# PediMag® Blood Pump

# Instructions For Use (IFU)

**READ ENTIRE CONTENTS PRIOR TO USING THE BLOOD PUMP**

**THIS PRODUCT IS LABELED FOR USE OUTSIDE THE UNITED STATES.**
**IT IS NOT AVAILABLE AS LABELED IN THE UNITED STATES.**

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|---|---|---|
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℞ Only

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**SUPPLIED STERILE AND READY FOR USE – DO NOT USE IF PACKAGING IS DAMAGED OR ANY STERILE SEALS ARE BROKEN.**

**WARNING (Definition)**

**Warnings are used if there is a potential for a serious hazard with misuse of the device, when special attention is required for safety of the patient, or when special care should be exercised to prevent improper operation of the device that may cause damage.**

**CAUTION (Definition)**

**Cautions are used to alert the user to exercise special care for the safe use of the device.**

## DESCRIPTION

The PediMag Blood Pump has an impeller that imparts rotary motion to the incoming blood, directing it through the outflow port. The PediMag Blood Pump is designed to allow improved blood handling and to decrease trauma, which may be associated with extracorporeal circulatory support during cardiopulmonary bypass, by magnetically levitating the impeller and by eliminating seals and bearings.

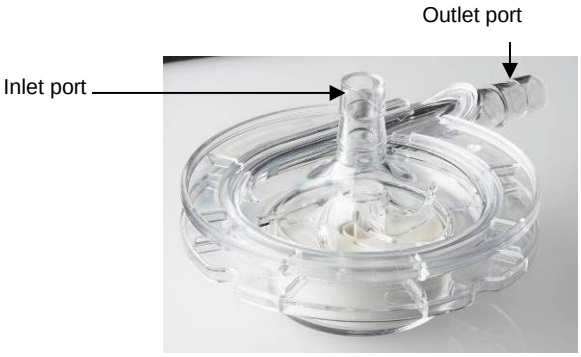



**Figure 1 – PediMag Blood Pump**

The PediMag Blood Pump couples to a magnetic drive motor which is connected to the CentriMag console.

## INDICATIONS FOR USE

The PediMag Blood Pump is indicated for use with the CentriMag Console and Motor to pump blood through a complete extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours) for surgical procedures such as a mitral valve reoperation. It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, surgery of the vena cava or aorta, liver transplants etc.).

The PediMag Pump can generate a maximum pump flow equal to 1.5 liters per minute, limiting its use to pediatric patients.

The PediMag Blood Pump is indicated for use only with the CentriMag Console and Motor.

## CONTRAINDICATIONS

The PediMag Blood Pump is contraindicated for use as a cardiotomy suction device. It is also contraindicated for patients who are unable or unwilling to be treated with heparin or an appropriate alternative anticoagulation.

## INSPECTION PRIOR TO USE

1. The package containing the blood pump should be inspected prior to use for any damage to the sterile barriers. The package seals should be intact to insure sterility. Do not use the Blood Pump if the package is damaged. Contact Thoratec regarding return of any damaged product.

2. The Blood Pump should be inspected prior to use for any damage or particulate matter contamination. Do not use the Blood Pump if damaged or if any particulate matter is found on or inside the Blood Pump. Contact Thoratec regarding return of any suspect Blood Pump.

## WARNINGS

1. The PediMag Blood Pump has not been qualified through in vitro, in vivo, or clinical studies for long term us (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or for extracorporeal membrane oxygenation.

2. Carefully read all Warnings, Precautions, Manuals, and Instructions for Use for this and all related Thoratec extracorporeal devices prior to use. Failure to read and follow all instructions, or failure to observe all stated warnings, could cause serious injury or death to the patient.

3. Possible side effects include, but are not limited to: infection, mechanical failure, hemolysis, end organ dysfunction, neurologic dysfunction, bleeding, and embolic phenomena. These are potential side effects with all mechanical circulatory support systems.

4. Ensure that the PediMag Blood Pump and circuit have been debubbled and primed properly prior to use to minimize the risk of air entry to the patient. The use of an arterial filter is recommended.

5. Massive air entry into the PediMag Blood Pump will cause the Blood Pump to deprime and blood flow to stop. Clamp the outlet tubing and stop the Blood Pump and remove air prior to resuming circulation.

6. Do not expose the PediMag Blood Pump to chemical agents as they may affect the integrity of this device. Anesthesia solutions such as forane are known to degrade polycarbonate plastics.

