HEMOLUNG® CR⁴

Instructions for Use

REF 80115
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Pioneered by ALUNG®

Published by ALung Technologies, Inc.

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TRADEMARKS AND ACKNOWLEDGMENTS

The products described are covered by one or more of the following patents:
US Patent No. 7,927,544. US and Foreign Patents Pending.

Caution: Federal law restricts this device to sale by or on the order of a physician.

This device has not been FDA cleared or approved;
This device has been authorized by FDA under an EUA;
This device is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of device under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Authorized physicians will review the authorized Fact Sheet for Healthcare Providers and provide to the individual being treated with the Hemolung RAS the authorized Fact Sheet for Patients.

Authorized physicians will use the Hemolung RAS as outlined in the Hemolung RAS Instructions for Use. Deviations from the authorized procedures, including the authorized Instructions for Use required to use the Hemolung RAS are not permitted.

Authorized physicians will collect information on the performance of the Hemolung RAS and report to DHT2B/OHT2/OPEQ/CDRH (via email CDRH-EUA-Reporting@fda.hhs.gov) and ALung Technologies, Inc. any suspected occurrence of significant deviations from the established performance characteristics of which they become aware.

All personnel using the Hemolung RAS must be appropriately trained in using the Hemolung RAS, use appropriate laboratory and personal protective equipment when interacting with the patient, and use the device in accordance with the authorized labeling.

ALung Technologies, Inc, its authorized distributor(s), and authorized physicians will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

SYMBOLS

Catalog Number

Serial Number

Batch Code

Non-Pyrogenic


Date of Manufacture


Manufacturer


Type CF Part

Humidity Limitation


Caution


Consult IFU


CE Mark


Do not use if package is damaged

Fluid Ingress Rating

Ethylene Oxide Sterilization

Irradiation Sterilization

EU Authorized Representative


Do not Reuse

Do not Re-sterilize

Not Sterilized


No Pushing


Temperature Limitation


Expiration Date


WEEE Recycle

cTUVus Mark


Consult IFU

MR unsafe

SYMBOLS

Notes Relevant information about topic.

Warnings Failure to observe these can cause serious injury or death to the patient.

Cautions Failure to observe these can cause damage to the Hemolung Respiratory Assist System.

ABBREVIATIONS

AC	Alternating Current
ACT	Activated Clotting Time
aPTT	Activated Partial Thromboplastin Time
°C	Degrees Celsius
CO_2	Carbon Dioxide
DIC	Disseminated Intravascular Coagulation
$ECCO_2R$	Extracorporeal Carbon Dioxide Removal
°F	Degrees Fahrenheit
Fr	French
HIT	Heparin Induced Thrombocytopenia
IEC	International Electrotechnical Commission
IFU	Instructions for Use
in	Inches
IV	Intravenous
kg	Kilogram
kPa	Kilopascal
lbs	Pounds
LED	Light Emitting Diode
L/min	Liters Per Minute
LPM	Liters Per Minute
m^2	Meter Squared
mL/hr	Milliliter per hour
mL/min	Milliliter per minute
mmHg	Millimeter of Mercury
NaCl	Sodium Chloride
O_2	Oxygen
pCO_2	Partial pressure of carbon dioxide
POST	Power-on self-test
RAS	Respiratory Assist System
RPM	Revolutions per minute
U/kg	Units per kilogram
U/kg/hr	Units per kilogram per hour

CONTENTS

SYMBOLS & ABBREVIATIONS

CONTENTS

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PREFACE

1.1 Device Description

The Hemolung RAS provides ultra low-flow, veno-venous extracorporeal carbon dioxide removal ($ECCO_2R$) using a single, 15.5 French catheter dual lumen inserted percutaneously in the femoral or jugular vein. Low-flow $ECCO_2R$ with the Hemolung RAS provides partial lung support independently of the lungs. The Hemolung RAS removes 25% - 50% of basal metabolic CO_2 production at circuit blood flows of 350-550 mL/min. The Hemolung RAS is a fully integrated system designed to minimize the complication risks associated with extracorporeal gas exchange therapy.

Low-flow $ECCO_2R$ offers an alternative or supplement to invasive mechanical ventilation (IMV) for patients suffering from acute hypercapnic respiratory failure. In contrast to IMV, low-flow $ECCO_2R$ provides partial ventilatory support independently of the lungs.

The Hemolung RAS is not intended to provide therapeutic levels of oxygenation. During Hemolung therapy, blood passing through the circuit is oxygenated via room air sweep gas; however, at ultra-low extracorporeal blood flows, the limited oxygen carrying capacity of blood precludes meaningful oxygenation of mixed venous blood.

The Hemolung RAS is for use in hospital critical care units by advanced health care providers including physicians, registered nurses, perfusionists, and respiratory therapists.

1.2 Intended Use of Device

The Hemolung RAS is intended to provide minimally-invasive, low-flow extracorporeal carbon dioxide removal ($ECCO_2R$). Low-flow $ECCO_2R$, or Respiratory Dialysis™, with the Hemolung RAS is a lung-independent ventilatory support therapy for removal of CO_2 waste molecules from venous blood via extracorporeal circulation through a single, 15.5 French, central venous catheter at blood flows of 350 – 550 mL/min.

The Hemolung RAS is intended to be used in a critical care setting as an adjunct to noninvasive or invasive mechanical ventilation to reduce hypercapnia and hypercapnic acidosis, and/or to maintain normalized levels of arterial PCO_2 and pH, in patients suffering from acute, reversible respiratory failure for whom ventilation of CO_2 cannot be adequately, safely, or tolerably achieved.

The Hemolung RAS is intended to remove 30% - 50% of basal metabolic CO_2 production. The Hemolung RAS is not intended to provide therapeutic levels of oxygenation. Oxygenation of the blood that passes through the circuit does occur via room air sweep gas. However, the limited oxygen carrying capacity of blood precludes meaningful therapeutic benefit at the flow rates which the Hemolung is intended to operate.

The disposable components of the Hemolung RAS have been validated for 7 days of continuous use and may be replaced for continuation of therapy as required.

1.3 Indications for Use

The Hemolung RAS is intended to be used as an adjunct to noninvasive or invasive mechanical ventilation to reduce hypercapnia and hypercapnic acidosis due to COVID-19, and/or to maintain normalized levels of PCO_2 and pH, in patients suffering from acute, reversible respiratory failure due to COVID-19 for whom ventilation of CO_2 cannot be adequately, safely, or tolerably achieved.

Contraindications

The Hemolung RAS is contraindicated for patients with known sensitivity to heparin (e.g., history of heparin-induced thrombocytopenia). The Hemolung Cartridge membranes are coated with heparin and systemic anticoagulation is required when using the device.

Use of the Hemolung 15.5 Fr Femoral Catheter is contraindicated for patients with an inferior vena cava filter.

1.4 Warnings

A WARNING is provided if reasonable evidence exist of an association of a serious hazard with the misuse of this device, or when special attention is required for the safety of the patient. Failure to observe these warnings can cause serious injury or death to the patient.

This Instructions for Use (IFU) is not intended as a substitute for the physician's experience and judgment in treating a patient. This IFU must be read prior to using the Hemolung RAS.

Additional warnings appear throughout this manual.

The safety and effectiveness of the Hemolung RAS has not been established in patients who:

- are less than 21 years old
- are pregnant or lactating

- Do not use this device unless you have completed the training program.

- Discuss the risks and benefits of extracorporeal respiratory support with the patient. The physician must weigh the benefits and risks involved in employing the Hemolung RAS based on best medical practice.

- Inspect each package and component prior to use. The fluid pathway is sterile and nonpyrogenic. Do not use if the package is opened or damaged. Do not use if any protective caps are damaged or missing, or if any product label is missing or shows signs of tampering. Do not use if a sterile package is missing the green inspection sticker which verifies sterilization.

- Do not use the Cartridge, Catheter, or any device components after the expiration date listed on the package.

- Do not reuse or resterilize the Cartridge, Catheter, blood tubing, or other sterile components. They are intended for "Single Use Only." Reuse of any of the sterile components can result in contamination that can cause infection of patients and user, component deterioration, and device failure.

- Only use smooth clamps when not using the clamps supplied with the tubing or Catheter. Alternate the clamping location to avoid damaging the tube. Avoid clamping near the adapters and the hub.

