



# CentriMag™ Acute Circulatory Support System

# PRODUCT CATALOG



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# CONSOLES AND HARDWARE

## CentriMag™ Console, 2nd Generation, With 3/8-Inch Flow Probe

Contents:

- 1 CentriMag™ Console, 2nd generation, for use with both CentriMag™ Blood Pumps and PediMag™ Blood Pumps
- 1 adult flow probe for 3/8-inch tubing (separate flow probe for 1/4-inch tubing required for PediMag™ Blood Pumps)
- 1 power cord
- 1 monitor cable
- 1 console standoff set



**MODEL NUMBER**

201-90411

**DESCRIPTION**

CentriMag™ Console, 2nd generation, with 3/8-inch flow probe

## Motor

Reusable motor attaches to CentriMag™ Console, 2nd generation. For use with both CentriMag™ Blood Pumps and PediMag™ Blood Pumps.



**MODEL NUMBER**

102956

**DESCRIPTION**

Motor

## Motor Bracket

Attaches motor to intravenous (IV) pole.



**MODEL NUMBER**

102961

**DESCRIPTION**

Motor bracket

## Monitor Kit

Compatible with CentriMag™ Console, 2nd generation. For use with both CentriMag™ Blood Pumps and PediMag™ Blood Pumps.

Contents:

- 1 monitor
- 1 monitor arm
- 1 monitor arm clamp



**MODEL NUMBER**

201-90404

**DESCRIPTION**

Monitor kit

## System Cart

Cart accommodates up to three CentriMag™ Consoles, 2nd generation; one monitor; three motors with motor brackets; and one oxygen tank (size D or E).

MODEL NUMBER	DESCRIPTION
107533	System cart



## Oxygenator Holder

Articulating arm and holder for AMG PMP oxygenators. Clamps onto vertical posts such as IV poles.

MODEL NUMBER	DESCRIPTION
US2257	Oxygenator holder



## CentriMag™ Transporter

Designed to provide the convenience and protection needed to safely transport patients. Space for core system components, including console, pump/motor and oxygenator.

MODEL NUMBER	DESCRIPTION
CM2TR00	CentriMag™ Transporter



# DISPOSABLES

## CentriMag™ Blood Pump

Supplied sterile.

MODEL NUMBER	DESCRIPTION
102953	CentriMag™ Blood Pump



## PediMag™ Blood Pump

Supplied sterile.

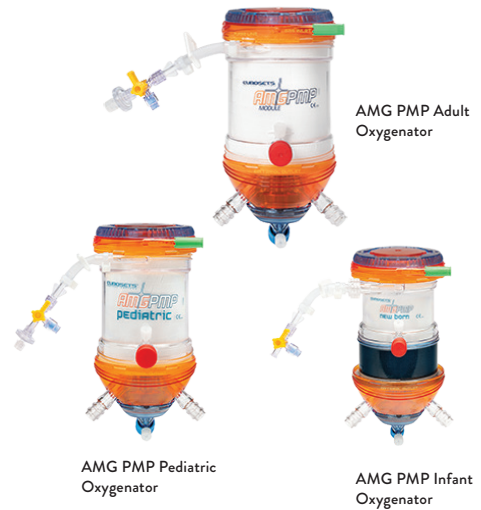
MODEL NUMBER	DESCRIPTION
201-90052	PediMag™ Blood Pump



## AMG PMP Oxygenators

Supplied sterile. Box of four.

MODEL NUMBER	DESCRIPTION
US5062	AMG PMP Adult Oxygenator, box of four
US5087	AMG PMP Pediatric Oxygenator, box of four
US5088	AMG PMP Infant Oxygenator, box of four



## CentriMag™ Pre-Connected Pack

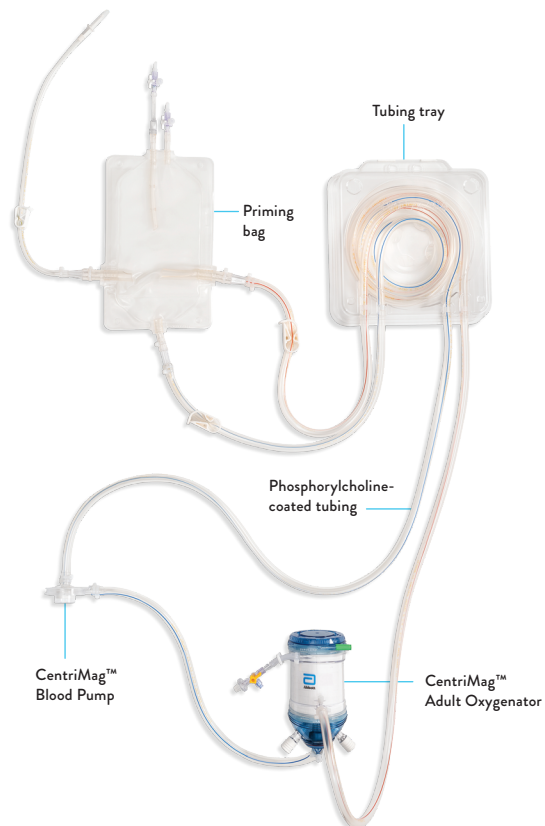
Contains all required components for initiation of cardiopulmonary support. All components provided are sterile and disposable.

