller should be positioned to allow easy access to the display screen and soft buttons to view alarms and make any necessary changes.
7. Maintain ACTs between 160 and 180 or at the level recommended by the physician responsible for the patient.
8. If possible, place the controller and the red Impella® plug at the level of the patient's heart during transport.
9. Decrease the flow rate if CPR is necessary.

Battery Operation

The Automated Impella® Controller is designed to operate for at least 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.

Transport with the Automated Impella Controller

1. Unplug the Automated Impella® Controller from AC power.
2. Rotate the T-knobs to unlock the controller from the cart.
3. Lift the controller off the cart using the blue handle.
4. Place the controller on a flat surface (seat, bench, shelf, or stretcher) or hang the controller on the end of the stretcher using the bed mount.
5. Remove the purge solution from the IV pole on the cart and place it on the IV pole of the stretcher or transport vehicle.
6. Secure the controller. If the controller is left unsecured, it can become a dangerous projectile inside the transport vehicle or aircraft.

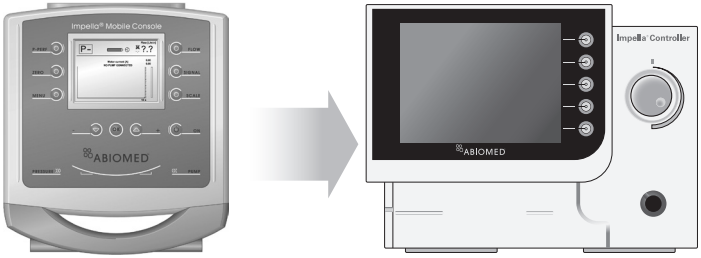
Securing the Automated Impella Controller

Options for securing the Impella® System during transport will vary by transport provider. Transport providers should take into consideration their particular vehicle, stretcher design, and accessory mounting options when planning to transport a patient supported by the Impella® System.

1. The Automated Impella® Controller has a bed mount on the back of the housing that may be used to hang the controller on the stretcher while the patient is transported inside the hospital.
2. Straps may be used to secure the Automated Impella® Controller to a flat surface in the transport vehicle.
3. The bed mount may be used as a loop through which to secure the straps.

TRANSFERRING SUPPORT FROM THE IMPELLA CONSOLE TO THE AUTOMATED IMPELLA CONTROLLER

If the sending hospital uses the Impella® Console (MPC), follow these steps to switch support from the Impella® Console to the Automated Impella® Controller *before* transport. This may require coordination with the receiving center to get the system to the sending hospital before transport.



Receiving Hospital Preparation

Gather the following items prior to switching support:

1. Automated Impella® Controller
2. White connector cable
3. Purge cassette
4. Purge solution (recommended 20% dextrose with 50 IU/mL of heparin)

How to Switch Support

1 Prepare

A. Turn on the Automated Impella® Controller.

B. Open the purge cassette and spike a new bag of purge solution.

C. Insert the purge cassette into the controller.

D. Open the white connector cable and plug it into the controller.

2 Switch

A. Disconnect the blue cable from the catheter.

B. Connect the white cable to the catheter.

C. Confirm re-starting the catheter on the controller. (The MPC system will still be purging the catheter at this point.)

3 Prime

A. Press **PURGE SYSTEM** on the controller and select Change Purge Fluid. (NOTE: There may be purge alarms on the console. Continue with the purge fluid change to complete the transfer. Check the alarms once the transfer has been completed.)

B. Complete the purge fluid change, making sure to flush the purge tubing.

C. Disconnect the old purge tubing.

D. Connect the new purge tubing.

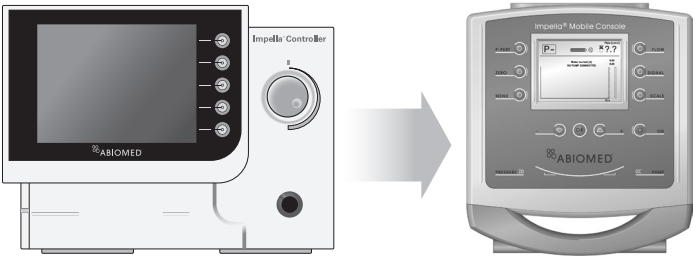
Patient Management Checklist

Check each of the following once patient support has been transferred:

- ☐ Confirm Impella® placement using echocardiography.
- ☐ Tighten the Tuohy bore on the Impella® Catheter to prevent catheter migration. (Tighten all the way to the right)
- ☐ For patients supported with the Impella® 2.5 Catheter, attach a saline pressure bag pressurized to 350 mmHg to the red sidearm and complete the "Transfer to Standard Configuration" under the **PURGE SYSTEM** menu.
- ☐ Contact the local team or the 24 hour clinical support line (1-800-422-8666) with any questions or concerns.

