Cardiohelp System

Extracorporeal life support wherever you need it

This document is intended to provide information to an international audience outside of the US.

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CARDIOHELP
CARDIOHELP

The world's leading ECLS System

Your choice for heart-lung support

With critically ill or injured patients, there's no time for delay. That's why Getinge has long been committed to advancing ECLS technology.

As one of the world's leading manufacturers of heart-lung machines and related components, we understand the impact that a portable extracorporeal life support (ECLS) system can have on patient outcomes.

A broad range of indications

The Cardiohelp System is a small and lightweight heart-lung support system. Although extracorporeal life support provided by the Cardiohelp System is not a therapy itself, it acts as a bridge for recovery or transplantation. This gives caregivers more time to optimize the patient's therapy while easing the body's workload.

It can be used for a wide range of indications in intensive care, emergency medicine, cardiology, and cardiac surgery.

We put patients first

For more than a century, Getinge and its well-known brands – such as Maquet – have put patients first. It's why we remain committed to close clinical relationships that identify real-world healthcare challenges, and address them with cost-effective, clinically relevant solutions.

Gentle extracorporeal circulation

Giving the organs time to heal

A multi-functional system

The Cardiohelp System is a compact heart-lung support system suitable for all indications requiring extracorporeal circulation for cardiopulmonary support. It can be used for up to 30 days in cases of myocardial or respiratory failure.

Highly portable, the Cardiohelp System can be rapidly deployed for transport of patients requiring respiratory and / or circulatory support.

Cardiohelp Emergency Drive Holder

Battery pack for at least 90 min

Control panel: user-friendly touchscreen

"Alarm outlet" connection, e.g., ward call

Main power supply: together with the DC device socket, the Cardiohelp device can be used with common voltages and currents worldwide.

Equipotential bonding connection

Adjustment of flow and speed

The protective frame protects the Cardiohelp Device against crushing

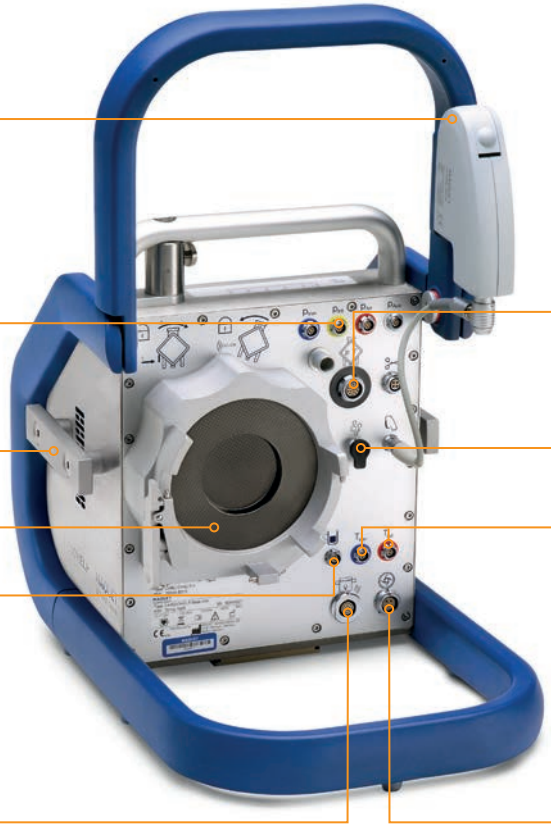
USB port type A and USB port type B

"Emergency mode" button

DC device socket

A cost-effective resource

As hospitals face increasing cost pressures, it's crucial to invest in cost-effective technologies that can be used by multiple departments. With the Cardiohelp System, patients can remain on the same system for the duration of treatment, making it a cost-effective solution for hospitals or transport.



One system

Multiple treatment options

The Cardiohelp System can support cardiac and / or pulmonary function using either veno-venous or veno-arterial ECLS.

Veno-arterial life support is used with patients whose hearts are not adequately supporting their circulation or patients who have arrested.