7. To prevent backflow of the patient's blood when the Blood Pump outlet tubing is open, establish and maintain a minimum pump speed that overcomes line and patient resistance. Failure to do this could allow retrograde flow and limit arterial pressure.

8. A Blood Pump stoppage will create a reverse flow shunt through the Blood Pump, as well as limit the body's ability to maintain adequate arterial pressure. If the Blood Pump is stopped, clamp the outlet tubing from the Blood Pump to prevent a low flow, low pressure, and reverse flow condition. The tubing clamp must be removed before returning to normal pumping activity.

9. It is intended that systemic anticoagulation be utilized while this device is in use. Anticoagulation levels should be determined by the physician based on risks and benefits to the patient.

10. The PediMag Blood Pump is designed to be operated only with the CentriMag drive Console. There are no safety or performance data known to Thoratec that establish compatibility of any other manufacturer's devices or components to the PediMag Blood Pump.

11. Potential risk to the patient should be evaluated prior to changing a PediMag Blood Pump.

12. Frequent patient and device monitoring is recommended.

13. Do not use the PediMag Blood Pump if the "Use Before" Date on the package has past or expired.

14. Do not operate the PediMag Blood Pump in the absence of forward flow. The temperature within the Blood Pump will rise and increased cellular damage and clotting may result.

15. The PediMag Blood Pump must be handled in an aseptic manner until primed and connected to a closed tubing circuit.

16. Do not operate the PediMag Blood Pump with its inlet tubing clamped as a negative pressure will be generated in the Blood Pump and air bubbles may be formed in the priming fluid or blood.

17. Monitor the patient's hemodynamics and the Console Flow display to insure adequate blood volume for the inlet cannula position, Blood Pump RPM, and desired flow. Increase Blood Pump RPM in small increments to minimize the risk of exceeding the available blood volume and causing inlet cannula obstruction, suction, outgassing, and/or cavitation.

18. As with all continuous flow pumps, operating at too high a speed can result in negative pressure at the inlet which can lead to collapse of the ventricle or blood vessels, inlet cannula obstruction, inspiration of air, outgassing, cavitation and increased risk of embolism. Always operate the system at the lowest speed consistent with the volume of blood available to be pumped and clinically acceptable circulatory support.

19. The PediMag Blood Pump contains a magnet. To avoid injury, keep all sharp metal objects and instruments at least six inches away for the Blood Pump. Do not remove the PediMag Blood Pump from its inner tray until ready to assemble the circuit and insert pump into the motor receptacle.

20. If PediMag Blood Pump operation is ever halted or flow reduced, consideration should be given to monitoring and adjustment of the patient's anticoagulation status.

21. Do not restart the PediMag Blood Pump if the Blood Pump has been stopped for more than 5 minutes without adequate anticoagulation, as the risk of thromboembolism is increased after blood has remained stagnant in the Blood Pump, extracorporeal circuit, and connectors.

22. Monitor the pump and tubing for air because the PediMag Blood Pump, similar to other centrifugal pumps, will pump air. Immediately clamp Pump outlet tubing if air enters the PediMag Blood Pump as gaseous emboli may be introduced into

the patient, with attendant risk of death or severe bodily injury. A massive air embolus will deprime the Pump, halting blood flow.

23. Use of this Pump for periods longer than durations appropriate to cardiopulmonary bypass procedures may result in pump failure, reduced pumping capacity, excessive blood trauma, degradation of blood contact materials with possibility of particles passing through the blood circuit to the patient, leaks, and increased potential for gaseous emboli.

**CAUTIONS**

1. Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

2. This device should only be used by persons thoroughly trained in extracorporeal circulation procedures.

3. Do not hit or strike the PediMag Blood Pump with hands, objects, or instruments. Do not strike the PediMag Blood Pump against any surface or object. Shock may cause damage to the device, which may cause device malfunction.

4. The PediMag Blood Pump is sterile in an unopened and undamaged unit package. Inspect device and package carefully prior to use. Do not use if the unit package or the product has been dropped, damaged or soiled.

5. Each PediMag Blood Pump is intended for single use only. Do not resterilize. Resterilization by any means may cause severe damage to the device or its components. Dispose of safely after single use to avoid risk of infection.

6. Attach tubing to the Blood Pump in such a manner as to prevent kinks or restrictions that may alter flow or cause regions of stasis or turbulence. Attach in a manner that does not bend or fracture the tubing connectors or ports. Advance tubing beyond the second barb point of the Blood Pump connectors.

