

HEART FAILURE **PRODUCT CATALOG**



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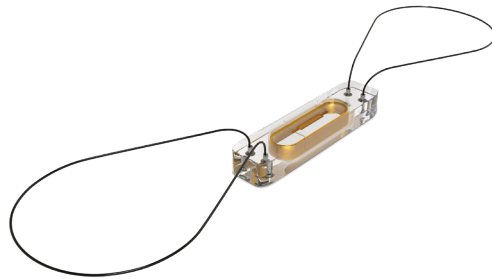
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PULMONARY ARTERY PRESSURE MONITORING SYSTEM



PULMONARY ARTERY PRESSURE MONITORING SYSTEM

CardioMEMS™ HF System

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CARDIOMEMS™ HF SYSTEM

HOSPITAL

CardioMEMS™ HF System Hospital Electronics System

The CardioMEMS™ HF System hospital electronics system is used by the implanting physician to zero the sensor, based upon simultaneous readings from the PA catheter during implant. It can also be used by healthcare professionals to record PA pressure from the sensor, eliminating the need for patients to carry their electronics to the hospital or doctor's office. The hospital electronics system powers the sensor using RF energy; receives and processes the frequency information from the sensor; and converts the data into pressure waveforms, PA pressure values and heart rate measurements.



Contents:

- Hospital Electronics System

MODEL NUMBER	DESCRIPTION
CM3000	CardioMEMS™ Hospital Electronics System
CM3010	Printer
CM3011	Printer Serial Cables
CM3012	Printer Power Cables
CM3013	Printer Paper
CM3020	Power Cord – 125V 7A
CM3022	Power Supply Cable
CM3024	Power Cord Clip
CM3030	Barcode Scanner
CM3040	Wi-Fi [®] Adaptor

HOME

CardioMEMS™ HF System Patient Electronics System

The CardioMEMS™ HF System patient electronics system is designed for patients to use at home. Patient-initiated sensor readings are wirelessly transmitted to the Merlin.net™ Patient Care Network for clinicians to securely access and review patient data.



Contents:

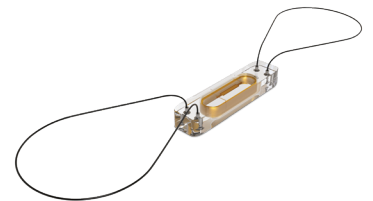
- Patient Electronics System

MODEL NUMBER	DESCRIPTION
CM1100	CardioMEMS™ HF System Patient Electronics System – (GSM, Wi-Fi†, Landline)
CM1130	Handheld Display
CM1140	GSM Modem
CM1170	Fabric Cover
CM1050	Accessory – Positioning Ball
CM3040	Accessory – Wi-Fi Adaptor
CM1120	Electronics Travel Case
CM3020	U.S. Power Cord – 125V 7A
CM1110	Power Supply
CM3024	Power Cord Clip

SENSOR

CardioMEMS™ HF System PA Sensor and Delivery System

The CardioMEMS™ HF System PA Sensor is implanted in the pulmonary artery using a delivery system via a right heart catheterization procedure.



Contents:

- 1 PA System
- 1 Delivery System

MODEL NUMBER	DESCRIPTION
CM2000	CardioMEMS™ HF System PA Sensor and Delivery System

ORDERING INFORMATION

U.S. orders only:

Customer Service: 1-844-692-6387

Email: CMEMSCustomerService@abbott.com

Technical Support: 1-866-244-4327

Payment: According to terms of agreement

Shipment: FOB Shipping Point

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

MECHANICAL CIRCULATORY SUPPORT ACUTE

ACUTE



ACUTE

CentriMag™ Acute Circulatory Support System

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CENTRIMAG™ ACUTE CIRCULATORY SUPPORT SYSTEM

CONSOLES AND HARDWARE

CentriMag™ 2nd Generation Console with 3/8 in Flow Probe

Contents:

- 1 CentriMag™ console for use with both CentriMag™ and PediMag™ pumps
- 1 Adult flow probe for 3/8 in tubing (separate flow probe for 1/4 in tubing required for PediMag™ pump)
- 1 Power cord
- 1 Monitor cable
- 1 Console standoff set



MODEL NUMBER	DESCRIPTION
201-90411	CentriMag™ 2nd Generation Console with 3/8 in Flow Probe

CentriMag™ Motor

Reusable motor attaches to CentriMag™ Console. For use with both CentriMag™ and PediMag™ pumps.



MODEL NUMBER	DESCRIPTION
102956	CentriMag™ Motor

CentriMag™ Motor Bracket

Attaches CentriMag™ Motor to IV pole.



