Patient Transport
with the Automated Impella® Controller
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>PURPOSE OF THESE INSTRUCTIONS</td>
<td>2</td>
</tr>
<tr>
<td>INDICATIONS/CONTRAINDICATIONS FOR USE</td>
<td>2</td>
</tr>
<tr>
<td>FAA ADVISORY</td>
<td>6</td>
</tr>
<tr>
<td>ABOUT THE IMPELLA® SYSTEM</td>
<td>7</td>
</tr>
<tr>
<td>PATIENT TRANSPORT WITH THE IMPELLA® SYSTEM</td>
<td>7</td>
</tr>
<tr>
<td>Important Considerations</td>
<td>8</td>
</tr>
<tr>
<td>Battery Operation</td>
<td>8</td>
</tr>
<tr>
<td>Transport with the Automated Impella® Controller</td>
<td>9</td>
</tr>
<tr>
<td>Securing the Automated Impella® Controller</td>
<td>9</td>
</tr>
<tr>
<td>TRANSFERRING SUPPORT FROM THE AUTOMATED IMPELLA® CONTROLLER TO A NEW AUTOMATED IMPELLA® CONTROLLER</td>
<td>10</td>
</tr>
<tr>
<td>Receiving Hospital Preparation</td>
<td>10</td>
</tr>
<tr>
<td>How to Switch Support</td>
<td>11</td>
</tr>
<tr>
<td>Patient Management Checklist</td>
<td>12</td>
</tr>
<tr>
<td>APPENDIX: ELECTRICAL SAFETY TESTING</td>
<td>13</td>
</tr>
</tbody>
</table>
PURPOSE OF THESE INSTRUCTIONS

These instructions are designed for healthcare professionals to facilitate 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.

INDICATIONS FOR USE

The Automated Impella® Controller is an extracorporeal bypass control unit intended to be used to provide circulatory support for periods up to 6 hours. It is also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass. The Automated Impella® Controller is intended to be used by trained healthcare professionals in healthcare facilities and medical transport (i.e. ambulance, helicopter, or fixed-wing aircraft) environments.

The Automated Impella® Controller also displays pressure measurement readings, which are useful in determining intravascular pressure.

Impella® 2.5

The Impella® 2.5 is a temporary (≤ 6 hours) ventricular support device indicated for use during high risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option. Use of the Impella® 2.5 in these patients may prevent hemodynamic instability which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Contraindications and Warnings

The Impella® 2.5 is contraindicated for use with patients experiencing any of the following conditions: (1) mural thrombus in the left ventricle; (2) Mechanical aortic valve or heart constrictive device; (3) Aortic valve stenosis/calcification (equivalent to an orifice of 0.6 cm² or less); (4) Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as ≥ +2; and (5) Severe peripheral arterial disease that precludes the placement of the Impella® 2.5.
Additionally, potential for the following risks has been found to exist with use of the Impella® 2.5: Acute renal dysfunction; Aortic insufficiency; Aortic valve injury; Atrial fibrillations; Bleeding; Cardiogenic shock; Cardiac tamponade; Cardiopulmonary resuscitation; Cerebral vascular accident/Stroke; Death; Device malfunction; Failure to achieve angiographic success; Hemolysis; Hepatic failure; Insertion site infection; Limb ischemia; Myocardial infarction; Need for cardiac, thoracic or abdominal operation; Perforation; Renal failure; Repeat revascularization; Respiratory dysfunction; Sepsis; Severe hypotension; Thrombocytopenia; Thrombotic vascular (non-CNS) complications; Transient ischemic attack; Vascular injury; Ventricular arrhythmia; fibrillation or tachycardia.