7. The inlet and outlet tubing connections must be secured with two small (approximately 10 cm length) cable-ties or tie bands on each connector. The locking mechanisms of the two ties should be oriented 180 degrees from each other to insure a tight seal of the tubing to the connector.

8. Ensure the PediMag Blood Pump is properly locked into the CentriMag Motor.

9. Monitor carefully for any signs of occlusion throughout the circuit.

10. Do not operate the PediMag Blood Pump when unprimed as it may damage the Blood Pump impeller.

11. Run the PediMag Blood Pump only on a properly maintained CentriMag drive Console and Motor.

12. Do not use the PediMag Blood Pump if it has been dropped. Dropping or other severe shock may cause damage which could lead to device malfunction.

13. Do not use excessive force to install tubing on the PediMag Blood Pump as damage to the Blood Pump and 1/4” pump ports may occur.

14. Take care to prevent damage to PediMag Blood Pump connectors when setting-up and de-airing the Blood Pump.

15. Always have a spare PediMag Blood Pump, Back-Up Console, motor, and accessories available for change out.

16. Do not place PediMag Blood Pump near items adversely affected by magnetic fields.

17. The PediMag Blood Pump has been qualified for use with the Transonic H7XLF-series flow probe. Do not use any other flow probe as their performance has not been qualified for use with the PediMag Blood Pump.

**PRE-PUMPING CHECKLIST**

1. Connect the CentriMag Motor to the CentriMag Console.

2. Check that all electrical connections are secure including flow probe and AC power cord.

3. Test the CentriMag Console by powering it up; verify that there are no self-test errors on boot-up.

4. Check the date and integrity of sterile PediMag Blood Pump package.

5. Check that a Transonic H7XLF flow probe is available for use with the CentriMag Primary Console and is clean and ready for use. CentriMag Back-Up Console does not have flow measurement capability hence a flow probe is not included with the Back-Up Console.

**BLOOD PUMP SETUP AND OPERATION**

The CentriMag System is designed to be operated safely during use of ESU’s (electrosurgery or electrocautery units). An ESU, a frequently used RF technology, is used to cut, cauterize, fulgurate or desiccate tissue. Note: ESUs have the potential for

interfering with other medical devices found in the operating and ICU room environment.

If the CentriMag Primary or Back-Up Consoles are used concurrently with an Electrosurgery unit, Thoratec recommends the user reads and follows the electrocautery manufacturer's instructions for prevention of interference with other electronic devices.

Follow the system preparation directions in the Operating Manual for the CentriMag Primary Console. Inspect the complete system; do not use a malfunctioning or damaged system.

1. Determine the proper position for the Pump in the extracorporeal circuit. During use, the Pump fills by gravity from the reservoir and by the gentle suction generated by the spinning impeller. To reduce the potential for air embolism from inadvertent emptying of the reservoir and subsequent introduction of air into the Pump, the Pump is typically positioned near and just below the outlet of the reservoir from which the blood will be pumped.

2. To mount the PediMag Blood Pump on the CentriMag Motor, remove the Blood Pump from the inner tray and insert the Blood Pump into the motor receptacle. Place the bottom of the Blood Pump into the motor receptacle with the outlet port positioned in the large groove. Match the grooves on the periphery of the Blood Pump with the fittings on the motor receptacle. **ROTATE BLOOD PUMP COUNTERCLOCKWISE** until the Blood Pump locks securely into place. Thread the retaining screw clockwise to secure in place. The PediMag Blood Pump must be fully seated into the receptacle to function properly.

   **Note:** If the PediMag Blood Pump is not properly seated an alarm "Pump Not Inserted" will be displayed on the CentriMag Console display.

3. Assemble the extracorporeal circuit; be sure to connect the inlet and outlet tubing to the correct pump inlet and outlet. Connect 1/4 inch Inner Diameter (ID) x minimum 3/32 inch wall tubing from the reservoir outlet to the pump inlet. Attach 1/4 inch ID tubing to the pump outlet. Band all connections.

4. **Note:** If a roller Pump is used for standby equipment, leave sufficient tubing so that the Blood Pump line can be placed in the roller Pump.

5. To remove the PediMag Blood Pump from the CentriMag Motor, unthread the retaining screw counterclockwise, and then rotate the Blood Pump clockwise until the grooves are matched. Lift and remove the Blood Pump.