TRANSFERRING SUPPORT FROM THE AUTOMATED IMPELLA CONTROLLER TO THE IMPELLA CONSOLE

If the receiving hospital uses the Impella® Console (MPC), follow these steps to transition from the Automated Impella® Controller to the Impella® Console *after* transport.



Receiving Hospital Preparation

Gather the following items prior to switching support:

1. Impella® Console system (Console, infusion pump, and Impella® Power Supply on cart)
2. Blue connector cable
3. Grey pressure transducer cable
4. Infusion pump tubing
5. CM-Set
6. Purge solution (recommended 20% dextrose with 50 IU/mL of heparin)

How to Switch Support

1 **Prepare**	A. Turn on the Impella® Console. B. Set up the infusion pump and tubing. C. Connect the gray pressure transducer cable to the CM-Set and the Impella® Console. D. Plug the blue cable into the console. E. Press **PURGE SYSTEM** on the Automated Impella® Controller, select Change Purge Fluid, and complete the procedure to bolus the purge system. (Do NOT flush the purge fluid from the cassette).
2 **Switch**	A. Disconnect the purge cassette tubing ("Purge System Open" alarm will sound) B. Connect the new purge tubing and start the infusion. C. Disconnect the white cable from the Impella® Catheter. D. Connect the blue cable to the Impella® Catheter.
3 **Confirm**	A. Once the Impella® Catheter is connected to the Impella® Console, a message will appear on the screen asking you to confirm re-starting the Impella® Catheter at the previously set performance level. B. Press **OK** within 10 seconds to confirm restarting the Impella® Catheter.

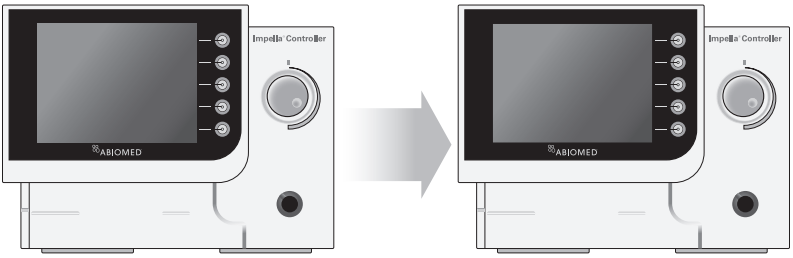
Patient Management Checklist

Check each of the following once patient support has been transferred:

- ☐ Confirm Impella® placement using echocardiography.
- ☐ Tighten the Tuohy bore on the Impella® Catheter to prevent catheter migration. (Tighten all the way to the right)
- ☐ For patients supported with the Impella® 2.5 Catheter, attach a saline pressure bag pressurized to 350 mmHg to the red sidearm.
- ☐ Contact the local team or the 24 hour clinical support line (1-800-422-8666) with any questions or concerns.

TRANSFERRING SUPPORT FROM THE AUTOMATED IMPELLA CONTROLLER TO A NEW AUTOMATED IMPELLA CONTROLLER

If the receiving hospital uses the Automated Impella® Controller, follow these steps to transition from the sending hospital's Automated Impella® Controller to the new Automated Impella® Controller after transport.



Receiving Hospital Preparation

Gather the following items prior to switching support:

1. Automated Impella® Controller from receiving hospital

How to Switch Support

1 Prepare

A. Confirm that the new controller is powered on and ready.

B. Press **PURGE SYSTEM** on the original controller, select Change Purge Fluid, and complete the procedure to bolus the purge system. (Do NOT flush the purge fluid from the cassette).

C. Disconnect the yellow luer connector from the Impella® Catheter to release the pressure in the purge cassette.

2 Switch

A. Transfer the purge cassette and purge solution from the original controller to the new controller.

B. Reconnect the yellow luer connector to the Impella® Catheter.

C. Remove the white connector cable from the original controller and plug it into the catheter plug on the front of the new controller.

3 Confirm

A. Once the Impella® Catheter is connected to the new controller, a message will appear on the screen asking you to confirm re-starting the Impella® Catheter at the previously set flow rate.