**Impella CP®**

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

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

Contraindications and Warnings

The Impella CP® is contraindicated for use with patients experiencing any of the following conditions: (1) Mechanical aortic valve or heart constrictive device; (2) Aortic valve stenosis/calcification (graded as ≥ +2 equivalent to an orifice of 1.5 cm² or less); (3) Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as ≥ +2; and (4) Severe peripheral arterial disease that would preclude Impella® device placement. Additionally, potential for the following risks has been found to exist with use of the Impella CP®: Aortic insufficiency; Aortic valve injury; Arrhythmia; Atrial fibrillation; Bleeding; Cardiogenic shock; Cardiac tamponade; Cerebral vascular accident (CVA)/Stroke; Death; Device malfunction; Hemolysis; Hepatic failure; Insertion site infection; Myocardial infarction; Perforation; Renal failure; Respiratory dysfunction; Sepsis; Thrombocytopenia; Thrombotic vascular (non-CNS) complication; Transient ischemic attack (TIA); Vascular injury; Ventricular fibrillation; Ventricular tachycardia.
**Impella® 5.0**

The Impella® 5.0 Circulatory Support System is intended for circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The Impella® 5.0 Circulatory Support System also provides pressure measurements which are useful in determining intravascular pressure.

**Contraindications and Warnings**

The Impella® 5.0 is contraindicated for use with patients experiencing any of the following conditions: (1) Mechanical aortic valve or heart constrictive device; (2) Aortic valve stenosis/calcification (graded as $\geq +2$ equivalent to an orifice of 1.5 cm$^2$ or less); (3) Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as $\geq +2$); and (4) Severe peripheral arterial disease that would preclude Impella® device placement. Additionally, potential for the following risks has been found to exist with use of the Impella® 5.0: Aortic insufficiency; Aortic valve injury; Arrhythmia; Atrial fibrillation; Bleeding; Cardiogenic shock; Cardiac tamponade; Cerebral vascular accident (CVA)/Stroke; Death; Device malfunction; Hemolysis; Hepatic failure; Insertion site infection; Myocardial infarction; Perforation; Renal failure; Respiratory dysfunction; Sepsis; Thrombocytopenia; Thrombotic vascular (non-CNS) complication; Transient ischemic attach (TIA); Vascular injury; Ventricular fibrillation; Ventricular tachycardia.

**Impella® LD**

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

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

**Contraindications and Warnings**

The Impella® LD is contraindicated for use with patients experiencing any of the following conditions: (1) Mechanical aortic valve or heart constrictive device; (2) Aortic valve stenosis/calcification (graded as $\geq +2$ equivalent to an orifice of 1.5 cm$^2$ or less); (3) Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as $\geq +2$). Additionally, potential
for the following risks has been found to exist with use of the Impella® 5.0:
Aortic insufficiency; Aortic valve injury; Arrhythmia; Atrial fibrillation; Bleeding;
Cardiogenic shock; Cardiac tamponade; Cerebral vascular accident (CVA)/Stroke;
Death; Device malfunction; Hemolysis; Hepatic failure; Insertion site infection;
Myocardial infarction; Perforation; Renal failure; Respiratory dysfunction; Sepsis;
Thrombocytopenia; Thrombotic vascular (non-CNS) complication; Transient
ischemic attach (TIA); Vascular injury; Ventricular fibrillation; Ventricular
tachycardia.

**Impella RP®**

The Impella RP® System is indicated for providing circulatory assistance for up
to 14 days in pediatric or adult patients with a body surface area ≥ 1.5 m² who
develop acute right heart failure or decompensation following left ventricular
assist device implantation, myocardial infarction, heart transplant, or open-heart
surgery.

**Contraindications and Warnings**

The Impella RP® is contraindicated for use with patients experiencing any
of the following conditions: (1) Disorders of the pulmonary artery wall that
would preclude placement or correct positioning of the Impella RP® device;
(2) Mechanical valves, severe valvular stenosis or valvular regurgitation of the
tricuspid valve or pulmonary valve; (3) Mural thrombus of the right atrium or
vena cava; (4) Anatomic conditions precluding insertion of the pump; (5) Other
illnesses or therapy requirements precluding use of the pump; and (6) Presence
of a vena cava filter or caval interruption device, unless there is clear access
from the femoral vein to the right atrium that is large enough to accommodate
a 22 Fr catheter. Additionally, potential for the following risks has been found
to exist with use of the Impella RP®: Arrhythmia; Atrial fibrillation; Bleeding;
Cardiac tamponade; Cardiogenic shock; Death; Device malfunction; Hemolysis;
Hepatic failure; Insertion site infection; Perforation; Phlegmasia cerulean dolens
(a severe form of deep venous thrombosis); Pulmonary valve insufficiency;
Respiratory dysfunction; Sepsis; Thrombocytopenia; Thrombotic vascular (non-
CNS) complication; Tricuspid valve injury; Vascular injury; Venous thrombosis;
Ventricular fibrillation and/or tachycardia.
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, Impella CP®, Impella® 5.0/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.