MODEL NUMBER	DESCRIPTION
102961	CentriMag™ Motor Bracket

CentriMag™ Monitor Kit

Compatible with CentriMag™ 2nd Generation Console. For use with both CentriMag™ and PediMag™ pumps.

Contents:

- 1 CentriMag™ Monitor
- 1 Monitor Arm Clamp
- 1 Monitor Arm



MODEL NUMBER	DESCRIPTION
201-90404	CentriMag™ Monitor Kit



CentriMag™ System Cart

Cart accommodates up to three CentriMag™ Consoles, one CentriMag™ Monitor, three CentriMag™ Motors and Motor Brackets and one oxygen tank (size D or E).

MODEL NUMBER	DESCRIPTION
107533	CentriMag™ System Cart

Oxygenator Holder

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



MODEL NUMBER	DESCRIPTION
US2257	Oxygenator Holder

CentriMag™ System Transporter

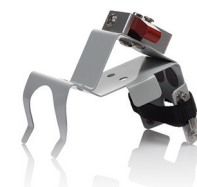
Allows for simple and safe transportation of the system. Transporter accommodates one CentriMag™ 2nd Generation Console, one CentriMag™ Motor, one oxygen tank (size M9, C or smaller) and one oxygenator. Oxygenator bracket not included.



MODEL NUMBER	DESCRIPTION
201-50140	CentriMag™ System Transporter

Square Oxygenator Bracket for Transporter

To fit adult, square-format oxygenators (e.g., Maquet Quadrox®).



MODEL NUMBER	DESCRIPTION
201-50144	Square Oxygenator Bracket for Transporter

Oxygenator Bracket for Transporter



MODEL NUMBER	DESCRIPTION
201-50143	Large-sized Oxygenator Bracket for Transporter To fit adult, tubular-format oxygenators (diameter of 3.5 in/90 cm) (e.g., Eurosets AMG PMP Adult Oxygenator).
201-50142	Medium-sized Oxygenator Bracket for Transporter To fit pediatric, tubular-format oxygenators (diameter of 2.2 in/55 cm).
201-50141	Small-sized Oxygenator Bracket for Transporter To fit neonatal, tubular-format oxygenators (diameter of 2.2 in/55 cm).

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 Adult Oxygenator

Supplied sterile. Box of 4.



MODEL NUMBER	DESCRIPTION
US5062	AMG PMP Adult Oxygenator, Box of 4

AMG PP Adult Oxygenator

Supplied sterile. Box of 4.



MODEL NUMBER	DESCRIPTION
US5400	AMG PP Adult Oxygenator, Box of 4

CentriMag™ 34 Fr Drainage (Venous) Cannula Kit

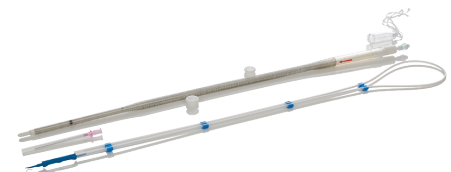
Supplied sterile. Cannula and assertion/fixation accessories.
For adult central cannulation only.



MODEL NUMBER	DESCRIPTION
201-50067	CentriMag™ 34 Fr Drainage (Venous) Cannula Kit, 56 cm length

CentriMag™ 24 Fr Return (Arterial) Cannula Kit

Supplied sterile. Cannula and assertion/fixation accessories.
For adult central cannulation only.



MODEL NUMBER	DESCRIPTION
201-50068	CentriMag™ 24 Fr Return (Arterial) Cannula Kit, 56 cm length

DTXPlus⁺ Pressure Transducers

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



MODEL NUMBER	DESCRIPTION
104304	DTXPlus ⁺ Pressure Transducers, Box of 10

SYSTEM ACCESSORIES AND SERVICE PARTS

CentriMag™ Monitor-Console Cable

Connects CentriMag™ Monitor to CentriMag™ 2nd Generation Console. Replacement part: also included with CentriMag™ 2nd Generation Consoles.



MODEL NUMBER	DESCRIPTION
201-52147	CentriMag™ Monitor-Console Cable

Monitor Arm

Attaches to CentriMag™ Monitor and Monitor Clamp. Replacement part: also included with CentriMag™ 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 CentriMag™ Monitor Kit.



MODEL NUMBER	DESCRIPTION
201-52171	Monitor Clamp

Flow Probes for Use with CentriMag™ 2nd Generation Console



MODEL NUMBER	DESCRIPTION
201-30105	3/8 in Flow Probe for Use with CentriMag™ 2nd Generation Console
201-30107	1/4 in Flow Probe for Use with CentriMag™ 2nd Generation Console

Lithium-ion Console Battery

Replacement battery for use with CentriMag 2nd™ Generation Console.