- Adhere to the recommended anticoagulation protocol or to an established institutional procedure for anticoagulation with heparin. Proper anticoagulation monitoring must be maintained during Hemolung therapy.

- Always observe proper sterile techniques when handling the Catheter and all other sterile items.

- Continuously monitor the patient while on the Hemolung therapy. Be diligent about recognizing signs and symptoms of fluid imbalance, abnormal laboratory values, infection/sepsis, bleeding, thrombocytopenia, hemolysis, or other complications related to extracorporeal support systems.

Catheter Warnings

- The Catheter should be inserted and/or removed by a qualified licensed practitioner. The size of the target vessel should be considered prior to insertion of the 15.5 French Hemolung Catheter.

- The Catheter is intended for use only with the Hemolung RAS and should not be used for any other purpose.

- Assess the patient's vascular anatomy and current use of any in-dwelling devices for proper Hemolung Catheter selection and placement. Failure to do so can result in patient harm and/or device malfunction.

- A pneumothorax can result during jugular catheter placement. Patients on ventilators are at increased risk of pneumothorax during internal jugular cannulation.

- Use the guidewire straightener to insert the "J" guidewire end into the introducer needle. Do not force the "J" guidewire during insertion. Forcing can cause the guidewire to kink or break. The "J" guidewire and dilators provided with the Hemolung Catheter Kit should be used for insertion of the Hemolung Catheter. Use of alternative components may increase risk of insertion complications.

- The "J" guidewire is 100 cm, be cautious to only insert the guidewire a depth of 2-5 cm longer than the insertion depth of the Catheter. Insertion of the guidewire beyond this depth may increase the risk of insertion complications (i.e. cardiac arrythmias or damage).

- Do not use the seal flush port on the Cartridge for drug infusion. Infusion of any fluids other than 0.45% or 0.9% saline may result in damage to the device.

- Do not force the guidewire, dilators, or Catheter during insertion. Improper use can result in vessel laceration or perforation.

- Do not place the jugular catheter into or allow it to remain in the right atrium or right ventricle. The tip of the jugular Catheter should be located at the junction of the superior vena cava and right atrium.

- Verification of the Catheter tip location must be confirmed by appropriate imaging guidance to ensure proper placement.

- Do not use alcohol or acetone on any part of the Catheter. Exposure may damage the Catheter.

- Always keep the catheter clamped to prevent air embolisms except when flushing the Catheter, when the stylet is in the Infusion Lumen (RED), or when connecting to bloodlines.

- Never clamp over the wire-reinforced section of the Catheter. Clamping can result in Catheter kinking, fracture, or device failure.

- Do not nick, puncture or move the Catheter when suturing as this could cause bleeding, infection, reduced blood flow, or therapy cessation.

- Do not place sutures around the Catheter body. Place suture around the groove in Catheter hub.

- Manage the Catheter insertion site per institutional wound care procedures for indwelling vascular catheters. Failure to do so can result in sepsis, bacteremia, and infection.

- Do not use sharp instruments or scissors to remove the patient's insertion site dressing.

- Promptly remove the Catheter when therapy is complete. Follow institutional procedures for percutaneous vascular catheter removal and disposal of biological hazards.

- Always ensure the Catheter is adequately secured using the provided Grip-Lok securement device and sutured utilizing the available suture groove. If mobilizing the patient, continuously monitor the Catheter and avoid excessive tension to the blood tubing to prevent Catheter dislodgement during mobilization.

Cartridge Warnings

- Do not use the seal flush port on the Cartridge for drug infusion. Infusion of any fluids other than saline may result in damage to the device.

- Only the BodyGuard 323 Volumetric Infusion Pump is to be used to provide a continuous saline infusion to the Cartridge.

- Ensure that the Hemolung Cartridge is positioned below the level of the patient.

Controller Warnings

- Keep the Controller plugged into an AC power source at all times, including during storage between treatments. Failure to do so will result in battery depletion and device failure. Only disconnect from AC power for patient transport. Battery life is approximately one hour. The pump does not operate when the battery is not properly charged.

- Route the silicone sweep gas outlet tubing through the purge valve on the side of the Hemolung Controller to prevent moisture buildup in the Cartridge fibers. Failure to comply can cause degradation of gas exchange performance and result in an alarm.

- The detachable AC plug is used to isolate the device from the supply mains. Be sure to position the equipment such that it is not difficult to access the plug.

- Clear all air bubbles from the Hemolung RAS and components prior to initiating Hemolung therapy. Air bubbles and/or leaks observed during priming and/or operation may result in an air embolism.

- Continuously monitor the system for leaks, cracks, clots, vibrations, air, or other system failures.

- Position all tubing in such a manner as to prevent kinks or restrictions. Restricted or kinked tubing may alter blood or sweep gas flow and cause device failure.

- A patient may experience heat loss (hypothermia) from blood exposure to atmospheric temperatures and evaporation of water vapor across the membranes. To minimize heat loss, set the sweep gas flow to the lowest rate that will provide the required level of CO_2 removal.

- Continuously monitor the CO_2 removal and sweep gas flow rates. Adjust therapy as needed.

- If the pump involuntarily turns off because of a system alarm or has intentionally been stopped for any duration, the treating physician must consider the length of time the pump was off, the individual patient's condition and anticoagulation status, the potential risks associated with thrombus formation, and local procedures when deciding to discontinue therapy or to continue therapy by turning the pump back on.

- Do not remove the instrument covers on the Hemolung Controller. The Hemolung RAS does not have any user serviceable parts and the battery cannot be replaced by the user. Contact ALung or your medical equipment distributor for service or repairs.

- Do not allow alcohol, alcohol-based fluids, anesthetic fluids (such as isoflurane), or corrosive solvents (such as acetone) to come into contact with the Hemolung RAS as they may jeopardize its structural integrity.

- Possible explosion hazard – the Hemolung RAS is not explosion proof and must not be operated in the presence of flammable anesthetics.

- Use of accessories and cables other than those specified, with the exception of cables sold by ALung, Inc. or its authorized representative, as replacement parts for internal components may result in increased emissions or decreased immunity of the Hemolung System.

- Extracorporeal blood flow through the Hemolung RAS may result in unknown sequestration and lowered levels of pharmacological agents.

1.5 Cautions

A CAUTION is provided when any special care is to be exercised by the physician to avoid causing damage to the System or other property. Failure to observe these can cause damage to the Hemolung RAS.

Additional cautions appear throughout this manual.

- Do not position the Controller to make it difficult to remove the power cord from the inlet connector. The inlet power connector and the power cord are used as the means to isolate the controller from the main supply power.

- Do not spill fluids onto the Controller. The Controller is not waterproof. If a spill occurs, wipe it up immediately.

- After turning off the Hemolung Controller, wait a minimum of 20 seconds before turning it back on again.

- To avoid risk of electric shock, this equipment must be connected to a power supply with a protective earth grounding line.

- Avoid striking the Cartridge during the priming and de-airing process. Use a series of gentle hand taps to remove air bubbles.

- Take caution when handling the seal flush port. Do not expose it to excessive force.

- Do not apply excessive upward force to the silicone tubing when inserting it into the purge valve.

1.6 Notes

A NOTE is provided to draw attention to special information.

Additional notes appear throughout this manual.

- Condensation/water droplets may appear in the gas outlet port area as a result of temperature differences between the blood and sweep gas. This has no significant effect on the performance of the Hemolung RAS.
- Routinely replace the vacuum canister every 24 hours to ensure the integrity of the canister and overall system performance.

1.7 Potential Complications

Air embolism
Anemia
Arterial cannulation
Arteriovenous fistula
Bacteremia
Bleeding
Brachial plexus injury
Cardiac arrhythmia
Cardiac tamponade
Catheter or circuit thrombosis
Central venous stenosis
Central venous thrombosis
Chylothorax
Compartment syndrome
Death
Dehydration
Disseminated intravascular coagulation
Edema
Endocarditis
Exit site necrosis
Extravasation
Fibrinogen changes
Foreign body reaction
Hematoma
Intracranial Hemorrhage
Hemolysis
Hemorrhage
Hemothorax
Hepatic dysfunction
Hydrothorax
Hypertension
Hypervolemia
Hypotension
Hypothermia
Hypovolemia
Infection
Pleural effusion
Pneumothorax
Pulmonary embolus
Renal dysfunction
Right atrium puncture, trauma
Septicemia
Shock
Stroke
Subcutaneous tunnel infection
Thoracic duct laceration
Thrombocytopenia
Thrombotic embolus
Vessel laceration

2

PRODUCT DESCRIPTION

2.1 Hemolung Cartridge Kit

Description

The Hemolung Cartridge is an integrated extracorporeal gas exchanger and blood pump. Blood is circulated around the outside of the Cartridge's hollow fiber membranes while a sweep gas flows through the inside of the membranes. Carbon dioxide diffuses out of the blood and is swept away by the sweep gas while oxygen diffuses from the sweep gas into the blood. Blood tubing and other accompanying disposable products are included in the Hemolung Cartridge Kit.