Contents:

- 1 CentriMag™ Blood Pump
- 1 CentriMag™ Adult Oxygenator
- 1 priming bag
- 1 tubing tray

Accessories:

- 1 gas line
- 2 3/8-inch connectors with luer
- 4 high-flow pigtails with three-way stopcock
- 8 tie bands
- 5 tubing clamps
- 1 cutter



MODEL NUMBER	DESCRIPTION
CMAEK00	CentriMag™ Pre-Connected Pack

## DTXPlus<sup>‡</sup> Pressure Transducers

Supplied sterile. Box of 10. Suitable for use with BD pressure cables.

MODEL NUMBER	DESCRIPTION
104304	DTXPlus <sup>‡</sup> pressure transducers, box of 10



# SYSTEM ACCESSORIES AND SERVICE PARTS

## Monitor-Console Cable

Connects monitor to CentriMag™ Console, 2nd generation. Replacement part. Also included with CentriMag™ Console, 2nd generation.

MODEL NUMBER	DESCRIPTION
201-52147	Monitor-console cable



## RS Data Cable

Allows transfer of live data stream by the monitor.

MODEL NUMBER	DESCRIPTION
201-52261	RS data cable



## Monitor Arm

Attaches to monitor and monitor clamp. Replacement part. Also included with monitor kit.

MODEL NUMBER	DESCRIPTION
201-52170	Monitor arm



## Monitor Clamp

Attaches to monitor arm, and clamps onto IV poles. Replacement part. Also included with monitor kit.

MODEL NUMBER	DESCRIPTION
201-52171	Monitor clamp



## Flow Probes for Use With CentriMag™ Console, 2nd Generation

Noninvasive flow monitor utilizing ultrasonic technology to provide accurate flow measurements up to 10 LPM.



MODEL NUMBER	DESCRIPTION
201-30105	3/8-inch flow probe for use with CentriMag™ Console, 2nd generation
201-30107	1/4-inch flow probe for use with CentriMag™ Console, 2nd generation

## Lithium-Ion Console Battery

Replacement battery for use with CentriMag™ Console, 2nd generation.



MODEL NUMBER	DESCRIPTION
201-50207	Lithium-ion console battery

## Pressure Cable for DTXPlus† Pressure Transducers

For use with CentriMag™ Console, 2nd generation, and DTXPlus† pressure transducers. Reusable.



MODEL NUMBER	DESCRIPTION
104303	Pressure cable for DTXPlus† pressure transducers

## Power Cord

Replacement cord for use with CentriMag™ Console, 2nd generation.



MODEL NUMBER	DESCRIPTION
102964	Power cord

## Training Loop

Supplied as one nonclinical pump attached to a reservoir. Includes gate clamp.

MODEL NUMBER	DESCRIPTION
102963	CentriMag™ Training Loop
201-50134	PediMag™ Training Loop

# RENTAL PROGRAM

The Abbott Mechanical Circulatory Support (MCS) Rental Program includes same-day shipping (when available) and delivery. Rate includes installation, inspection, and standby or active use. All services, repairs and/or replacements, if any, throughout the rental period are included.

The Abbott MCS Rental Program has been established to help hospitals defer the cost/inventory of capital equipment during sporadic increases in clinical caseload. **This is not a Rent-to-Own Program.**

- The length of rental may be unknown at the time of ordering but must be for a minimum of 30 days for the CentriMag™ Acute Circulatory Support System. A valid purchase order (PO) with monetary value must be issued by the hospital. The value should cover at least the first 6 months of rental charges. The PO must be amendable should the rental exceed that length of time/rental charges.
- The hospital is responsible for contacting Abbott Customer Service to obtain a returned material authorization number prior to returning the rental or other products to Abbott. The PO for rental charges will terminate upon receipt and complete inspection of the product at Abbott.

- All products noted on the delivery note of rental equipment must be returned to Abbott. Rental charges continue until all components of the rental are received at Abbott.
- Customer responsibility for charges begins as soon as the product leaves Abbott’s shipping dock. Seven days of the daily rate fee will be applied, regardless of whether the product is used, returned unopened, refused at customer dock or canceled in transit.
- If needed, Abbott’s Technical Service personnel will schedule installation of equipment based on time of arrival and urgency.
- The customer is responsible to retain console, cart or other product packaging for return of any product. Packaging must be stored in a dry, secure environment throughout the rental period by the customer. Shipping charges will apply to any packaging replacement.