MODEL NUMBER	DESCRIPTION
201-50207	Lithium-ion Console Battery

CentriMag™ Pressure Cable for BD DTXPlus[‡] Transducer

For use with CentriMag™ Console and BD DTXPlus[‡] transducers. Reusable.



MODEL NUMBER	DESCRIPTION
104303	CentriMag™ Pressure Cable for BD DTXPlus [‡] Transducer

Power Cord

Replacement cord for use with CentriMag™ 2nd Generation Consoles.



MODEL NUMBER	DESCRIPTION
102964	Power Cord

CentriMag™ Training Loop

Supplied as 1 non-clinical pump attached to a reservoir. Includes gate clamp.

MODEL NUMBER	DESCRIPTION
102963	CentriMag™ Training Loop

PediMag™ Training Loop

Supplied as 1 non-clinical pump attached to a reservoir. Includes gate clamp.

MODEL NUMBER	DESCRIPTION
201-50134	PediMag™ Training Loop

ORDERING INFORMATION

U.S. orders only:

Customer Service: HeartLine™ Support — Toll Free: 800 456 1477

Email: MCSCustomerService@abbott.com

Technical Support: HeartLine™ Support — Toll Free: 800 456 1477

Email: 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 System can be further supported with an extended warranty for up to 5 years, or with a Preservation Plan for equipment greater than 5 years.

CHRONIC



CHRONIC

HeartMate 3™ LVAD

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HEARTMATE 3™ LVAD

SURGICAL PROCEDURE

HeartMate 3™ Left Ventricular Assist System (LVAS) Implant Kit

Supplied sterile. Contents:

- 1 HeartMate 3™ Left Ventricular Assist Device (LVAD) with Tunneling Adapter
- 1 HeartMate 3™ LVAD System Controller with 11-Volt Lithium-ion Backup Battery (non-sterile)
- 1 Outflow Graft with Bend Relief
- 1 Apical Cuff
- 1 Skin Punch (6 mm)
- 1 Thread Protector Set
- 1 Modular Cable
- 1 Apical Coring Knife

Supplied non-sterile. Contents:

- 1 Wearables Accessory Kit (1 System Controller Neck Strap, 1 Belt Attachment, 1 Protection Bag)
- 1 Instructions for Use
- 1 Patient Handbook



MODEL NUMBER	DESCRIPTION
106524US	HeartMate 3™ LVAS Implant Kit

HeartMate 3™ LVAD Tunneling Tools

Supplied non-sterile. Contents:

- 1 Long Tunneling Lance
- 1 Short Tunneling Lance
- 1 Handle
- 1 Instructions for Use



MODEL NUMBER	DESCRIPTION
10010372GBL	HeartMate 3™ LVAD Tunneling Tools

HeartMate 3™ LVAD Outflow Graft with Bend Relief

Supplied sterile. Contents:

- 1 Outflow Graft
- 1 Outflow Graft Bend Relief



MODEL NUMBER	DESCRIPTION
105581US	HeartMate 3™ LVAD Outflow Graft with Bend Relief

HeartMate 3™ LVAD Outflow Graft Clip

Supplied sterile.



MODEL NUMBER	DESCRIPTION
10012390GBL	HeartMate 3™ LVAD Outflow Graft Clip

HeartMate 3™ LVAD Surgical Hand Tools

Supplied non-sterile, reusable. Contents:

- 1 Unlock Tool
- 1 Pliers
- 1 Instructions for Use
- 1 Cleaning and Sterilization Instructions



MODEL NUMBER	DESCRIPTION
10002222US	HeartMate 3™ LVAD Surgical Hand Tools

HeartMate 3™ LVAD Modular Cable

Supplied sterile. Modular Cable with Cap.



MODEL NUMBER	DESCRIPTION
106525US	HeartMate 3™ LVAD Modular Cable

HeartMate 3™ LVAD Modular Cable Cap (package of 3)

Supplied sterile.

MODEL NUMBER	DESCRIPTION
106526US	HeartMate 3™ LVAD Modular Cable Cap (package of 3)

Apical Coring Knife

Supplied sterile. Can be used for HeartMate II™ and HeartMate 3™ LVADs.



MODEL NUMBER	DESCRIPTION
1050	Apical Coring Knife

HeartMate™ Explant Kit

For explanted pump return. Can be used for HeartMate II™ and HeartMate 3™ LVADs.

MODEL NUMBER	DESCRIPTION
28717	HeartMate™ Explant Kit

HeartMate 3™ Mini Apical Cuff Kit

Supplied sterile. Contents:

- 1 Mini Apical Cuff
- 1 Apical Cuff Holder

Supplied non-sterile. Contents:

- 1 Instructions for Use



MODEL NUMBER	DESCRIPTION
10005877	HeartMate3™ Mini Apical Cuff Kit

HeartMate 3™ Coring Tool

Supplied sterile.