Contents

Ref #	Product Description
14000	Hemolung® Cartridge Kit (XG4) Contains all subsequent equipment used to set up therapy
10003	Hemolung® Cartridge Membrane oxygenator with integrated centrifugal pump
14100	Hemolung® 7 Day Accessories Kit Contains the following equipment to set up or stop therapy: Hemolung Rinse Back Kit Soda Lime Column IV Administration Sets Vaseline Jelly (7) 1500 mL Vacuum Canisters
80102	Hemolung Cartridge Kit IFU Printed Instructions for Use

Spare Parts Kit

Ref #	Product Description
50400	Spare Parts Kit Contains the following equipment: (1) Sweep-Gas Outflow Tubing (7) 1500mL Vacuum Canisters (4) Universal Catheter Securement (4) IV Administration Set

Diagram

Hemolung Cartridge

1 Blood Inlet (BLUE)
2 Sweep Gas Inlet
3 Sweep Gas Outlet
4 Blood Outlet (RED)
5 Seal Flush Port with One Way Valve

2.2 Hemolung Catheter Kit

Description

The Hemolung Catheter is a dual lumen venous catheter designed specifically for use with the Hemolung RAS. It exhibits low resistance to flow while also resisting kinks. Individual femoral and jugular Hemolung Catheter Kits are available for use. Each kit includes a Catheter Insertion Kit.

Hemolung Catheter Kit Contents

Ref #	Product Description
30030	Hemolung 15.5 Fr Femoral Catheter Kit (XG4) (1) 15.5 Fr Femoral Catheter with Stylet (2) Grip-Lok™ Wide Adhesive Universal Catheter Securement (5) 6, 9, 12, 14, & 16 Fr Dilator (1 of each) (3) 20 mL Syringe (1) 10 mL Syringe (1) #11 Scalpel (1) 18 Ga x 7 cm (2.75 in) Introducer Needle (1) 0.038 in x 100 cm Guidewire with Straightener and J-Tip
30130	Hemolung 15.5 Fr Jugular Catheter Kit (XG4) (1) 15.5 Fr Jugular Catheter with Stylet (2) Grip-Lok™ Wide Adhesive Universal Catheter Securement (5) 6, 9, 12, 14, & 16 Fr Dilator (1 of each) (3) 20 mL Syringe (1) 10 mL Syringe (1) #11 Scalpel (1) 18 Ga x 7 cm (2.75 in) Introducer Needle (1) 0.038 in x 100 cm Guidewire with Straightener and J-Tip

Hemolung Catheter Insertion Kit

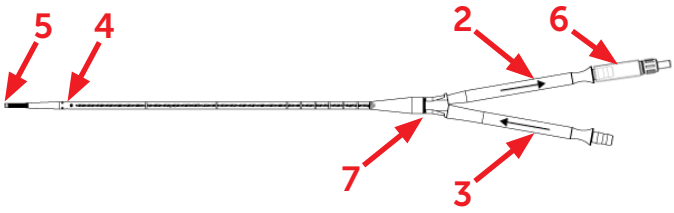
Ref #	Product Description
50200	Hemolung Catheter Insertion Kit (2) Grip-Lok™ Wide Adhesive Universal Catheter Securement (5) 6, 9, 12, 14, & 16 Fr Dilator (1 of each) (3) 20 mL Syringe (1) 10 mL Syringe (1) #11 Scalpel (1) 18 Ga x 7 cm (2.75 in) Introducer Needle (1) 0.038 in x 100 cm Guidewire with Straightener and J-Tip

Diagram

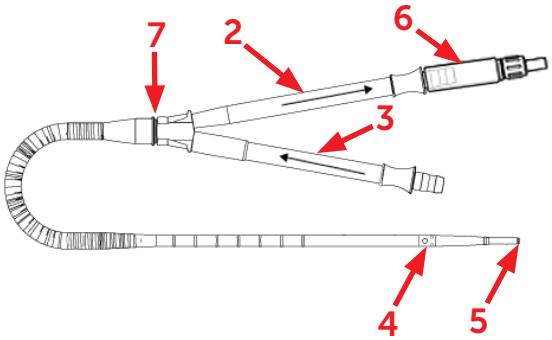
Catheter

Stylet

Femoral



Jugular



1	Stylet
2	Drainage Lumen (BLUE)
3	Infusion Lumen (RED)
4	Drainage Port
5	Infusion Port
6	Removable Priming Adapter
7	Suture Groove

2.3 Hemolung Controller

Description

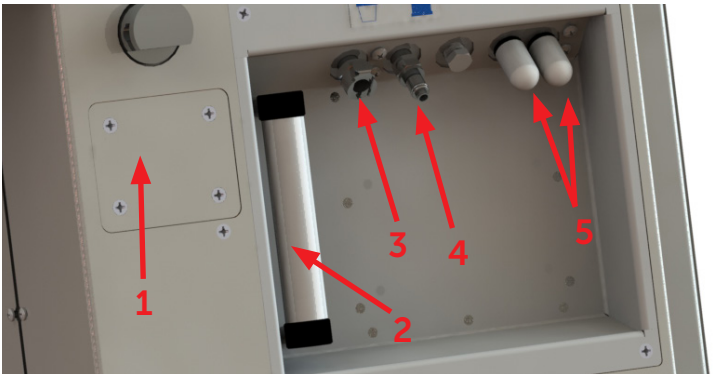
The Hemolung Controller is the mechanism for operating the Hemolung Respiratory Assist System. It controls the extracorporeal blood flow rate and the sweep gas flow rate.

Contents

P/N	Product Description
21000	Hemolung Controller - CR4 The reusable part of the Hemolung RAS. This self-contained unit holds all electronics and monitoring sensors.

Diagram

Hemolung Controller (Side)



1 Diagnostic Ports Access **(Refer to CAUTION)**
2 Soda Lime Column
3 Vacuum Canister Port
4 Sweep Gas Port to Hemolung Cartridge
5 Air Inlet Filters (Porex)

Hemolung Controller (Back)