Veno-venous life support provides respiratory assistance for lung disorders. Support can be extended to complete substitution of the organ function.

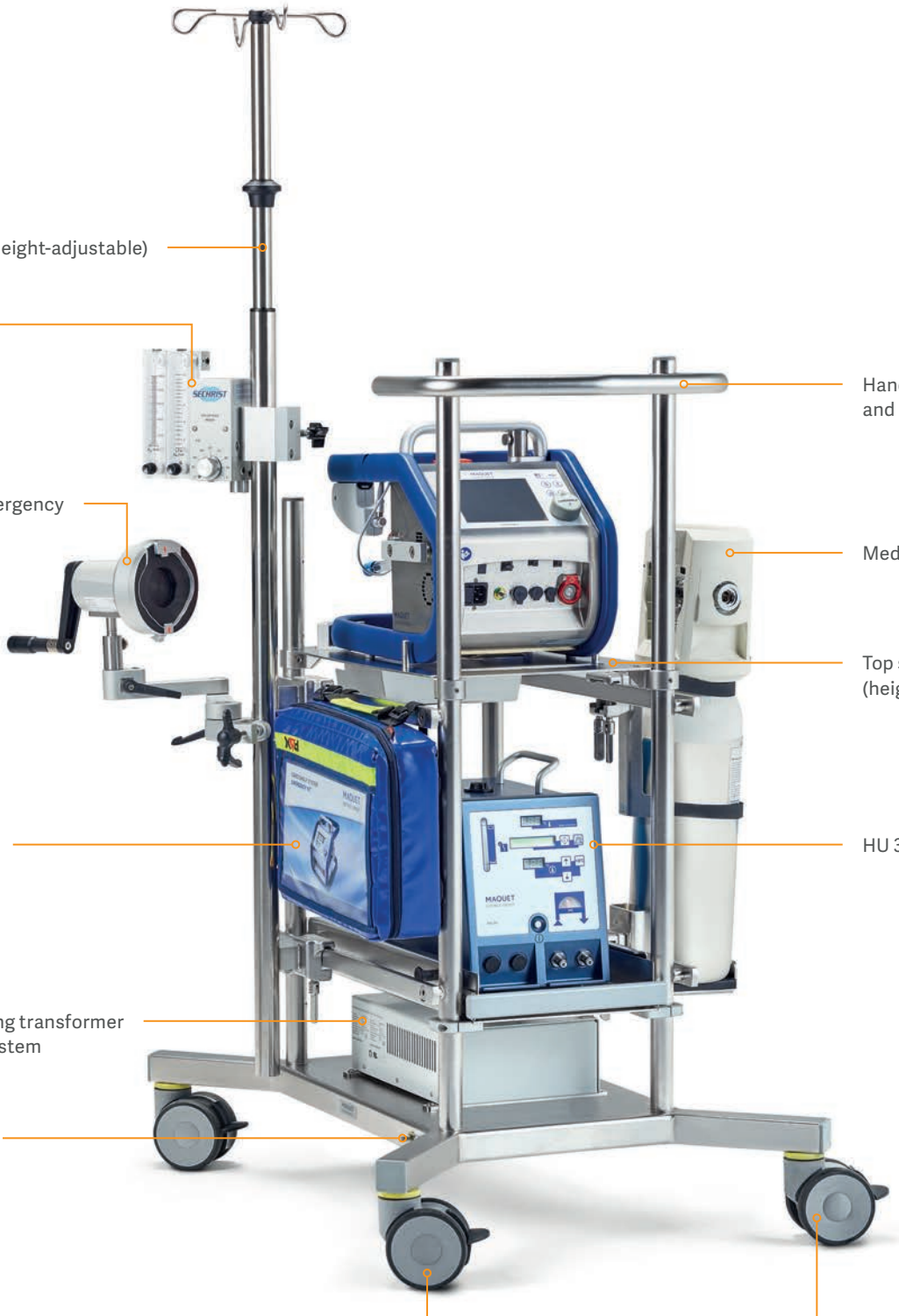
When paired with optimized ventilation techniques, the Cardiohelp System provides adaptable treatment for a variety of conditions.