MODEL NUMBER	DESCRIPTION
10005872	HeartMate 3™ Coring Tool

HeartMate 3™ Apical Cuff (package of 3)

Supplied sterile.

MODEL NUMBER	DESCRIPTION
106522US	HeartMate 3™ Apical Cuff (package of 3)

HeartMate 3™ Skin Punch

Supplied sterile.

MODEL NUMBER	DESCRIPTION
106528US	HeartMate 3™ Skin Punch

HeartMate 3™ Thread Protector Set (package of 5)

Supplied sterile.

MODEL NUMBER	DESCRIPTION
106532US	HeartMate 3™ Thread Protector Set (package of 5)

HeartMate 3™ Tunneling Adapters (package of 3)

Supplied sterile.



MODEL NUMBER	DESCRIPTION
106534US	HeartMate™ Tunneling Adapters (package of 3)

SYSTEM OPERATIONS

HeartMate 3™ LVAD System Controller with 11-Volt Lithium-ion Backup Battery

Supplied sterile. Contents:

- 1 System Controller with 11-Volt Lithium-ion Backup Battery (non-sterile)

Supplied non-sterile. Contents:

- 1 Patient Handbook



MODEL NUMBER	DESCRIPTION
106531US	HeartMate 3™ LVAD System Controller with 11-Volt Lithium-ion Backup Battery

11-Volt Lithium-ion System Controller Backup Battery

Supplied non-sterile. Can be used with HeartMate II™ System Controller and HeartMate 3™ System Controller.



MODEL NUMBER	DESCRIPTION
106128	11-Volt Lithium-ion System Controller Backup Battery

PATIENT SUPPORT KITS

HeartMate 3™ LVAD Patient Support Kit with Mobile Power Unit™ Module and Battery Charger

Contents:

- 1 Mobile Power Unit™ Module with Locking Power Cord, North America
- 1 Battery Charger
- 1 HeartMate 3™ LVAD System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)



MODEL NUMBER	DESCRIPTION
B10002193	HeartMate 3™ LVAD Patient Support Kit with Mobile Power Unit™ Module and Battery Charger

HeartMate 3™ LVAD Patient Support Kit

Contents:

- 1 HeartMate 3™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)



MODEL NUMBER	DESCRIPTION
B10002194	HeartMate 3™ LVAD Patient Support Kit

HEARTMATE II™ LVAD

SURGICAL PROCEDURE

HeartMate II™ LVAS Implant Kit with Sealed Grafts and System Controller*

Supplied sterile. Contents:

- 1 HeartMate II™ LVAD with Tunneling Bullet
- 1 HeartMate II™ Sealed Inflow Conduit
- 1 HeartMate II™ Sealed Outflow Graft with Bend Relief, 4 in (10.2 cm)
- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery (non-sterile)
- 1 Apical Coring Knife
- 1 HeartMate II™ Apical Sewing Ring
- 1 HeartMate II™ Skin Coring Punch
- 1 HeartMate II™ Thread Protector Set

Supplied non-sterile. Contents:

- 1 Wearable Accessories Kit (includes 1 System Controller Neck Strap, 1 Belt Attachment and 1 Protection Bag)
- 1 HeartMate II™ LVAS Instructions for Use
- 1 HeartMate II™ LVAS Patient Handbook



MODEL NUMBER	DESCRIPTION
106015	HeartMate II™ LVAS Implant Kit with Sealed Grafts and System Controller*

HeartMate II™ Sealed Outflow Graft Bend Relief Collar

Supplied sterile.



MODEL NUMBER	DESCRIPTION
107315	HeartMate II™ Sealed Outflow Graft Bend Relief Collar

*HeartMate II Outflow Graft Bend Relief Collar must be ordered separately, #107315.

HeartMate II™ LVAS Mini Implant Kit (Used for pump exchange)

Supplied sterile. Contents:

- 1 HeartMate II™ LVAD with Tunneling Bullet
- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery (non-sterile)
- 1 HeartMate™ Apical Coring Knife
- 1 HeartMate II™ Apical Sewing Ring
- 1 HeartMate II™ Skin Coring Punch
- 1 HeartMate II™ Thread Protector Set

Supplied non-sterile. Contents:

- 1 HeartMate II™ LVAS Instructions for Use
- 1 HeartMate II™ LVAS Patient Handbook



MODEL NUMBER	DESCRIPTION
107801	HeartMate II™ LVAS Mini Implant Kit (Used for pump exchange)

HeartMate II™ Sealed Inflow Conduit, Standalone

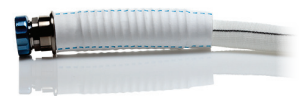
Supplied sterile.



