CentriMag™ Acute Circulatory Support System

BLOOD PUMP OVERVIEW[1,2]

There are two parameters monitored by the CentriMag™ Acute Circulatory Support System: pump speed, measured in revolutions per minute (RPM), and flow, measured in liters per minute (LPM) via an ultrasonic flow probe. When using the CentriMag™ Acute Circulatory Support System, pressure monitoring can be utilized.

SPECIFICATIONS

- Fully magnetically levitate pump; no bearings or seals
- Centrifugal pump
- Utilized for right, left, biventricular and cardiopulmonary support
- 3/8" barbed inlet
- Made of polycarbonate housing
- Disposable
- Priming volume: 31 mL
- Maximum flow: 10 LPM
- Maximum pressure: 600 mmHg

SPEED

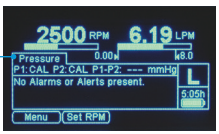
- Fixed speed range is 0–5,500 RPM
- Typical operating speed range is 3,000–5,000 RPM
- At least 1,000 RPM is needed to obtain forward flow (keep the outflow clamped until >1,000 RPM)
- Minor speed changes may have impact on flow
- Speed can be changed using either the monitor or console speed toggle button
- Monitor and console display the pump speed in RPM

FLOW

- Flow is measured in LPM via the flow probe
  - Accurate to 10 LPM; typical flow is 4–5 LPM
- Reposition the flow probe per hospital guidelines
- Increase flow by increasing pump speed
- Contribution from the native heart may impact flow
- Minimum and maximum flow alerts should be set per hospital guidelines

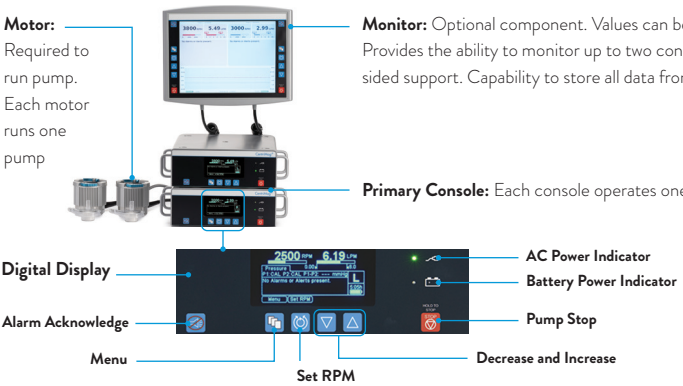
PRESSURE MONITORING

- CentriMag™ Acute Circulatory Support System has the ability to support two pressure sensors: P1 and P2
- Pressure transducers can be connected to the primary console
- When the cables are connected to the primary console, the screen will automatically configure to display pressure measurements from the transducer
- Parameters are adjustable
- Pressure ranges from -150–900 mmHg
- Pressures can be zeroed at any time during support



Pressure

SYSTEM COMPONENTS | Motor, console, flow probe and optional monitor



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CLINICAL CONSIDERATIONS

CONTINUOUS-FLOW PUMP

- Continuously provides support to the patient
- Plug the console into a protected power outlet
- Battery: 120 minutes
- Recharge time: 5 hours
- In the event of an emergency, clamp the outflow and switch to the backup console

Hemodynamics

- Afterload sensitive pump: Consider mean arterial pressure < 90 mmHg
- Monitor the filling pressure because the CentriMag™ Pump is preload dependent
  - If utilizing for BiVAD, RVAD flow should be less than LVAD flow

ASSESSMENT

Assess all cannulas, tubing and connectors

- Allow for complete visibility of the circuit. Ensure the motor remains uncovered and two clamps are available at the bedside. Continually assess for clot formation and tubing kinks
- Any change in parameters should be evaluated with all clinical considerations taken into account