Application	Respiratory and cardiac assist	Respiratory assist	Cardiac surgery and intervention	
Disposable	**HLS Set Advanced 5.0** **HLS Set Advanced 7.0**	**HLS Set Advanced 5.0** **HLS Set Advanced 7.0**	**MECC-i Set**	**Cardiac Intervention Set**
Place	ICU / CathLab / ER / OR	ICU / ER / OR	OR / Hybrid OR	CathLab / Hybrid OR
Fields of application	• Respiratory failure with cardiac impairment • Circulatory failure with respiratory impairment • Cardiogenic shock • Myocardial infarction • Resuscitation • Bridge to transplant	• Acute respiratory distress syndrome (ARDS) • Pulmonary embolism • Septic shock • Bridge to lung transplant	• Coronary artery bypass grafting surgery (CABG) • Aortic valve replacement (AVR) • Pre- and post-operative heart-lung support	• Elective high risk PCI • Other elective cardiac interventions
Duration of use	Up to 30 days*	Up to 30 days*	Up to 6 hours	Up to 6 hours
Flow	HLS 5.0: 0.5–5.0 l/min HLS 7.0: 0.5–7.0 l/min	HLS 5.0: 0.5–5.0 l/min HLS 7.0: 0.5–7.0 l/min	0.5–7 l/min	0.5–7 l/min
Transport	Air / ground	Air / ground	-	-
	 v-a ECLS	 v-v ECLS	 MECC	

** HLS Set Advanced in combination with HLS Cannulae with Bioline Coating can be used for up to 30 days in CE region.*

The Cardiohelp System

The fully equipped Sprinter Cart XL



HLS Set Advanced

Combining a low damage blood pump with a highly efficient gas module

When a patient's heart or lungs are failing, they need safe and effective cardiopulmonary support to avoid hypoxic injury.

The right technology can ease the body's workload, providing support both at the bedside and during transport.

Improved safety for critically ill patients

The HLS Set Advanced, with the HLS Module Advanced as its core component, is a state-of-the-art oxygenator providing circulatory and / or respiratory extracorporeal life support (ECLS). It expands therapy applications with a continuous use for veno-venous or veno-arterial extracorporeal support up to 30 days*.
Integrated monitoring technology helps to improve patient safety and handling of the device in a high risk setup.

The core of the HLS Set Advanced, the HLS Module Advanced

The core is an integrated low-trauma centrifugal pump. With the HLS Set Advanced, patient safety is integrated into the system. Multiple sensors measures important blood parameters, including:

- Venous oxygen saturation (S_vO_2)
- Hematocrit (Hct)
- Hemoglobin (Hb)
- Venous temperature (T_{Ven})

Integrated sensors provide continuous measurement:

- Venous pressure
- Arterial pressure
- Internal pressure (measured between centrifugal pump and gas module)
- Arterial temperature

Flow Bubble Sensor (FBS) for bubble detection and for reducing the risk of embolisms.

The HLS Set Advanced is available in different versions:

HLS Set Advanced 5.0 accommodates a blood flow of up to 5 l/min and HLS Set Advanced 7.0 accommodates a blood flow of up to 7 l/min. Both HLS Set Advanced have a biocompatible Bioline Coating.

For patients who are susceptible to heparin-induced thrombocytopenia a set with Softline Coating is available, the HIT Set Advanced 5.0 and HIT Set Advanced 7.0.

* HLS Set Advanced in combination with HLS Cannulae with Bioline Coating can be used for up to 30 days in CE region.

HLS Set Advanced

Benefits at a glance

Safety

- Integrated noninvasive sensor technology minimizes the hazards of air embolism, stagnant zones, clotting and cavitation from external pressure sensors. There are no pressure lines that need flushing.
- Rapidly detect cannulae misplacement and kinking by monitoring pressure changes with Cardiohelp.
- Various sensors reduce the risk of embolism caused by air entering the circuit and helps to early recognize formation of clots.
- Low priming volume minimizes hemodilution.
- Changing a component or set always represents a risk for the patient. The HLS set was developed for up to 30 days continuous use.