CATALOG NUMBER	DESCRIPTION
9-1509DR	Motor
9-1511DR	CentriMag™ Console, 2nd generation
9-1512DR	Monitor kit

# WARRANTY PLANS

The limited and extended warranty plans\* provide hassle-free preventative maintenance and repairs for this critical, life-saving device.

## WHAT WE OFFER

Our warranty plans include preventative maintenance in addition to servicing that includes but is not limited to electrical, mechanical, cosmetic and structural issues with the CentriMag™ Acute Circulatory Support System components.

PLAN INCLUDES*	LIMITED WARRANTY (1 YEAR)	EXTENDED WARRANTY (5 YEARS)
24/7 support line	✓	✓
Parts and labor or replacement in the event of equipment failure	✓	✓
Battery replacement and full system checkup every 2 years or as required		✓
No-charge loaner system while units are with Abbott	✓	✓
Software updates performed free of charge		✓
Optional for-charge battery maintenance performed by Abbott either on-site or with a no-charge loaner offered during service		✓

## LET'S GET YOU TAKEN CARE OF

### Peace of Mind

- Improved customer service
- 24/7 support line throughout the life of the warranty
- Fast claims process
- Consistent patient care

### Budget Control

- Savings on major repair costs
- Reduced rental costs
- Customizable protection plan
- Flexible and easy annual payment options

### System Support for the Life of the Contract

- Full system refurbishment every 2 years with a maintenance certificate
- Electronic access to documented service records
- Backup loaner device available within 24 hours
- Scheduled preventative maintenance to ensure optimal operating conditions

**To get more information and a custom quote, contact your local Abbott representative.**

\*The limited and extended warranty plans do not cover damage or malfunction of the device resulting from abuse or neglect.

# PRESERVATION PLAN

The Preservation Plan\* provides hassle-free, scheduled annual servicing and maintenance for this critical, life-saving device.

## PLAN CHECKLIST

- Annual comprehensive system inspection by Abbott-certified service engineers
- Primary console preventative maintenance and battery replacement required every 2 years
- Complimentary loaner systems within 24 hours while units are with Abbott
- Shipping of products and loaner systems at no additional charge
- Access to documented service records for documentation compliance (Joint Commission on Accreditation of Healthcare Organizations<sup>†</sup> and state Department of Health)
- Customer notification when service is due
- 24/7 support line (clinical and technical)



## Extend the Life of the Device

You can keep your equipment operating at manufacturer settings with annual preventative maintenance and service support. Preventative care will reduce expected wear and tear and extend the life of the CentriMag™ Acute Circulatory Support System.



## Increase Reliability

Regular maintenance reduces the probability of an unexpected system downtime or noncompliance operating conditions and keeps your device safe to support your patients.



## Reduce Repair Costs

Unexpected repairs and replacements can be expensive. Regular maintenance of the system components gives you an opportunity to check whether there are any signs of wear and tear and fix any issues preemptively.

\*The Preservation Plan does not cover damage or malfunction of the device resulting from abuse or neglect. The Preservation Plan applies to new and used equipment. Repair and replacement of parts can be purchased separately through Abbott Service. Consult with your local Abbott representative to choose the right plan for your CentriMag™ Acute Circulatory Support System.

# ORDER INFORMATION

## U.S. orders only:

### CUSTOMER SERVICE

HeartLine™ Support

**Toll-free:** 1-800-456-1477

**Email:** [MCSCustomerService@abbott.com](mailto:MCSCustomerService@abbott.com)

### TECHNICAL SUPPORT

HeartLine™ Support

**Toll-free:** 1-800-456-1477

**Email:** [TTechServices@abbott.com](mailto:TTechServices@abbott.com)

### PAYMENT

According to terms of agreement

### SHIPMENT

FOB shipping point

*All Abbott products are supported with a comprehensive 1-year manufacturer's warranty, including parts and labor.*

*The CentriMag™ Acute Circulatory Support System can be further supported with an extended warranty for up to 5 years or with a preservation plan for equipment older than 5 years.*

AMG PMP Adult, Pediatric, Infant Oxygenators and Oxygenator Holder are manufactured by Eurosets s.r.l. and distributed by Abbott.

#### Abbott

6101 Stoneridge Dr., Pleasanton, CA 94588 USA, Tel: 1 925 847 8600  
Cardiovascular.Abbott

#### 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 cardiomy 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, cardiac 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 cardiomy 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.