B. Press **OK** within 10 seconds to confirm restarting the Impella® Catheter.

Patient Management Checklist

Check each of the following once patient support has been transferred:

- ☐ Confirm Impella® placement using echocardiography.
- ☐ Tighten the Tuohy bore on the Impella® Catheter to prevent catheter migration. (Tighten all the way to the right)
- ☐ For patients supported with the Impella® 2.5 Catheter, attach a saline pressure bag pressurized to 350 mmHg to the red sidearm and complete the "Transfer to Standard Configuration" under the **PURGE SYSTEM** menu.
- ☐ Contact the local team or the 24 hour clinical support line (1-800-422-8666) with any questions or concerns.

APPENDIX: ELECTRICAL SAFETY TESTING

EMI – Conducted and Radiated Emissions		
Country or Standard	**Test Description**	**Test Standard**
60601-1-2	Radiated emissions, 30 – 1000 MHz, Group 1 Class A	CISPR 11 / EN55011
60601-1-2	Conducted emissions, 150 kHz – 30 MHz, Group 1 Class A	CISPR 11 / EN55011
US	FCC 47CFR 15C Cert	Title 47 CFR Part 15 Subpart C Intentional Radiator
EU	ETSI EN300-330-1 V1.5.1 (2006-04)	V1.5.1 (EMC) &(ERM); (SRD); Radio Equip. in the Frequency Range 9 KHz to 25 MHz and Inductive Loop Systems in the Frequency Range 9 KHz to 30 MHz; Part 1: Technical Characteristics and Test Methods
EU	ETSI EN300-330-2 V1.3.1 (2006-04)	V1.3.1 (EMC)& (ERM); Short Range Devices (SRD); Radio Equipment in the Frequency Range 9 KHz to 25 MHz and Inductive Loop Systems in the Frequency Range 9 KHz to 30 MHz; Part 2
EU	ETSI EN 301 489-1 Issued: 2007/04/01	V1.7.1 Electromagnetic compatibility and Radio spectrum Matters (ERM);Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common Technical Requirements
EU	ETSI EN 301 489-3 Issued: 2002/08/01	V1.4.1 (ERM) & (EMC) Standard for Radio Equipment and Services; Part 3: Specific Conditions for Short-Range Devices (SRD) Operating on Frequencies between 9 KHz and 40 GHz
Canada	RSS 210 Issue: 7 June 2007 A2.6	Low Power License – Exempt Radiocommunication Devices (All Frequency Bands)
Canada	RSS-GEN Issue: 2 June 2007	General Requirements and Information for the Certification of Radiocommunication Equipment

EMC Tests and Standards IEC 60601-1-2	
Test Description	**Test Standard**
Harmonic current emissions; Class A	IEC 61000-3-2
Limitation of voltage fluctuations and flicker	IEC 61000-3-3
Electromagnetic radiated field immunity	IEC 61000-4-3
Electromagnetic conducted field immunity	IEC 61000-4-6
Voltage dips and interruptions on AC power mains	IEC 61000-4-11
Magnetic fields immunity	IEC 61000-4-8
Electrically fast transients on AC power mains	IEC 61000-4-4
Surge on AC power mains	IEC 61000-4-5
Electrostatic discharge	IEC 61000-4-2
Review of EMC identification, markings and documents	Section 6

Automated Impella Controller Electrical Specifications	
Parameter	**Specification**
Temperature	Operating: 10°C to 40°C (50°F to 104°F) Storage: -15°C to 50°C (5°F to 122°F)
Relative humidity	Operating: 95% Storage: 95%
Atmospheric pressure	Operating: 8000 ft (750 hPa) to -1000 ft (1050 hPa) Storage: 18,000 ft (500 hPa) to -1000 ft (1050 hPa)
Dimensions	Height: 351 mm (13.8 in), Width: 443 mm (17.4 in), Depth: 236 mm (9.3 in)
Weight	Maximum: 11.8 kg (26.1 lbs)
Maintenance and repair interval	12 months (work must be performed by technicians authorized by Abiomed)
AC operation	100-230 V AC (nominal); 47-63 Hz; 1.1 A
Internal battery operation	14.4 V DC (nominal); lithium ion
Characteristic values	Max. power consumption under load 120 VA 9.7 fuses; 2 Amp. 250 V. 5 mm x 20 mm, slow blow fuses Run time without AC power (full charged batteries) 60 minutes minimum (charging duration of at least 5 hours)
Electrical system	Installation in accordance with pertinent regulations is required for use in medical facilities (eg, VDE 0100, VDE 0107, or ICE stipulations). Observe country-specific regulations and national deviations.

ABIOMED®

Recovering hearts. Saving lives.

Clinical support 24 hours per day, 7 days a week:
1-800-422-8666 (US)
+49 (0) 1805 2246633 (EU)
www.abiomed.com

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

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

December 2011 HCS-PM-1211-0267-0

CE 0086