

HEMOLUNG[®] RAS

TECHNOLOGY OVERVIEW



The **Hemolung Respiratory Assist System (RAS)**, developed by ALung Technologies, is a dialysis-like alternative or supplement to mechanical ventilation. It removes carbon dioxide and delivers oxygen directly to the blood through a process called **Respiratory Dialysis®**. The Hemolung RAS can provide partial extracorporeal respiratory support in cases of acute hypercapnic respiratory failure, including acute respiratory distress syndrome (ARDS) and acute exacerbation of chronic obstructive pulmonary disease (COPD). And because the device uses techniques similar to hemodialysis, requiring only a simple extracorporeal circuit and a small venous catheter, the Hemolung RAS is easy to use.

Three Components – One Integrated System

The Hemolung RAS is composed of three devices which together provide a completely integrated extracorporeal CO₂ removal system.

The Hemolung Cartridge

- Integrated gas exchange membrane and centrifugal blood pump
- Patented ActivMix™ technology for efficient CO₂ removal at low blood flow rates
- CO₂ removal rate: 50 to 100 mL/min.
- Blood flow rate: 350 to 550 mL/min
- Priming volume: 260 mL
- Advanced dual-layer membrane coating (siloxane/heparin)
- Membrane surface area: 0.59 m²



Cartridge



Catheter



Controller

The Hemolung Catheter

- 15.5 Fr dual lumen venous catheter
- Low resistance design provides high blood flow rates at low pressures
- Wire-reinforced catheter body to prevent kinking
- Available in jugular (17 cm) and femoral (26 cm) versions

The Hemolung Controller

- Bedside console that controls the Hemolung RAS
- Rotates the Hemolung Cartridge (to pump blood and enhance gas exchange)
- Intuitive user interface with on-screen instructions
- Real-time and historical display of CO₂ removal and blood flow
- Digital controls for sweep gas flow, with automatic switching between O₂ and air
- Automatic removal of membrane condensation for steady gas exchange

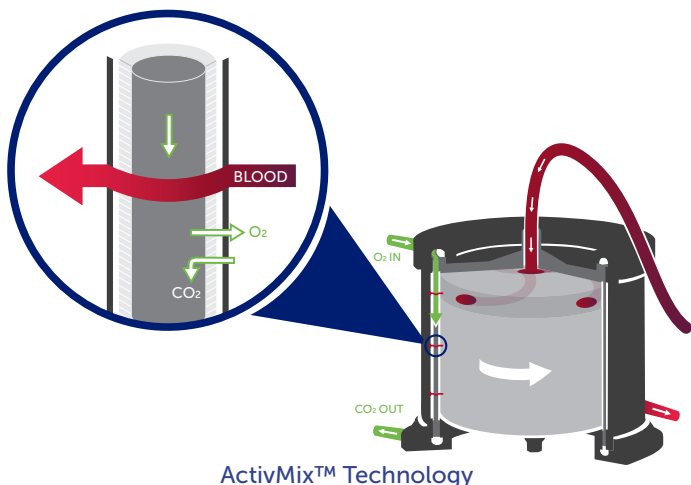
Hemolung Cartridge Technology

The Hemolung Cartridge is a highly efficient extracorporeal gas exchange device that couples an actively mixed gas exchange membrane with a centrifugal blood pump. Within the Hemolung Cartridge, hollow fiber membranes are arranged in a thin ring around a rotating core. Vacuum-driven oxygen or air flows through the inside of the hollow fibers, and a portion of the gas diffuses through the fiber walls into the blood flowing on the outside of the fibers. Carbon dioxide diffuses from the blood into the fibers and is removed via the exiting gas stream. Blood flow through the Hemolung Cartridge is generated by centrifugal force. An impeller located on the rotating core spins at approximately 1250 RPM, generating pressures of up to 200 mmHg.

ActivMix™ Gas Exchange Technology

The primary impediment to gas exchange in modern artificial lung devices is the diffusion of gas through a layer of slow-moving blood at the fiber surface. To enhance gas exchange, the thickness of this boundary layer must be reduced and a constant supply of fresh blood must be provided to maintain a favorable diffusion concentration gradient.