Usability

- Quick and easy set-up and priming for routine and rapid deployment in emergency situations.
- The sterile packaging contains all the necessary components and tubing.
- An integrated heat exchanger helps to precisely manages temperature.
- Color-coded tubing supports safe patient connection.
- Provided as a standard set it allows for consistent trainings of users, familiarity with the product in any situation and routine handling.
- With Cardiohelp and HLS Set Advanced, patients can be safely transported between hospitals.

Cardiac Intervention

Short term support - a life-saving decision

Supporting patients during high-risk percutaneous cardiac interventions

When treating patients with high-risk PCI, the physician should take into account a 7 - 10% risk of acute hemodynamic instability; this almost always leads to the need for urgent circulatory support [1]. Cardiac assist devices can be used to regain stability and to support the patient as quickly and effectively as possible.

Background:

- Rising numbers of cardiac interventions are occurring, especially in older and sicker patients [2, 3, 4]
- Increasingly complex cardiac interventions occur after the introduction of new stent variations (e.g. drug eluting or dissolving stents) and evolving technologies (e.g. minimally invasive valve-replacement) [5]
- Increased need for, and acceptance of circulatory support during high-risk PCI [1, 6, 7] or valve replacement.

1 Briguori C et al. Elective versus provisional intra-aortic balloon pumping in ULMS. Am. Heart J. 2006; 152 (3): 565-572

2 Vainer J et al. Elective high-risk percutaneous coronary interventions supported by extracorporeal life support. Am. J. Cardiol. 2007; 99 (6): 771-3

3 Anastasiadis K et al. Successful high-risk percutaneous coronary intervention with the use of minimal extracorporeal cirulation system. Catheter Cardiovasc Interv. 2012; 80 (5): 845–9

4 Tsao et al. Extracorporeal membrane oxygenation-assisted primary percutaneous coronary intervention may improve survival of patients with acute myocardial infarction complicated by profound cardiogenic shock. J. Crit. Care. 2012; 27 (5): 530.e1-530.e11

5 Dardas P et al. ECMO as a bridge to high-risk rotablation of heavily calcified coronary arteries. Herz. 2012; 37 (2): 225-30