The Impella RP® is an intravascular microaxial blood pumps that support a patient’s pulmonary circulation. It pushes blood from the IVC into the pulmonary artery, bypassing the right ventricle.

PATIENT TRANSPORT WITH THE IMPELLA® SYSTEM

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. 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.

Patients are placed on the Automated Impella® Controller for either partial (Impella® 2.5 and Impella CP®) or full (Impella® 5.0/LD) circulatory support for periods up to 6 hours. Patients on the Impella RP® may be on support for up to 14 days. If, during this time, a patient requires additional resources and specialized teams at another location (a larger facility such as a transplant center), the patient may be transferred 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 to P2 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 AUTOMATED IMPELLA® CONTROLLER TO A NEW 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 backup 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 backup 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 backup controller.

3 Confirm

A. Once the Impella® Catheter is connected to the backup controller, a message will appear on the screen asking you to confirm re-starting the Impella® Catheter at the previously set P-level
B. Press OK within 10 seconds to confirm restarting the Impella® Catheter at the previously set P-level.
C. If the message to restart the Impella® Catheter does not appear within 1 minute, restart the Impella® Catheter using the FLOW CONTROL soft button.

To get accurate purge values after changing to a backup controller, perform the Change Purge Fluid procedure.
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 or Impella CP® 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

<table>
<thead>
<tr>
<th>Country or Standard</th>
<th>Test Description</th>
<th>Test Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>60601-1-2</td>
<td>Radiated emissions, 30 – 1000 MHz, Group 1 Class A</td>
<td>CISPR 11 / EN55011</td>
</tr>
<tr>
<td>60601-1-2</td>
<td>Conducted emissions, 150 kHz – 30 MHz, Group 1 Class A</td>
<td>CISPR 11 / EN55011</td>
</tr>
<tr>
<td>US</td>
<td>FCC 47CFR 15C Cert</td>
<td>Title 47 CFR Part 15 Subpart C Intentional Radiator</td>
</tr>
<tr>
<td>Canada</td>
<td>RSS 210 Issue: 7 June 2007 A2.6</td>
<td>Low Power License – Exempt Radiocommunication Devices (All Frequency Bands)</td>
</tr>
<tr>
<td>Canada</td>
<td>RSS-GEN Issue: 2 June 2007</td>
<td>General Requirements and Information for the Certification of Radiocommunication Equipment</td>
</tr>
</tbody>
</table>

## EMC Tests and Standards

**IEC 60601-1-2**

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Test Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmonic current emissions; Class A</td>
<td>IEC 61000-3-2</td>
</tr>
<tr>
<td>Limitation of voltage fluctuations and flicker</td>
<td>IEC 61000-3-3</td>
</tr>
<tr>
<td>Electromagnetic radiated field immunity</td>
<td>IEC 61000-4-3</td>
</tr>
<tr>
<td>Electromagnetic conducted field immunity</td>
<td>IEC 61000-4-6</td>
</tr>
<tr>
<td>Voltage dips and interruptions on AC power mains</td>
<td>IEC 61000-4-11</td>
</tr>
<tr>
<td>Magnetic fields immunity</td>
<td>IEC 61000-4-8</td>
</tr>
<tr>
<td>Electrically fast transients on AC power mains</td>
<td>IEC 61000-4-4</td>
</tr>
<tr>
<td>Surge on AC power mains</td>
<td>IEC 61000-4-5</td>
</tr>
<tr>
<td>Electrostatic discharge</td>
<td>IEC 61000-4-2</td>
</tr>
<tr>
<td>Review of EMC identification, markings and documents</td>
<td>Section 6</td>
</tr>
</tbody>
</table>
### Automated Impella® Controller Electrical Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Operating: 10°C to 40°C (50°F to 104°F)</td>
</tr>
<tr>
<td></td>
<td>Storage: -15°C to 50°C (5°F to 122°F)</td>
</tr>
</tbody>
</table>
| 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     | 12 months (work must be performed by technicians authorized by Abiomed)      |
| interval                   | 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)
www.abiomed.com