6 USB Port

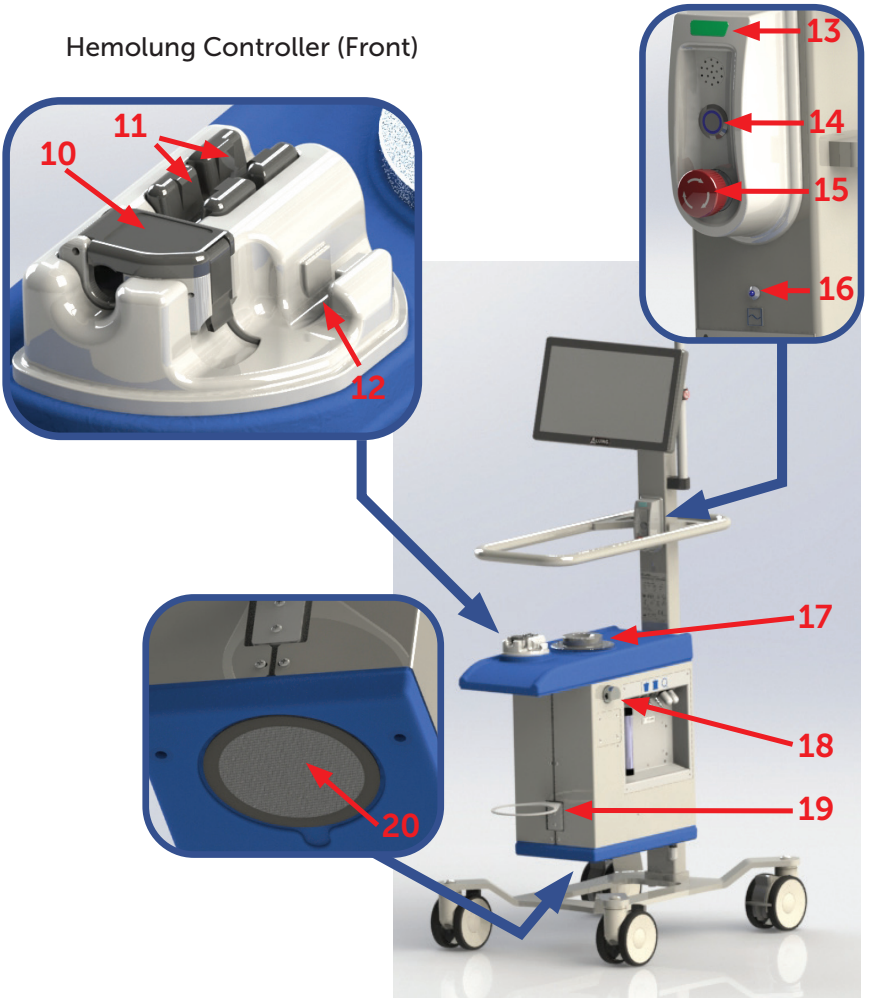
7 AC Power Inlet

8 Grounding Port

9 Battery Fuse

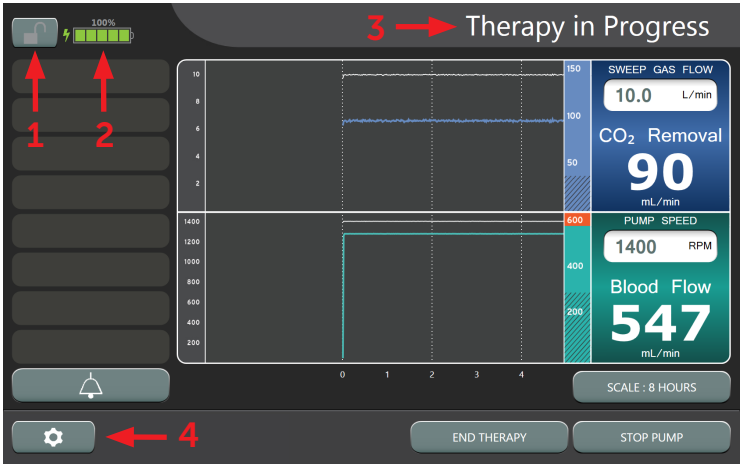
CAUTION: The Diagnostic ports must be covered at all times during use of the Hemolung system. Removal of the Diagnostic Port cover may result in electrical damage (ESD). The Diagnostic Ports have no user functionality and should only be accessed by ALung authorized service personnel.

Hemolung Controller (Front)



10 Blood Flow Sensor
11 Bubble Detectors
12 Tubing Strain Relief
13 Alarm LED
14 Controller Power Button
15 Pump Stop Switch
16 AC Power Present
17 Magnetic Drive
18 Purge Valve
19 Vacuum Canister Bracket
20 Magnetic Fan Cover

Hemolung Controller Display



The display incorporates touch screen controls for interfacing with the system.

1 Screen Lock

2 Battery Status

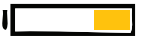
3 Current Mode

4 Settings

Screen Display Symbols

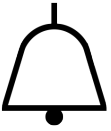
Charging Icon

Battery Status



Low Battery

Critical Battery



Alarm Sound ON

Alarm Sound OFF

Alarm Sound Temporarily Muted

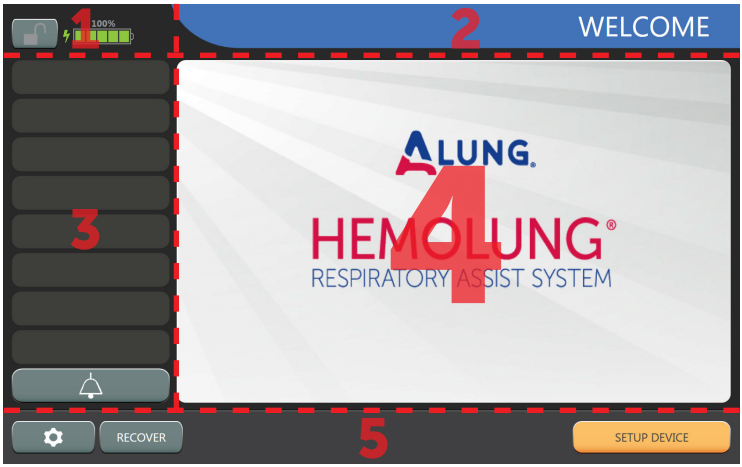
Setting

Screen Locked

Screen Unlocked

CAUTION: Pump will not operate when battery is critical.

User Interface



1 Display Symbol Area
Indicates the following system status:
- AC power status
- Battery status

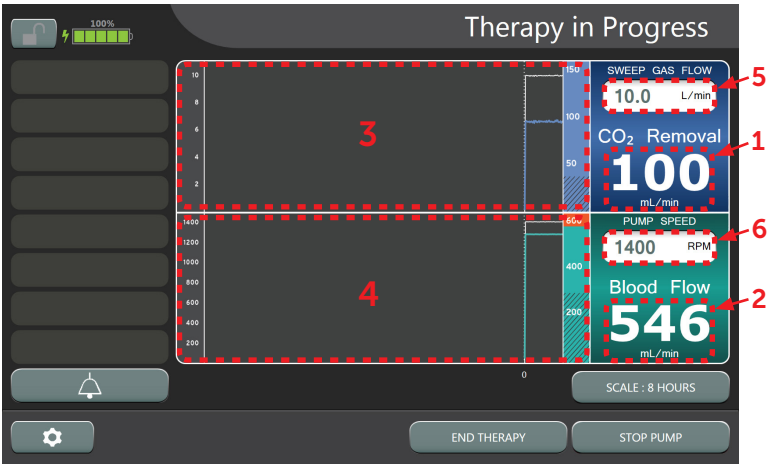
2 Current Mode
Displays current operational mode (device state).

3 Alarm List
Active alarms are displayed in this area. Click any alarm listed for additional information. The Audible Alarm Icon is also located at the bottom.

4 Main Area
Information relevant to the current operational mode and user inputs are displayed here, such as instructions, settings, and therapy parameters.

5 Navigation Area
Use the buttons located in the navigation area to interact with the system.

Therapy Mode Interface



1 Measured CO_2 Removal Rate
Displays the measured CO_2 removal rate

2 Measured Blood Flow Rate
Displays the measured blood flow rate

3 CO_2 Removal Rate Trending Graph
This area displays the graph for CO_2 removal. Default period is 8 hr but can be cycled through 8 hr, 24 hr, or 7 days.

4 Blood Flow Trending Graph
This area displays the graph for blood flow rate. Default period is 8 hr but can be cycled through 8 hr, 24 hr, 7 days, or 14 days.

5 Programmed Sweep Gas Flow Rate
Displays the measured sweep gas flow rate

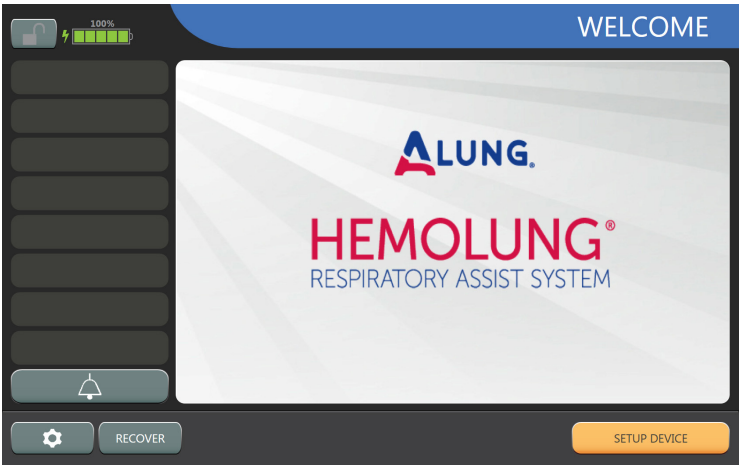
6 Programmed Pump Speed
Displays the measured pump speed (RPM) of the Hemolung Cartridge

Pump Off Notice

Description The pump-off timer displays whenever the pump is turned off by the user or when an alarm shuts down the pump. The physician should use this information to determine whether it is safe to resume therapy. Pausing therapy can result in thrombosis.