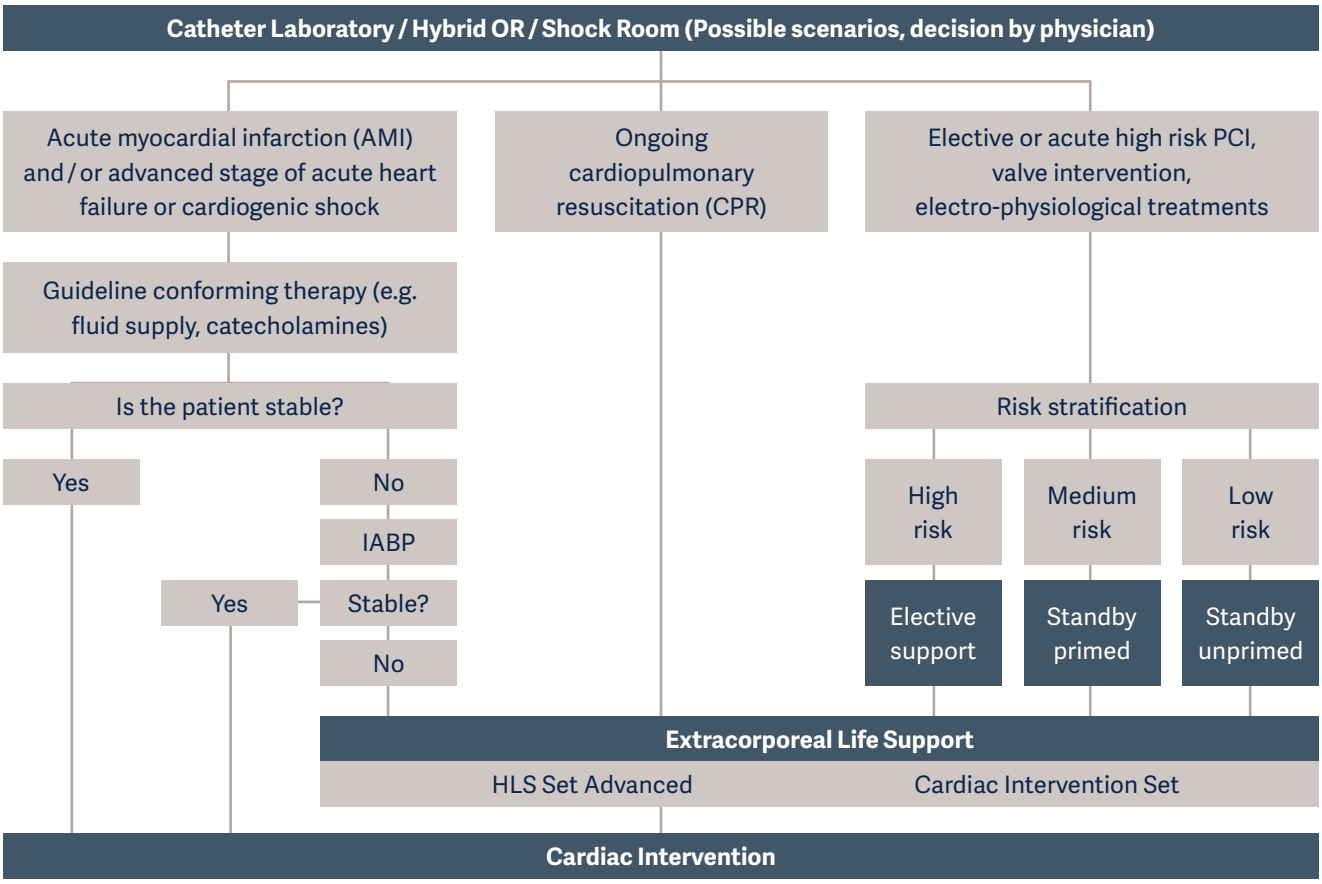
6 Bagai J et al. Efficacy and safety of percutaneous life support during high-risk percutaneous coronary intervention, refractory cardiogenic shock and in-laboratory cardiopulmonary arrest. J. Invasive Cardiol. 2011; 23 (4): 141-7

7 Webb DP et al. Novel multi-functional life support system. J. Extra Corpor. Technol. 2010; 42 (3): 232-4

Cardiac Intervention Set

Benefits at a glance

- First standardized tubing set for ECLS during high-risk PCI
- Designed to be used for up to 6 hours this set can serve as a back-up solution to cover the phase of highest risk of instability and take over full support if necessary
- Quick and easy set-up and priming for fast deployment in emergency situations
- Low priming volume minimizes hemodilution
- Connection of external pressure measurement and arterial temperature is possible
- Integrated centrifugal pump and heat exchanger for precise temperature management



According to ESC and ACC / AHA guidelines

Avalon Elite

Bi-Caval Dual Lumen Catheter

Reduce patient trauma with a single cannulation site for extracorporeal life support.

The Avalon Elite Bi-Caval Dual-Lumen Catheter permits for single site cannulation into the patient's internal jugular vein. This facilitates patient extubation and mobilization, increases patient comfort and improving patient outcomes.

The Avalon Elite Bi-Caval Dual-Lumen Catheter is the world's first single site, kink resistant, veno-venous device designed to enable optimal extracorporeal life support. It matches the body's natural flow ratios by simultaneously removing deoxygenated blood from both the superior vena cava (SVC) and inferior vena cava (IVC), and returning oxygenated blood to the right atrium (RA).