EMERGENCY CARE

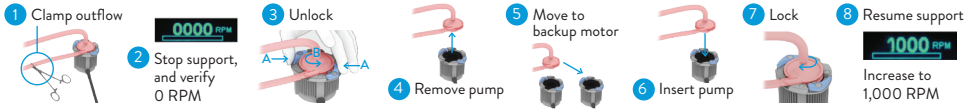
- Defibrillation or cardioversion is allowed, if necessary
- There may be risks associated with performing chest compressions. Use clinical judgment

EQUIPMENT

- The console should be plugged into AC power when not transporting
- Battery life is 120 minutes under nominal operating conditions
- A backup system must be accessible at all times

SAFETY INSPECTION

- Ensure pump is fully secured into the motor
- Report any areas of weak connection; ensure tiebands are in place
- Do not twist, kink or sharply bend the tubing
- Ensure minimum and maximum flow alerts are set



ANTICOAGULATION

- Use AC per hospital policy
- Higher AC may be considered with low flow or weaning

REVIEW AND DOCUMENTATION

Document: Flow, speed, P1/P2 pressures (if applicable), minimum/maximum flows set and flow probe repositioning (every 8 hours)

Alarms: To clear or silence an alarm, depress Alarm Acknowledge button, and decide on next steps

ADDITIONAL CONSIDERATIONS

- Assess clinical considerations
- Perform battery maintenance every 6 months
- Change the battery every 2 years
- Assess for signs of hemolysis, including lab work
- Ensure the console is plugged into the AC power outlet

WARNINGS

- No magnetic resonance imaging
- Do not cover the includeconsole with blankets or drapes; ensure the console fans remain unblocked

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AC = anticoagulation
BiVAD = biventricular assist device
LVAD = left ventricular assist device
RVAD = right ventricular assist device

1. Abbott. CentriMag™ Circulatory Support System, Clinical Reference Manual. ARTEN600254981, rev B. 2024.
2. Abbott. CentriMag™ Circulatory Support System Operating Manual. ARTEN600254997, rev B. 2024.

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Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

CentriMag™ Circulatory Support System Indications [PMA Approval; 30-day use]: Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy.

CentriMag™ Circulatory Support System Contraindications [PMA Approval; 30-day use]: The CentriMag™ Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

CentriMag™ Circulatory Support System Adverse Events [PMA Approval; 30-day use]: Adverse events that may be associated with mechanical circulatory support can include, but are not limited to, the following: bleeding on device support, hemolysis, infection, renal failure/dysfunction/complication, respiratory dysfunction, hepatic dysfunction, cardia arrhythmias (atrial or ventricular), thromboembolism (venous and arterial non-CNS), hypotension, hypertension, device malfunction or failure, psychiatric events, right heart failure, and death.

CentriMag™ RVAS Indications [Humanitarian Exemption Device (HDE) Approval; 30-day use]: The CentriMag Circulatory Support System is intended to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure.

CentriMag™ RVAS Contraindications [Humanitarian Exemption Device (HDE) Approval; 30-day use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

Humanitarian Device Statement: Caution: Humanitarian Device. The CentriMag Circulatory Support System is authorized by Federal Law for temporary circulatory support for up to 30 days for patients in cardiogenic shock due to right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

CentriMag™ Circulatory Support System Indications [510(k) Clearance; 6-hour use]: The CentriMag Extracorporeal Blood Pumping System is a non-roller-type cardiopulmonary and circulatory bypass blood pump used to pump a patient's blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:
i. Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or
ii. Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava

CentriMag™ Circulatory Support System Contraindications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

PediMag™ Blood Pump Indications for Use [510(k) Clearance; 6-hour use]: The PediMag Blood Pump is indicated for use with the CentriMag™ Console and Motor. It is a non-roller-type cardiopulmonary and circulatory bypass blood pump used to pump a patient's blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:
1. Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels: or
2. Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava

PediMag™ Blood Pump Contraindications [510(k) Clearance; 6-hour use]: The PediMag Blood Pump is contraindicated for use as a cardiotomy suction device. The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

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Item approved for U.S. use only.

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