NOTE: In the event of a critical error, the pump-off timer will not display. When critical errors occur, the interface is non-operational and requires the power to be cycled for the system to become operational again.

Welcome Screen

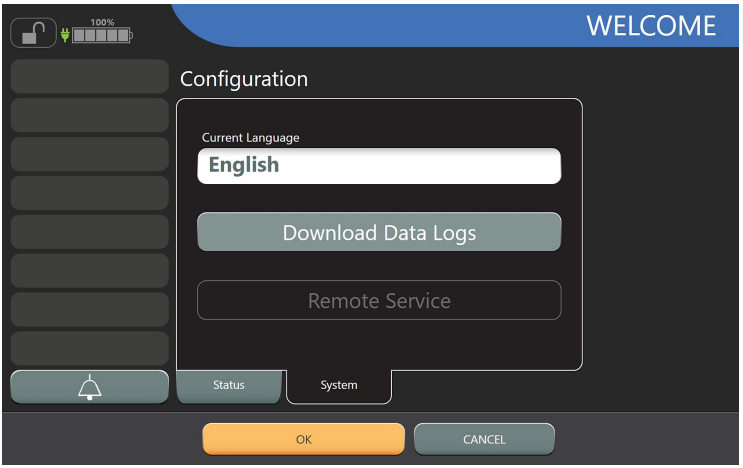


Description Home screen when starting the Hemolung RAS. This is the only screen from which you can use Recover Mode to directly re-enter therapy (e.g., following inadvertent Controller restart). Pressing **SETUP DEVICE** will show the steps required to set up the Controller and disposables to start therapy.

Status

Description During therapy, the status screen shows a list of system parameters. The system information listed can be used during troubleshooting or servicing.

System

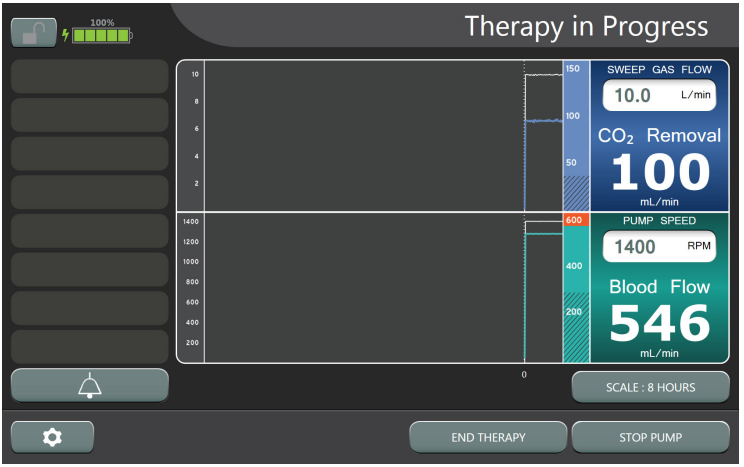


Description To access the language selection, data download, select the system tab from within the settings menu. This is accessed by pressing the settings (⚙) icon at the bottom left of the screen.

Language

Description Select between different languages by pressing the settings (⚙) icon at the bottom left of the screen and then pressing the language at the top of the menu. This presents a list of available languages. Select the desired language and then press OK to return.

Main Menu Therapy Mode



Description Therapy parameters and settings are displayed. Selecting Scale will temporarily change the time period of the graph (8 hours, 24 hours, 7 days, & 14 days). Pressing End Therapy will provide instructions for rinsing back blood after therapy.

3
ANTICOAGULATION

WARNING: Failure to adequately anticoagulate the patient may result in thromboembolism and/or loss of circuit functionality. The benefits of extracorporeal support must be weighed against the risks of systemic anticoagulation and must be assessed by the prescribing physician.

NOTE: Patients on the Hemolung RAS require systemic anticoagulation to prevent clotting of the extracorporeal circuit. The following heparin-based anticoagulation protocol is meant to serve as a general guideline and not as a substitute for the physician's experience and judgment when treating a specific patient. Additionally, differing methods for anticoagulation measurement may affect the implementation of this suggested protocol.

3.1 Initial Anticoagulation Bolus

Systemic anticoagulation before insertion of the Hemolung Catheter is required in order to prevent Catheter thrombus.

1. Insert the guidewire in the target vessel.
2. Anticoagulate the patient with a 50-100 U/kg heparin bolus.
3. Wait approximately 5 minutes for the heparin to circulate and then insert the Catheter.

Prior to connection to the Hemolung RAS, a target activated clotting time (ACT) >150 seconds or activated partial thromboplastin time (aPTT) > 1.5 times baseline is recommended. If a significant delay occurs between administering the heparin bolus and starting Hemolung therapy, verify the anticoagulation level and re-bolus as necessary.

3.2 Maintenance Anticoagulation

The patient should be anticoagulated using an intravenous heparin drip. A separate IV line must be established as the Hemolung extracorporeal circuit has no infusion ports.

3.3 ACT Protocol

If Activated Clotting Time (ACT) is used to monitor and titrate heparin anticoagulation, the following guidelines are recommended:

1. Administer heparin to target an ACT range of 150–180 seconds.
2. Measure the ACT every 30 minutes until two repeated readings fall within the targeted therapeutic range (150–180 seconds).
3. Once two ACT readings are within range, ACT can be measured hourly (q1h).
4. Once two sequential hourly measurements fall within the therapeutic range, decrease the monitoring frequency to once every 2 hours (q2h).
5. The following table provides a guideline for adjusting the heparin infusion.

ACT PROTOCOL

Initial bolus: 80 U/kg
Initial maintenance drip: 18 U/kg/hr
Target ACT: 150–180 sec

ACT (sec)	Bolus	Infusion Titration
< 90	30 U/kg	Increase infusion by 4 U/kg/hr
90–100	15 U/kg	Increase infusion by 3 U/kg/hr
100–126	10 U/kg	Increase infusion by 2 U/kg/hr
126–150	5 U/kg	Increase infusion by 1 U/kg/hr
151–180	None	No change
181–200	None	Decrease infusion by 1 U/kg/hr

3.4 aPTT Protocol

If activated Partial Thromboplastin Time (aPPT) is used to monitor and titrate heparin anticoagulation, the following guidelines are recommended:

1. Administer heparin to target an activated partial thromboplastin time (aPTT) range of 1.5 to 2.3 times baseline (46–70 for baseline of 30 seconds).
2. Measure aPTT 3 hours and then 6 hours following the bolus dose and then every 6 hours thereafter.

aPTT PROTOCOL

Initial bolus: 80 U/kg
Initial maintenance drip: 18 U/kg/hr
Target aPTT: 1.5 to 2.3 x baseline

aPTT (sec)	Bolus	Infusion Titration
< 1.2 x baseline	80 U/kg	Increase infusion by 4 U/kg/hr
1.2 to 1.5 x baseline	40 U/kg	Increase infusion by 2 U/kg/hr
1.5 to 2.3 x baseline	None	No change
2.3 to 3 x baseline	None	Decrease infusion by 2 U/kg/hr
> 3 x baseline	None	Interrupt infusion for 1 hr, then decrease infusion by 3 U/kg/hr

Hirsh, Jack. *Guide to Anticoagulant Therapy: Heparin.* Circulation: Journal of the American Heart Association. American Heart Association. 2001, 103:2994-3018 doi: 10.1161/01.CIR.103.24.2994

4
SEAL FLUSH PUMP

4.1 Description

The seal flush pump is an integral part of the Hemolung system. It is used to provide an infusion of saline at 30 mL/hr to provide a continuous flush of the blood pump seal. This flush must be maintained to prevent coagulation within the pump.

See *Section 10.4 Change Seal Flush Fluid* for instructions on changing the saline to maintain the flush. For detailed instructions on setup and operation of the pump, see the BodyGuard 323 Infusion Pump's Instructions for Use.

WARNING: The seal flush port should not be used for drug infusion.

WARNING: The Hemolung Cartridge requires a continuous infusion of saline (0.45% to 0.9% NaCl) at a rate of 30 mL/hr to protect the Cartridge shaft seal. Insensible water loss occurs from the sweep gas of up to 20 mL/hr (depending on the sweep gas flow rate). These factors should be taken into account when managing a patient's electrolyte and fluid balance.

WARNING: Only the BodyGuard 323 Infusion Pump is approved for use with the Hemolung Controller.