**AMG PMP Adult Oxygenator Indications [510(k) Clearance; 6-hour use]:** The AMG MODULE PMP NO T.P. STERILE is intended for use in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. The AMG MODULE PMP NO T.P. STERILE is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration. Contact with blood for a longer period of time is inadvisable. AMG MODULE PMP NO T.P. STERILE is an adult oxygenator. The AMG MODULE PMP NO T.P. STERILE should be used in combination with medical devices listed in section "Medical devices for use with the AMG MODULE PMP NO T.P. STERILE."

**AMG PMP Adult Oxygenator Contraindications [510(k) Clearance; 6-hour use]:** This device used for any other purposes than for the indicated intended use is the responsibility of the user. See Instructions for Use.

**AMG PMP Pediatric Oxygenator Indications [510(k) Clearance; 6-hour use]:** The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for 6 hours or less with a maximum blood flow rate of 4 liters/minute.

**AMG PMP Pediatric Oxygenator Contraindications [510(k) Clearance; 6-hour use]:** No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions. Do not use the device for any purpose other than indicated.

**AMG PMP Infant Oxygenator Indications [510(k) Clearance; 6-hour use]:** The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for 6 hours or less with a maximum blood flow rate of 1.5 liters/minute.

**AMG PMP Infant Oxygenator Contraindications [510(k) Clearance; 6-hour use]:** No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions. Do not use the device for any purpose other than indicated.

**CentriMag™ Blood Pump Indications [ECMO, 510(k) Clearance; >6-hour use]:** The CentriMag™ Blood Pump for use with CentriMag™ Acute Circulatory Support System (Motor, Monitor, Console, and Flow Probes) is indicated for controlling blood flow as part of an extracorporeal membrane oxygenation (ECMO) circuit. ECMO is intended to provide assisted extracorporeal circulation and physiologic gas exchange of the patients' blood for adult patients with acute respiratory failure and/or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

**CentriMag™ Blood Pump Contraindications [ECMO, 510(k) Clearance; >6-hour use]:** The CentriMag™ System is contraindicated for use as a cardiomy 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™ Blood Pump Adverse Events [ECMO, 510(k) Clearance; >6-hour use]:** Potential adverse events associated with the use of extracorporeal membrane oxygenation include, but are not limited to the following: Death, Mechanical Failures/Dysfunction, Bleeding (including Cardiac Tamponade), Hemolysis (including Hemoglobinuria, Anemia, Hyperbilirubinemia), Neurologic Dysfunction (including Stroke, Seizures), Cardiac Dysfunction (including Myocardial Infarction, Arrhythmias, Right/Left Heart Failure), Hypertension, Hypotension, Vascular (including Air Embolism, Thromboembolism (venous/arterial), Limb Ischemia, Vascular Damage) Pulmonary Dysfunction (including Pulmonary Embolism, Respiratory Failure), Renal Dysfunction, Cardiogenic Shock, Hypovolemia, Hypervolemia, Hepatic Dysfunction, Coagulation Disorders (including Thrombocytopenia, DIC), Infection (including Wound Dehiscence), Metabolic/Respiratory Acidosis, Psychiatric Disorder.

**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 cardiomy 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 cardiomy suction device. The CentriMag Circulatory Support System is contraindicated for use as a cardiomy 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™ Pre-connected Pack Indications for Use [510(k) Clearance; 6-hour use]:** The CentriMag™ Pre-connected Pack is indicated for use with the CentriMag™ Acute Circulatory Support System to provide physiologic gas exchange of the blood and to pump a patient's blood through an extracorporeal circuit for periods lasting less than six (6) hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass 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™ Pre-connected Pack Contraindications [510(k) Clearance; 6-hour use]:** The CentriMag™ Acute Circulatory Support System is contraindicated for use as a cardiomy suction device. The system is also contraindicated for adult patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

**CentriMag™ Pre-connected Pack Adverse Events [510(k) Clearance; 6-hour use]:** Potential adverse events associated with the use of any extracorporeal circuit include, but are not limited to the following: Death, Respiratory Failure, Cardiac Arrhythmias, Right Heart Failure, Left Heart Failure, Thrombocytopenia, Hyper-anticoagulation, Therapeutic Management Hypo-anticoagulation, Exsanguination, Hyper-anticoagulation Bleeding, Vascular Access Sites, Phrenic Nerve Damage and Diaphragm Paralysis, Vagus Nerve Damage and Larynx Muscle Dysfunction, Pneumothorax, Renal Failure/Dysfunction, Neurologic Dysfunction, Hemolysis, Hepatic Dysfunction, Hypotension, Cardiac Tamponade, Pericardial Effusion, Wound Dehiscence, Psychiatric Episode, Myocardial Infarction, Hyperthermia, Hypothermia, Anoxia, Hypercarbia.

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‡ Indicates a third-party trademark, which is property of its respective owner.

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