MODEL NUMBER	DESCRIPTION
104142	HeartMate II™ Sealed Inflow Conduit, Standalone

HeartMate II™ Sealed Outflow Graft with Bend Relief, Standalone

Supplied sterile. 4 in (10.2 cm) bend relief.



MODEL NUMBER	DESCRIPTION
103393	HeartMate II™ Sealed Outflow Graft with Bend Relief, Standalone

HeartMate II™ Short Outflow Graft Bend Relief, Standalone

Supplied sterile. 3 in (7.6 cm) bend relief.

MODEL NUMBER	DESCRIPTION
104692	HeartMate II™ Short Outflow Graft Bend Relief, Standalone

HeartMate II™ Skin Coring Punch

Supplied sterile.

MODEL NUMBER	DESCRIPTION
105557	HeartMate II™ Skin Coring Punch

HeartMate II™ Thread Protectors Set

Supplied sterile.

MODEL NUMBER	DESCRIPTION
105558	HeartMate II™ Thread Protectors Set

HeartMate II™ Driveline Tunneler

Supplied non-sterile, reusable.



MODEL NUMBER	DESCRIPTION
102137	HeartMate II™ Driveline Tunneler

HeartMate II™ Sizer

Supplied non-sterile, reusable.



MODEL NUMBER	DESCRIPTION
102772	HeartMate II™ Sizer

HeartMate II™ Spanner Wrench

Supplied non-sterile, reusable.



MODEL NUMBER	DESCRIPTION
102138	HeartMate II™ Spanner Wrench

HeartMate II™ Apical Sewing Ring with Centering Fixture

Supplied sterile. 3 per box.



MODEL NUMBER	DESCRIPTION
1065	HeartMate II™ Apical Sewing Ring with Centering Fixture

Apical Coring Knife

Supplied sterile. Can be used for HeartMate II™ and HeartMate 3™ LVADs.



MODEL NUMBER	DESCRIPTION
1050	Apical Coring Knife

HeartMate™ Explant Kit

For explanted pump return. Can be used for HeartMate II™ and HeartMate 3™ LVADs.

MODEL NUMBER	DESCRIPTION
28717	HeartMate™ Explant Kit

SYSTEM OPERATIONS

HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery

Supplied sterile. Contents:

- 1 HeartMate II™ System Controller

Supplied non-sterile. Contents:

- 1 HeartMate II™ System Controller 11-Volt Lithium-ion Backup Battery
- 1 HeartMate II™ LVAS Patient Handbook



MODEL NUMBER	DESCRIPTION
106762	HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery

11-Volt Lithium-ion System Controller Backup Battery

Supplied non-sterile. Can be used with HeartMate II™ System Controller and HeartMate 3™ System Controller.



MODEL NUMBER	DESCRIPTION
106128	11-Volt Lithium-ion System Controller Backup Battery

PATIENT SUPPORT KITS

HeartMate II™ Patient Support Kit* with Power Module

- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)
- 1 Power Module
- 1 Power Module Automobile DC Power Cable
- 1 Power Module Patient Cable (14-Volt)
- 1 HeartMate II™ LVAS Patient Handbook
- 1 Battery Charger



MODEL NUMBER	DESCRIPTION
106101	HeartMate II™ Patient Support Kit* with Power Module

HeartMate II™ Patient Support Kit* with Automobile DC Power Cable and Power Module Patient Cable

- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)
- 1 Power Module Automobile DC Power Cable



MODEL NUMBER	DESCRIPTION
106102	HeartMate II™ Patient Support Kit* with Automobile DC Power Cable and Power Module Patient Cable

*For convenience, Abbott offers a number of patient accessories in different sizes. These accessories must be ordered separately from patient support kits.

HeartMate II™ Patient Support Kit*

- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)



MODEL NUMBER	DESCRIPTION
10002192	HeartMate II™ Patient Support Kit

HeartMate II™ Patient Support Kit* with Mobile Power Unit™ Module

- 1 Mobile Power Unit™ Module with Locking Power Cord
- 1 Battery Charger
- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)



MODEL NUMBER	DESCRIPTION
10002191	HeartMate II™ Patient Support Kit with Mobile Power Unit™ Module

*For convenience, Abbott offers a number of patient accessories in different sizes. These accessories must be ordered separately from patient support kits.

COMMON HEARTMATE™ LVAD COMPONENTS

HEARTMATE TOUCH™ COMMUNICATION SYSTEM

HeartMate Touch™ Communication System

The HeartMate Touch™ Communication System is an intuitive and user-friendly tool setting a new standard in left ventricular assist device (LVAD) patient care for more clinical independence in patient management.