**RECOMMENDED PUMPHEAD PRIMING PROCEDURE**

1. With accepted aseptic technique, attach the appropriate tubing to the inlet and outlet of the Pump. (Applying a sterile saline solution to the inlet/outlet connectors may aid tubing attachment.)

2. Where practical, flush the circuit and the Pump with $CO_2$ (from filter or reservoir bag.)

3. Fill the Pump with prime, by gravity, to a point beyond the flow probe and clamp. Eliminate air from the device by "walking" the air out of the inlet.

**CAUTION**

**Do not hit or strike the PediMag Blood Pump with hands, objects, or instruments. Do not strike the PediMag Blood Pump against any surface or object. Shock may cause damage to the device, which may cause device malfunction.**

**WARNING**

**Ensure that the Blood Pump and circuit have been debubbled and primed properly to minimize the risk of air reaching the patient. The use of an arterial filter is recommended.**

**WARNING**

**Massive air entry into the Blood Pump will cause the Blood Pump to deprime and blood flow to stop. Clamp the outlet tubing, stop the Blood Pump, and remove air prior to resuming circulation.**

6. Connect the Transonic H7XLF-series flow probe to the outlet tubing according to the instructions provided in the CentriMag Console Operating Manual.

7. With the inlet tubing unclamped, and the outlet tubing clamped, turn the CentriMag Console ON.

8. Remove all remaining tubing clamps, bring the PediMag Blood Pump's RPM up to a sufficient speed to achieve a positive flow, inspect the integrity of the Blood Pump, the tubing, and the connections, if any anomalies are noted, immediately stop the Blood Pump, clamp the outlet tubing and correct the anomaly before unclamping and restarting.

**WARNING**

**Do not operate the Blood Pump in the absence of forward flow. The temperature within the Blood Pump may rise and increased cellular damage may result.**

**WARNING**

**Do not operate the Blood Pump with the inlet tubing or cannula clamped as a negative pressure will be generated in the Blood Pump and bubbles may form in the Pump.**

**WARNING**

**If leaks or other anomalies are found on the PediMag Blood Pump, remove the Blood Pump and replace with a new, sterile Blood Pump, repeating the above steps to prime.**

9. If no anomalies are noted, continue the priming of your circuit in the usual fashion.

10. Verify all connections and the integrity and flow of your circuit prior to use.

**CAUTION**

**Placing a tubing clamp on the tubing near a tubing connection point can damage the connector, resulting in thrombus formation at the area of the damage.**

11. Increase RPM to produce desired flow.

12. Set the Console's low flow alarm to the desired minimum flow point.

13. Secure the motor in order to maintain its location in relation to the patient.

**WARNING**

**As with any continuous flow pump, operating at too high a speed can result in negative pressure at the inlet which can lead to inspiration of air, out gassing, cavitation and increased risk of embolism. Always operate the system at the lowest speed consistent with the volume of blood available to be pumped.**

**CAUTION**

**Any time the PediMag Blood Pump is stopped the pump outlet should be clamped to prevent retrograde flow. The clamp used should be a smooth jawed tubing clamp.**

**PRE-BYPASS CHECKLIST**

**1. EQUIPMENT ASSEMBLY**

a. Mount Motor correctly, relative to venous reservoir.
b. Check that all electrical connections are secure.
c. Check Console power and display.
d. Check the date and integrity of sterile Blood Pump package.
e. Check that flow probe is sized properly.
f. Assemble perfusion circuit in sterile manner.
g. Allow sufficient tubing length for standby pumping unit.
h. Connect flow probe to circuit in correct location and flow direction.

**2. PRIME, PUMP AND CIRCUIT**

a. $CO_2$ flush Pump and circuit. If indicated, turn OFF $CO_2$.
b. Gravity-prime and debubble Pump and perfusion circuit.
c. Check Pump for leaks, irregular motion, and noise.
d. Check circuit for visible air.
e. Check that all tubing connections are secure.
f. Check Pump outlet line completely.

g. Clamp venous return line completely.

**3. OPERATING PARAMETERS**

a. Set low flow alarm.
b. Verify low flow alarm.
c.

**4. EMERGENCY BACK-UP EQUIPMENT**

a. A CentriMag back-up Console must be plugged in with motor and flow probe connected (if designed to accommodate a flow probe), and kept near the patient ready for use.
b. A sterile back-up PediMag Blood Pump circuit and priming accessories must be available.
c. Back-up power must be available.
d. Two smooth jawed tubing clamps must be available.