The Hemolung Cartridge incorporates ALung's patented ActivMix™ technology, which significantly increases CO₂ removal at low blood flow rates. Rotation of the core next to the fiber bundle creates secondary flow patterns and increases the relative velocity between the fibers and the blood, increasing gas exchange efficiency.



Hemolung Fibers

The secondary flow patterns responsible for this enhancement are called Taylor vortices. Taylor vortices penetrate the fiber bundle, promoting the mixing of blood and reducing the thickness of the boundary layer. Experimental testing and computational fluid dynamics (CFD) analysis has shown that the Taylor vortices generated in the Hemolung Cartridge are stable, non-turbulent, and non-hemolytic. This active mixing process allows the Hemolung Cartridge to achieve clinically significant gas exchange at lower blood flow rates and with less membrane surface area than other devices.

Hemolung Fiber and Coating Technology

Plasma wetting and thrombus formation are the two primary impediments to maintaining gas exchange over long periods of time in artificial lung devices. The Hemolung Cartridge utilizes two proprietary coating technologies on its hollow fiber membranes to redress these problems and ensure reliable performance.

Plasma wetting occurs when blood plasma fills the micropores of the fibers, causing the gas permeance of the fibers to decrease. To prevent plasma wetting, the Hemolung fibers are coated with a thin layer of siloxane that creates a plasma-tight skin on the surface of each fiber. The fiber walls thus become impermeable to plasma while remaining very permeable to CO₂ and O₂.

Thrombus formation on the fibers reduces gas exchange by impairing gas diffusion. To prevent thrombus formation, heparin is covalently bound to the siloxane coating.

Hemolung Catheter Technology

The Hemolung RAS uses a high-performance, 15.5 Fr dual-lumen venous catheter developed by ALung Technologies. The catheter consists of two wire-reinforced tubes, one inside the other, which creates two independent lumens, an inner and an outer. Blood from the patient is drawn through the outer drainage lumen and transported to the Hemolung Cartridge. Decarbonated blood from the Cartridge is then returned to the patient via the circular inner lumen.

The use of wire reinforcement in the catheter allows for thin walls and large lumens while preventing kinks from forming. Higher flow rates can be achieved with the Hemolung Catheter than with standard hemodialysis catheters.

The catheter is percutaneously inserted using standard techniques. Insertion accessories are included with every catheter to facilitate easy placement.



Hemolung 15.5 Fr Jugular Catheter



Hemolung 15.5 Fr Femoral Catheter



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Hemolung Controller Technology

The Hemolung Controller is a fully-integrated and easy-to-use control system. The primary functions of the controller are:

- to rotate the Hemolung Cartridge core to generate blood flow and active mixing;
- to provide continuous measurement of the Hemolung's CO₂ removal;
- to drive sweep gas flow through the membrane to remove CO₂; and
- to provide safety monitoring with a full set of alarms.

An electric motor within the Hemolung Controller is magnetically coupled to the core of the Hemolung Cartridge and spins the core to pump blood with centrifugal force. The pump speed is digitally controlled via the user interface, and a real-time measurement of the blood flow rate is provided with an ultrasonic flow meter.

Unique to the Hemolung Controller is its real-time measurement of CO₂ removal. For the first time, the performance of an extracorporeal membrane can be continuously monitored without taking blood samples from the circuit. Historical data can also be displayed on the Controller.

Another feature unique to the Hemolung Controller is its use of digitally-controlled, vacuum-driven sweep gas. The vacuum-driven gas flow is inherently safe, as pressures on the gas-side of the membrane remain sub-atmospheric. This eliminates the risk of air entering the bloodstream in the event of a membrane failure. The Controller also allows for automatic switching between O₂ and air. Finally, patent-pending technology automatically removes membrane condensation, ensuring steady gas exchange and further simplifying the delivery of therapy.

The Hemolung Controller facilitates the safe delivery of therapy through significant monitoring and alarm technology — a first in the field of extracorporeal support. On-screen priming instructions and help screens make the device easy to use.