MODEL NUMBER	DESCRIPTION
HMT1100	HeartMate Touch™ Communication System

HeartMate Touch™ Communication System Rental

MODEL NUMBER	DESCRIPTION
HMT1100-R	HeartMate Touch™ Communication System Rental

HeartMate Touch™ Communication System Bluetooth® Wireless Technology Adapter



MODEL NUMBER	DESCRIPTION
HMT2100	HeartMate Touch™ Communication System Bluetooth Adapter

Flash Drive for HeartMate Touch™ Communication System



MODEL NUMBER	DESCRIPTION
HMT2900	Flash Drive for HeartMate Touch™ Communication System

Power Adapter for HeartMate Touch™ Communication System



MODEL NUMBER	DESCRIPTION
HMT2133	Power Adapter for HeartMate Touch™ Communication System

USB Cable for HeartMate Touch™ Communication System

MODEL NUMBER	DESCRIPTION
HMT2166	USB Cable for HeartMate Touch™ Communication System

POWER SUPPLIES

Mobile Power Unit™ Module and Locking Power Cord

Mobile Power Unit™ Module with Integrated Patient Cable and Locking Power Cord



MODEL NUMBER	DESCRIPTION
107754	Mobile Power Unit™ Module and Locking Power Cord

Locking AC Power Cord for Mobile Power Unit™ Module

MODEL NUMBER	DESCRIPTION
107760	Locking AC Power Cord for Mobile Power Unit™ Module

Power Module

Contents:

- 1 Power Module with Patient Cable
- 1 Power Module Backup Battery
- 1 Power Cord



MODEL NUMBER	DESCRIPTION
1340	Power Module

Power Module Backup Battery

A backup power source inside the HeartMate™ Power Module that provides up to 30 minutes of support if power to the HeartMate Power Module fails or is disconnected.



MODEL NUMBER	DESCRIPTION
109200	Power Module Backup Battery

Power Module Patient Cable

Connects the HeartMate II™ or HeartMate 3™ System Controller to the HeartMate™ Power Module.



MODEL NUMBER	DESCRIPTION
103426	Power Module Patient Cable

Power Module Automobile DC Power Cable*

Connects the Power Module to automobile DC power.

MODEL NUMBER	DESCRIPTION
2230	Power Module Automobile DC Power Cable

AC Power Cord for Power Module or Battery Charger

AC power cord that is compatible with both the HeartMate™ Power Module and Battery Charger.

MODEL NUMBER	DESCRIPTION
103860	AC Power Cord for Power Module or Battery Charger

Battery Charger



MODEL NUMBER	DESCRIPTION
1440	Battery Charger

14-Volt Lithium-ion Battery Set



MODEL NUMBER	DESCRIPTION
2465	14-Volt Lithium-ion Battery Set (set of 4)
2865	14-Volt Lithium-ion Battery Clip Set (set of 2)

*Approved for use with HeartMate II LVAS only.

WEAR AND CARE ACCESSORIES

Stabilization Belts

Supplied non-sterile. 2 Stabilization Belts with 6 Lead Locks.



MODEL NUMBER	DESCRIPTION
100760	Stabilization Belts, Medium/Large
100759	Stabilization Belts, Small

Consolidated Bag



MODEL NUMBER	DESCRIPTION
106449	Left-handed Consolidated Bag
104233	Right-handed Consolidated Bag

Holster Vest



MODEL NUMBER	DESCRIPTION
104229	Holster Vest, Small – Recommended for patients weighing less than 160 pounds.
104230	Holster Vest, Medium – Recommended for patients weighing 160–240 pounds.
104231	Holster Vest, Large – Recommended for patients weighing more than 240 pounds.

Wearable Accessories Kit

Supplied non-sterile. Contents:

- 1 System Controller Neck Strap
- 1 Belt Attachment
- 1 Protection Bag



MODEL NUMBER	DESCRIPTION
106129	Wearable Accessories Kit

Battery Holster



MODEL NUMBER	DESCRIPTION
104234	Battery Holster

Shower Bag (package of 2)



MODEL NUMBER	DESCRIPTION
104232	Shower Bag (package of 2)

Travel Bag



MODEL NUMBER	DESCRIPTION
1260	Travel Bag

SYSTEM MONITOR

System Monitor II

Contents:

- 1 System Monitor (can be used with HeartMate II™ LVAD or HeartMate 3™ LVAD Systems)
- 1 System Monitor Data Card
- 1 System Monitor Data Cable
- 1 System Monitor Instructions for Use



MODEL NUMBER	DESCRIPTION
1286	System Monitor II

System Monitor Data Card

Data card for collecting log files and/or waveform information stored in the System Controller. Used for troubleshooting.