4.2 Seal Flush Pump Occlusion

Refer to the BodyGuard 323 Infusion Pump's Instruction Manual for instructions on how to prime, operate, and troubleshoot the infusion pump. If a "DOWN OCCLUSION" alarm occurs on the BodyGaurd 323 during therapy:

1. Make sure the clamp on the IV administration set is open.
2. Check for any obstruction of the distal tubing.
3. If the alarm still occurs after the previous steps have been taken, disconnect the IV administration set from the check valve on the Hemolung Cartridge. Connect a syringe filled with sterile normal saline for injection into the check valve and slowly inject the saline. DO NOT APPLY EXCESSIVE FORCE TO FLUSH.
4. Any excessive resistance to the saline flush is most likely the result of an occlusion in the seal flush tube.
5. Reconnect the IV administration set and resume flow at 30 mL/hr.
6. If the preceding steps do not clear the alarm, replace the Hemolung Cartridge according to the instructions in Section 11.4 Cartridge Change.

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5 HEMOLUNG SETUP

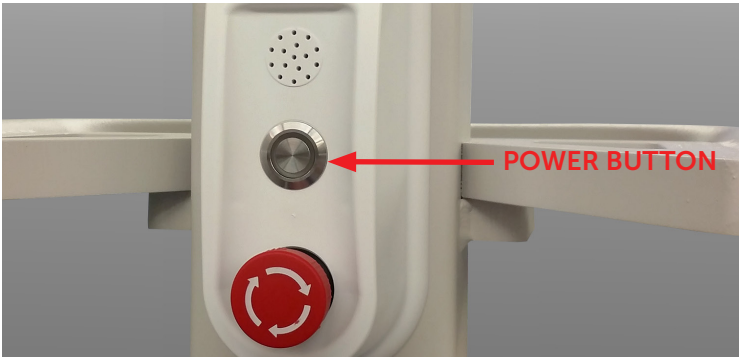
5.1 Overview

This section describes the steps to prepare the Hemolung for connection to the patient. The steps for Hemolung setup include:

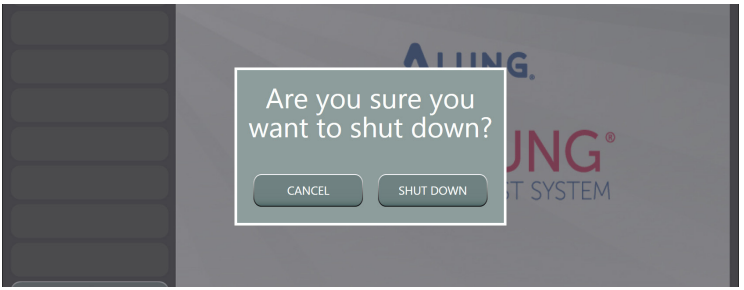
- Connecting the blood tubing and sweep gas tubing circuits
- Priming the blood tubing circuit
- Recirculating the priming fluid to check system operation and to remove air

Power On/Power On Self Test

Pressing the power button will turn on the Controller.



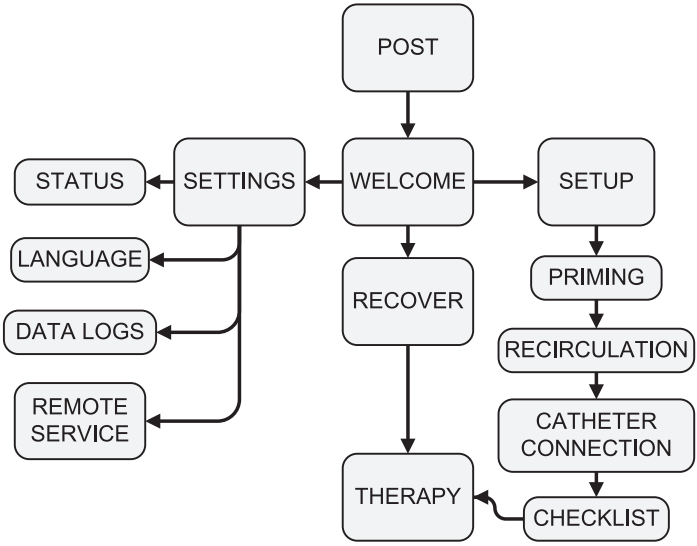
Pressing the power button while the Controller is on, will prompt a shutdown dialog box. Pressing and holding the power button down will bypass the dialog box and shut the Controller down completely.



After turning the Controller on, a Power On Self Test (POST) will be done to ensure proper operation of the Controller. If a POST failure occurs, a particular error code will be displayed. Contact your authorized ALung representative to report the error code.

Start Up Workflow/Screen Navigation

The following diagram shows the welcome screen workflow used for Hemolung setup:

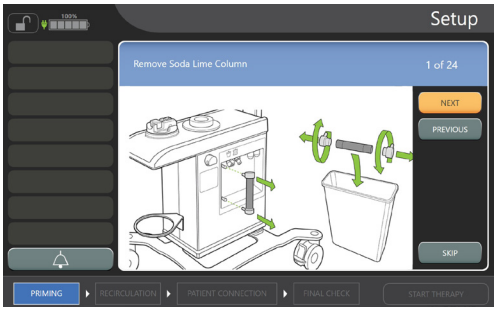


After successful completion of the POST, the system will show the Initial (WELCOME) screen. From here you can enter Settings, Setup, or Recover to skip right into therapy.

The Settings screen provides access to auxiliary features and settings. This includes system status, language selection, downloading of the data logs, and remote service access.

Setup navigates you through preparations for use (including priming, recirculation, Catheter connection, and final checklist). You can move back and forth freely between all Settings and Setup screens until you enter Therapy mode. Once Therapy is started, you cannot return to any of the initial screens.

Preparation for Use Screens



For Priming, Recirculation, and Catheter Connection the Preparation for Use screens provide the user with directed guidance on properly setting up the system to administer Therapy. Each Priming screen contains **Next**, **Previous** and **Skip** buttons**.** Pressing Next allows the user to page through the Priming screens sequentially, while pressing Skip allows for the remaining priming screens to be passed over to access the final priming screen, just before Recirculation. The **Back** button on all Preparation for Use screens allows the user to review any previous steps. The ability to go back is available until Therapy is started.

5.2 Preparing the Hemolung RAS

Procedure

STEP 1 **Plug Hemolung Controller into AC Outlet**

Lock the casters on the Controller and plug into an AC outlet. Press the power switch located on the column to power on the system. It will then enter a POST sequence during which the audible and visible alarm indicators are tested. LED sequence will be as follows:

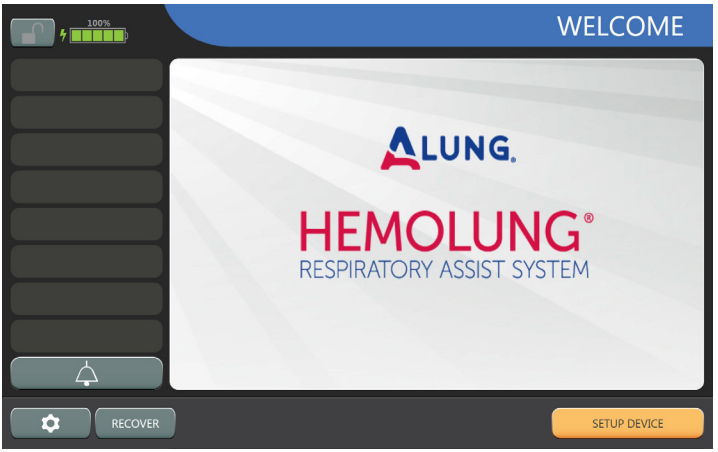
Low Priority Alarm Solid yellow
Medium Priority Alarm Flashing yellow with 3 long beeps, a pause, then 3 long beeps
High Priority Alarm Flashing red with 10 short beeps, pause, 10 short beeps, long pause, repeat once

WARNING: The detachable AC plug is used to isolate the device from the supply mains. Be sure to position the equipment such that it is not difficult to access the plug.

WARNING: If the POST indicator lights do not turn on or if the audible alarm is not activated, there is a problem with the Hemolung RAS. **Do not** use the device. Contact Technical Support.

NOTE: During POST, the vacuum pump and cartridge motor are tested. Noise coming from the vacuum pump and motor during POST is expected.