Advantages

- A broad range of sizes for all patient types: neonatal, pediatric or adult
- Radiopaque to assist in catheter insertion and placement
- Constructed with an unique material that combines the durability of polyurethane with the flexibility and biocompatibility of silicone

Characteristics:

- Wire-reinforced catheter with a one-piece, dual lumen construction.
- The Catheter consists of two separate lumina, this allows for both venous drainage and reinfusion of blood during extracorporeal life support procedures.
- The product is offered in a range of sizes to address varying patient size requirements.

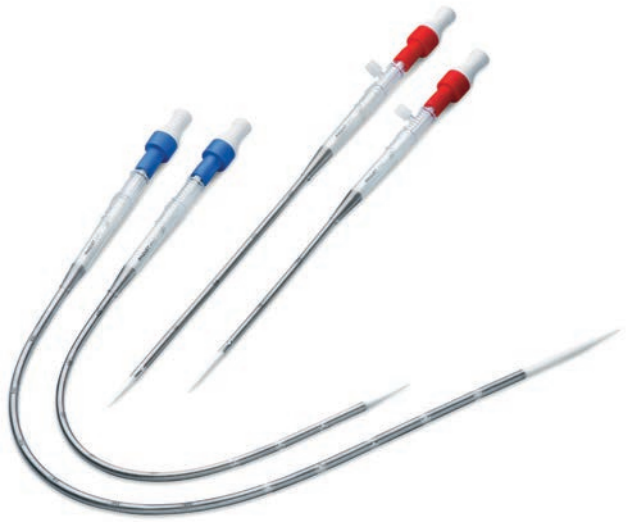
HLS Cannulae

Up to 30 days* of VV and VA access

Reliable and minimally traumatic solution for vascular access.

HLS cannulae can be inserted percutaneously or through surgical cut-down, offering reliable veno-venous or veno-arterial connection of peripheral vessels to the extracorporeal circuit.

HLS cannulae is also available with Bioline Coating (heparin-albumin coating) for improvement of the physical surface properties of products for the extended respiratory and / or circulatory support.



* HLS Set Advanced in combination with HLS Cannulae with Bioline Coating can be used for up to 30 days in CE region.

Exceptional performance characteristics:

- Reinforced with a flat wire for the thinnest wall and highest flow rates.
- Reinforced side holes for reduced kinking risk
- Versions with Bioline Coating for extended respiratory and / or circulatory support.
- Extended application time of 30 days in combination with a PLS Set (Bioline Coating) or HLS Set*

Easy to use:

- Locking mechanism keeps introducer in place during insertion
- Optimized transition between introducer and cannula tip
- Depth marks to control insertion depth, a stop ring to define maximum insertion depth
- Selectively hardened proximal cannula body, reduces the risk of kinking after insertion

The portable life support system
– anytime, anywhere

The Cardiohelp System can be easily and rapidly deployed at the bedside or in the field, offering patients portable, seamless heart-lung support.

It is effective in all forms of patient transport, including intra-hospital transport between departments, or inter-hospital transport by helicopter or ambulance. The portable system enables adequate patient oxygen supply and CO_2 reduction for efficient organ perfusion.

Key features include:

- Secure installation in any ambulance or helicopter
- Integrated lithium-ion batteries provide at least 90 minutes of operating time when fully charged
- The Cardiohelp Transport Guard provides additional stability and crash protection

A broad variety of transport-specific accessories are available, including mobile holder and base plate for secure fixation of the device.

Cardiohelp with additional transport guard

Trolley transport system

Benefits at a glance: A proven life support system

- Ideal for use in multiple settings in the ICU, OR, CathLab, Hybrid OR, and the emergency room
- Compact and functional design provides flexibility and easy handling
- The touchscreen user interface allows intuitive control even in emergency situations
- Integrated sensor technology enables continuous monitoring of patients blood parameters, pressures and bubble detection
- Individual alarms, warning limits, and interventions assure safety during use
- The back-up system offers a 90 min battery supply when fully charged, and an emergency drive

GETINGE

Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people – today and tomorrow.

This document is intended to provide information to an international audience outside of the US. The products in this brochure may be pending regulatory approvals to be marketed in your country. Contact your Getinge representative for more information.

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