## PERFUSION

a. Achieve minimum Pump speed prior to unclamping lines.
b. Monitor Console for message and alarms.
c. Monitor perfusion circuit for visible air.
d. Maintain minimum Pump speed prior to clamping lines.

## DEVICE REMOVAL/DISPOSAL

Properly discard disposable components according to hospital procedure for contaminated materials.

## RETURNING HARDWARE TO STORAGE

a. Turn OFF power to the CentriMag Primary and Back-Up Consoles.
b. Clean CentriMag Console and CentriMag Motor according to established hospital procedure.
c. Clean flow probe according to established hospital procedure.
d. Reconnect CentriMag Consoles to AC power to maintain charge on batteries.

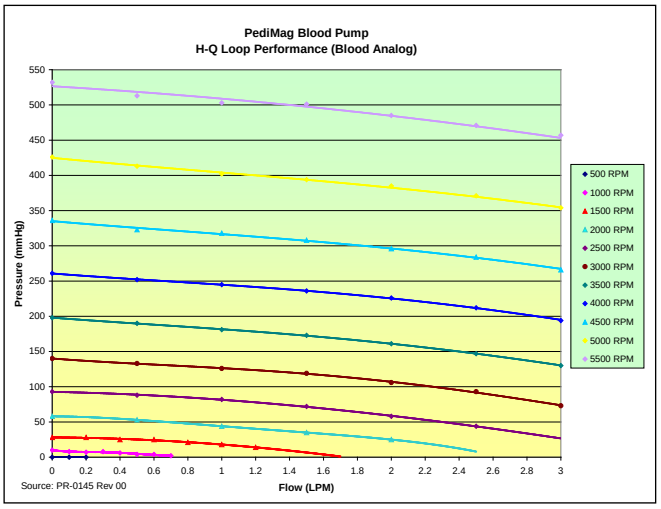
## EMERGENCY PUMP REPLACEMENT

If the PediMag Blood Pump has been OFF for more than five minutes without adequate anticoagulation it will be necessary to replace all of the disposable components before support can be resumed. If there has been a CentriMag Motor overheating condition, it will be necessary to either terminate pumping OR replace the Blood Pump and return circuit components.

To replace the PediMag Blood Pump, disconnect the Blood Pump from the CentriMag Motor and any affected tubing. Attach the replacement Blood Pump per the standard procedures described above, prime and debubble. Operate the CentriMag Console as described in the CentriMag Console Operating Manual.

## PRESSURE VS FLOW GRAPH

The PediMag Blood Pump output is pressure responsive. In the graph below, the Pump flow rate (L/min) versus the outlet pressure (mmHg) is plotted at a variety of pump speeds using a blood analog with a viscosity of 3.9 cp at 37°C. This graph does not necessarily reflect the rates to be achieved under clinical conditions.




**Note:** Actual obtainable flow is dependent on the difference between the preload and afterload of the Blood Pump (pump pressure differential).

## BLOOD PUMP SPECIFICATIONS

| | |
|---|---|
| Blood contact materials: | Polycarbonate |
| Pump priming volume: | 14 ml |
| Pump rotational range: | 0-5,500 RPM |
| Outflow capacity: (see graph) | 0-1.5 L/min |
| Outflow pressure: (see graph) | 0-540 mmHg |
| Circuit tubing: | 1/4 X 3/32 inch |

## STORAGE CONDITIONS

Temperature: 0 – 40°C (32 – 104°F)

## OPERATING CONDITIONS

Temperature: 15 – 40°C (59 – 104°F)

## PRODUCT RETURNS

Prior to returning any product, contact your Thoratec Customer Service Representative for a return authorization and instructions.

## SYMBOLS ON THE PRODUCT PACKAGE

The following table describes the symbols used on PediMag Blood Pump package:

| Symbol | Description |
|---|---|
|  | Catalog Number. |
|  | Lot Number. |
|  | Use By Date. |
|  | For single use only. Do not reuse. |
|  | Sterilized with ethylene oxide gas. |
|  | See Instructions for Use. |
|  | Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. |
|  | The contents of the packaging are by means of a validated method proven to be PYROGEN free. |
|  | Symbol for manufacturer. |
|  | Symbol for temperature limitation/temperature range. Both upper and lower limits are indicated adjacent to horizontal lines. |