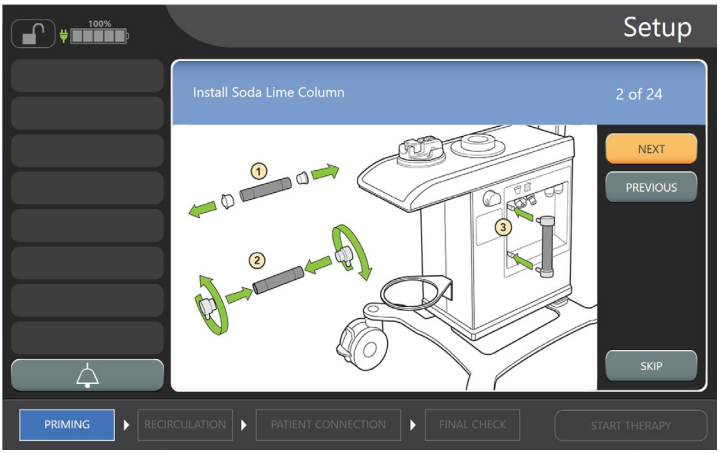
STEP 2 **Setup Overview**



The Setup screen will be displayed after successfully passing the POST

- Press the ⚙ button to enter the settings menu.
- Press the **SETUP DEVICE** button to prime a new circuit.
- Press the **RECOVER** button to resume therapy if the patient is already catheterized and connected to the Cartridge.

STEP 3 **Follow On Screen Instructions**

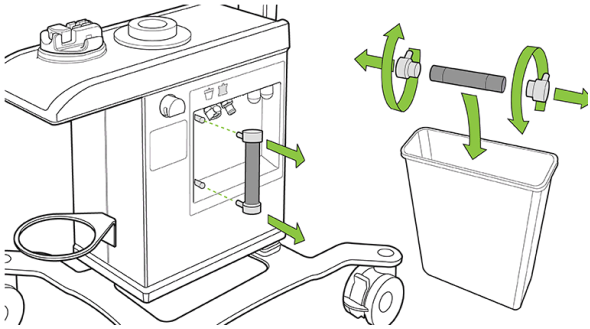


Follow the on screen instructions and press the **NEXT** button to advance through the procedure.

5.3 Circuit Priming

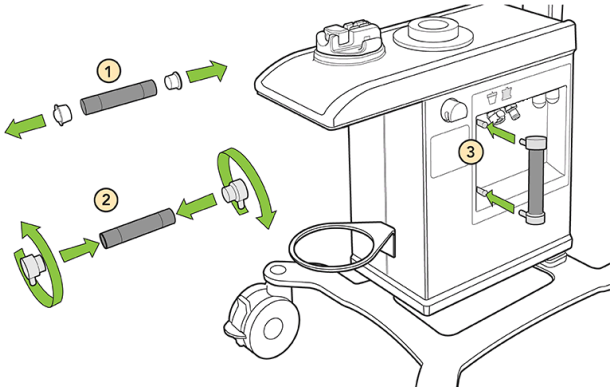
NOTE: Changing the soda lime at the beginning of each new setup is required for accurate CO_2 removal measurements. Failure to change soda lime before each new setup may result in inaccurate measurements.

STEP 1 **Remove Old Soda Lime**



Pull the old soda lime column out of the Controller and remove the reusable end caps. Discard the old soda lime column.

STEP 2 **Assemble and Attach New Soda Lime Column**

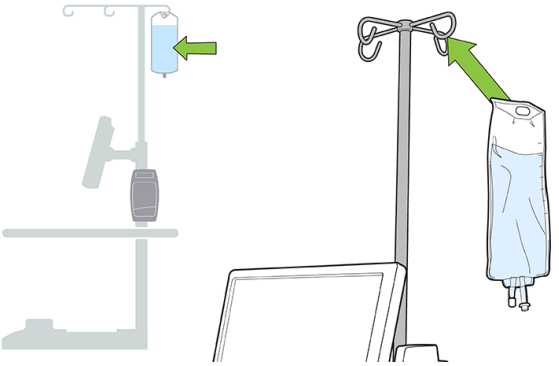


1 Remove the red shipping plugs from the new column. Do not remove the foam plugs.

2 Attach the reusable end caps to the column.

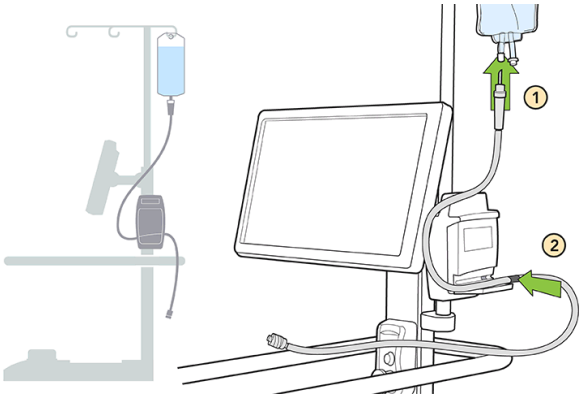
3 Install the new soda lime column on the Controller.

STEP 3 **Hang the Saline for Seal Flush**



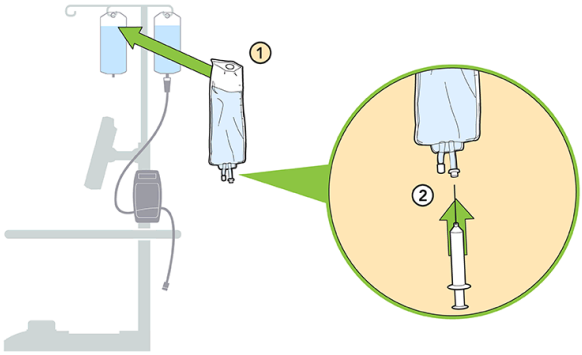
Hang the container of saline for providing the seal flush on the Controller. If necessary, adjust the height of the pole so that the bottom of the saline container is between 6 inches and 12 inches above the seal flush pump.

STEP 4 **Set up Seal Flush**



1 Load the IV administration set into the pump. Refer to the Quick Reference Guide and/or Instructions for Use for infusion pump procedures.

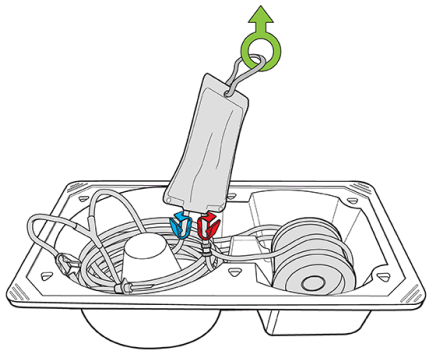
STEP 5 **Prepare Priming Solution**



Prepare a priming solution of at least 500 mL and hang on the Controller. One (1) unit (U) heparin per milliliter (mL) saline is recommended as the priming solution.

NOTE: Other priming fluids have not been qualified for use with the Hemolung RAS. Use only at the discretion of the prescribing physician.

STEP 6 **Open Disposables**



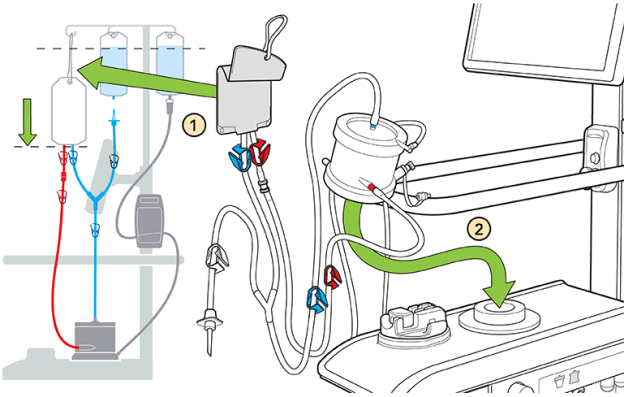
1 Remove the sterile cover from the tray.

2 To remove the contents from the tray, begin by lifting the string at the top of the recirculation bag to unravel the tubing.

3 Then remove the Cartridge from the tray last.

NOTE: Maintain sterility of the blood tubing beneath the plastic sheath that will connect to the Hemolung Catheter.