MODEL NUMBER	DESCRIPTION
101609	System Monitor Data Card

System Monitor Data Cable

Connects Power Module to System Monitor.



MODEL NUMBER	DESCRIPTION
103859	System Monitor Data Cable

PC Card Reader

Used for transmitting data from CompactFlash media to a computer so that the data can be sent via email.

MODEL NUMBER	DESCRIPTION
102504	PC Card Reader

RENTAL PROGRAMS



RENTAL PROGRAMS

CentriMag™ Acute Circulatory Support System and HeartMate™ LVAD Rental Programs

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CENTRIMAG™ ACUTE CIRCULATORY SUPPORT SYSTEM AND HEARTMATE™ LVAD RENTAL PROGRAMS

The Abbott 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 replacement, 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 seven (7) days for the Heartmate™ LVAD, and a minimum of thirty (30) days for the CentriMag™ System. A valid purchase order with monetary value must be issued by the hospital. The value should cover at least the first six (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 (RMA) number prior to returning rental or other products to Abbott. Purchase Order for Rental charges will terminate upon receipt and complete inspection of product at Abbott.
- All products noted on “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 product leaves Abbott’s shipping dock. Seven (7) days of the Daily Rate Fee, regardless of whether product is used, returned unopened, refused at customer dock or canceled in transit, will be applied.
- 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 customer. Shipping charges will apply to any packaging replacement.

CENTRIMAG™ SYSTEM PRODUCT RENTALS

CentriMag™ Motor

Reusable motor attaches to CentriMag™ Console.
For use with both CentriMag™ and PediMag™ pumps.



CATALOG NUMBER	PRODUCT NAME AND DESCRIPTION
9-1509DR	CentriMag™ Motor

CentriMag™ 2nd Generation Console

For use with both CentriMag™ and PediMag™ pumps. Separate flow probe required for PediMag™ pump.

Supplied non-sterile. Contents:

- 1 CentriMag™ Console
- 1 Flow Probe (3/8 in)
- 1 Power Cord
- 1 Console Standoff Set
- 1 Monitor-Console Cable



CATALOG NUMBER	PRODUCT NAME AND DESCRIPTION
9-1511DR	CentriMag™ 2nd Generation Console

CentriMag™ Monitor Kit

Compatible with 2nd Generation Console.

Contents:

- 1 CentriMag™ Monitor
- 1 Monitor Arm Clamp
- 1 Monitor Arm



CATALOG NUMBER	PRODUCT NAME AND DESCRIPTION
9-1512DR	CentriMag™ Monitor Kit

HEARTMATE™ LVAD PRODUCT RENTALS

Power Module

Provides power to the HeartMate™ system when connected via a power cord to a functioning AC electrical outlet. Connects to the HeartMate™ System Monitor for purposes of transferring data from the HeartMate II™ or HeartMate 3™ System Controller for display on the HeartMate™ System Monitor screen.

Connects to HeartMate II™ or HeartMate 3™ System Controller through the HeartMate™ Power Module Patient Cable (14 Volt).



CATALOG NUMBER	PRODUCT NAME AND DESCRIPTION
9-1340DR	Power Module

Battery Charger

Used to charge, calibrate and test the HeartMate™ 14-Volt Lithium-ion Batteries used to power the HeartMate™ System during battery-powered operation.



CATALOG NUMBER	PRODUCT NAME AND DESCRIPTION
9-1440DR	Battery Charger

HeartMate™ System Monitor II

Touch-screen programmer for HeartMate™ LVAS used to monitor and adjust system parameters and to view and save performance data.



CATALOG NUMBER	PRODUCT NAME AND DESCRIPTION
9-1286DR	HeartMate™ System Monitor II

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

AMG PP Adult Oxygenator and Oxygenator Holder are manufactured by Eurosets s.r.l. and distributed by Abbott.

HeartMate Touch™ Communication System Overview: The HeartMate Touch™ Communication System is intended for use by clinicians in the hospital to wirelessly monitor a patient's HeartMate II™ Left Ventricular Assist System or HeartMate 3™ Left Ventricular Assist System. The HeartMate Touch Communication System is required during implant procedures and any time close monitoring of system operation is needed. It provides clinicians with the ability to program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data.

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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.

CardioMEMS™ HF System Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

CardioMEMS™ HF System Contraindications: The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

CardioMEMS™ HF System Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: infection, arrhythmias, bleeding, hematoma, thrombus, myocardial infarction, transient ischemic attack, stroke, death, and device embolization.

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.

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™ 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.

AMG PMP Adult Oxygenator Temporary Expanded Indication: A.M.G. MODULE PMP NO T.P. STERILE is indicated for use as part of an ECMO circuit for longer than 6 hours to treat patients with acute respiratory failure and/or acute cardiopulmonary failure during the COVID-19 public health emergency.

AMG PMP 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 unadvisable. 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 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 PP Adult Oxygenator Temporary Expanded Indication: A.M.G. MODULE PP NO T.P. STERILE is indicated for use as part of an ECMO circuit for longer than 6 hours to treat patients with acute respiratory failure and/or acute cardiopulmonary failure during the COVID-19 public health emergency.

AMG PP Oxygenator Indications [510(k) Clearance; 6-hour use]: The A.M.G. MODULE PP 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 A.M.G. MODULE PP 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 unadvisable. A.M.G. MODULE PP NO T.P. STERILE is an adult oxygenator. The A.M.G. MODULE PP NO T.P. STERILE should be used in combination with medical devices listed in section "Medical devices for use with the A.M.G. MODULE PP NO T.P. STERILE."

AMG PP Oxygenator Contraindications [510(k) Clearance; 6-hour use]: Do not use the device for any purpose other than indicated. This device used for any other purposes than for the indicated intended use is the responsibility of the user. Relative contraindications to CPB procedures applies.

CentriMag™ Acute Circulatory Support System Temporary Expanded Indication: The FDA issued an enforcement policy guidance document in April 2020 allowing for FDA-cleared or approved cardiopulmonary bypass devices to be used in an ECMO circuit to treat patients who are experiencing acute respiratory failure

and/or acute cardiopulmonary failure during the COVID-19 public health emergency. The CentriMag™ System including the CentriMag™ Blood Pump and PediMag™ Blood Pump are indicated for use as part of an ECMO circuit for longer than 6 hours to treat patients with acute respiratory failure and/or acute cardiopulmonary failure.

CentriMag™ Blood Pump Indications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

CentriMag™ Blood Pump 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 Circulatory Support System console and motor to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours) for surgical procedures such as 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, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

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 also 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™ Drainage (Venous) Cannula Kit Indications for Use [510(k) Clearance; 6-hour use]: The CentriMag Drainage (Venous) Cannula is indicated for use with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

CentriMag™ Drainage (Venous) Cannula Kit 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. The CentriMag Drainage (Venous) Cannula is not intended for peripheral cannulation.

CentriMag™ Return (Arterial) Cannula Kit Indications for Use [510(k) Clearance; 6-hour use]: The CentriMag Return (Arterial) Cannula is indicated for use as an arterial return cannula with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

CentriMag™ Return (Arterial) Cannula Kit 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. The CentriMag Return (Arterial) Cannula is not intended for peripheral cannulation.

HeartMate 3™ Coring Tool Indications: For the HeartMate 3™ Left Ventricular Assist System (LVAS) Indications for Use, please refer to the HeartMate 3 LVAS Instructions for Use. The HeartMate 3™ Coring Tool is intended for use with the HeartMate 3 LVAS. The HeartMate 3 Coring Tool provides a means to resect a plug of myocardium from the left ventricle, which allows for HeartMate 3 inflow cannula insertion.

HeartMate 3™ Coring Tool Contraindications: The use of the HeartMate 3 Coring Tool is contraindicated in patients who are contraindicated for HeartMate 3 Left Ventricular Assist System (LVAS) therapy.

HeartMate 3™ Coring Tool Adverse Events: The following adverse events may be associated with the use of the HeartMate 3 Coring Tool. Adverse events are listed in anticipated decreasing order of frequency, except for death, which appears first as it is a non-reversible complication: death, bleeding (perioperative or late), local infection, local ischemia, cardiac arrhythmia, stroke, peripheral thromboembolic event, neurologic dysfunction, hemolysis, sepsis.

HeartMate 3™ LVAS Indications: The HeartMate 3™ Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in adult and pediatric patients with advanced refractory left ventricular heart failure and with an appropriate body surface area.

HeartMate II™ LVAS Indications: The HeartMate II™ Left Ventricular Assist System is indicated for use as a "bridge to transplantation" for cardiac transplant candidates who are at risk of imminent death from non-reversible left ventricle failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure, who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II Left Ventricular Assist System is intended for use both inside and outside of the hospital, or for transportation of Left Ventricular Assist Device patients via ground ambulance, airplane, or helicopter.

HeartMate 3™ and HeartMate II™ LVAS Contraindications: The HeartMate 3 and HeartMate II Left Ventricular Assist Systems are contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3™ and HeartMate II™ LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 or HeartMate II Left Ventricular Assist System are listed below: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and possible pump thrombosis.

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