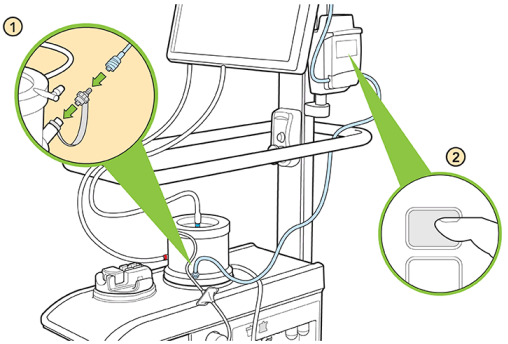
STEP 7 Hang Recirculation Bag and Temporarily Sit Cartridge on Controller



1 Hang the recirculation bag by the attached string on the IV pole so that it is below the saline bags.

2 Temporarily set the Cartridge on top of the Controller.

STEP 8 Connect Infusion Pump and Run at 30 mL/hr



1 Remove the cap from the seal flush port on the Cartridge, then attach the check valve to the port, and connect the IV line.

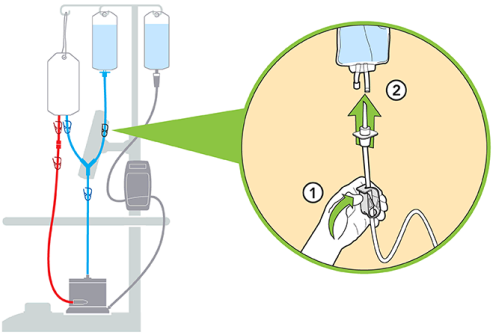
2 Open the clamps on the IV administration set and start the seal flush infusion at 30 mL/hr.

CAUTION: Do not place excessive force on the one-way valve and seal flush port on the Cartridge when priming.

WARNING: The seal flush port must never be used for drug infusion.

WARNING: The Hemolung Cartridge requires a continuous infusion of saline (0.45% to 0.9% NaCl) at a rate of 30 mL/hr to protect the Cartridge shaft seal. Insensible water loss occurs through the sweep gas of up to 20 mL/hr (depending on the sweep gas flow rate). These factors should be taken into account when managing a patient's electrolyte and fluid balance.

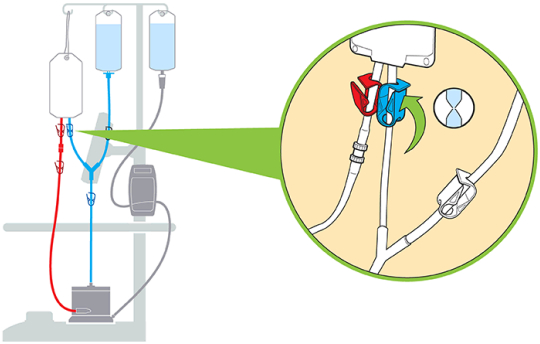
STEP 9 Close White Clamp and Spike Heparin + Saline



1 Completely close the white clamp located near the priming spike on the blue tubing.

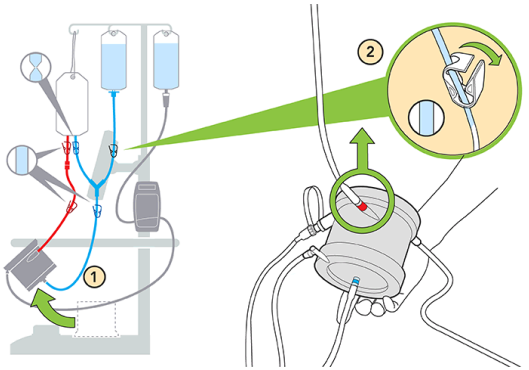
2 Spike the priming solution with the spike line from the recirculation bag.

STEP 10 Close Blue Clamp on Recirculation Bag



Close the blue clamp on the recirculation bag.

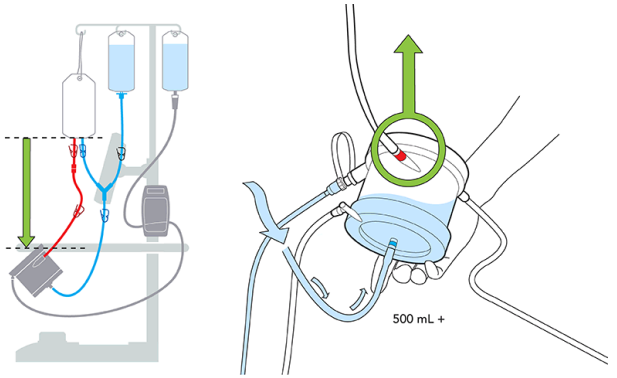
STEP 11 **Prime the Cartridge**



1 Hold the Cartridge upside-down with the red blood outlet port facing up.

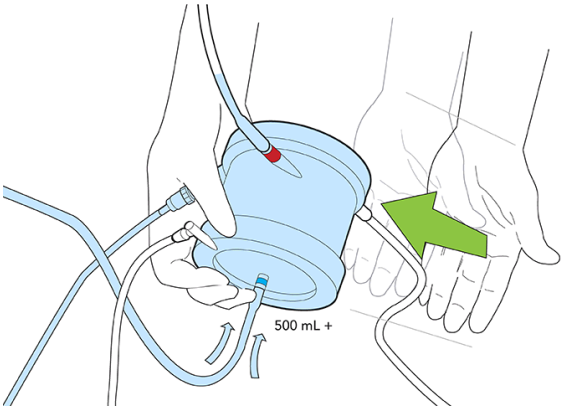
2 Open the white clamp located near the priming spike. This will start the flow of priming solution into the Hemolung circuit. Walk the air through the tubing until it is completely primed and solution begins to enter the Cartridge.

STEP 12 **Fill the Cartridge**



Fill the Cartridge by keeping the red port up and the entire Cartridge below the saline bags.

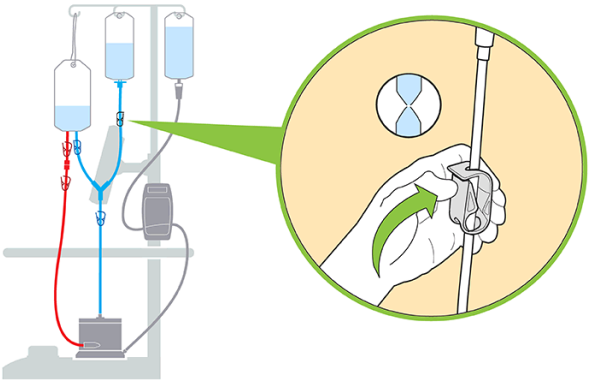
STEP 13 **Remove Air**



With the Cartridge in the same position, tap the side to remove any trapped air. Prime the Cartridge with at least 500 mL of priming solution.

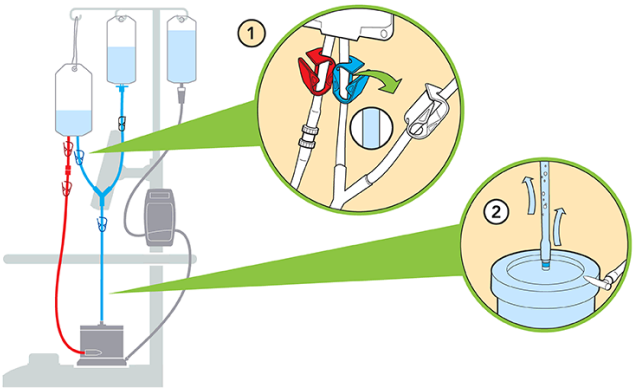
CAUTION: Take caution when handling the seal flush port. Do not expose it to excessive force.

STEP 14 **Close the White Clamp**



Once the Cartridge and circuit is full, close the white clamp.

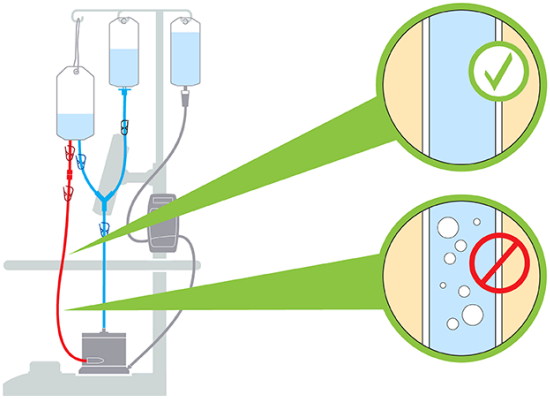
STEP 15 **Open Blue Clamp and Remove Air**



1 Open the blue clamp to allow any trapped air to travel up and into the recirculation bag.

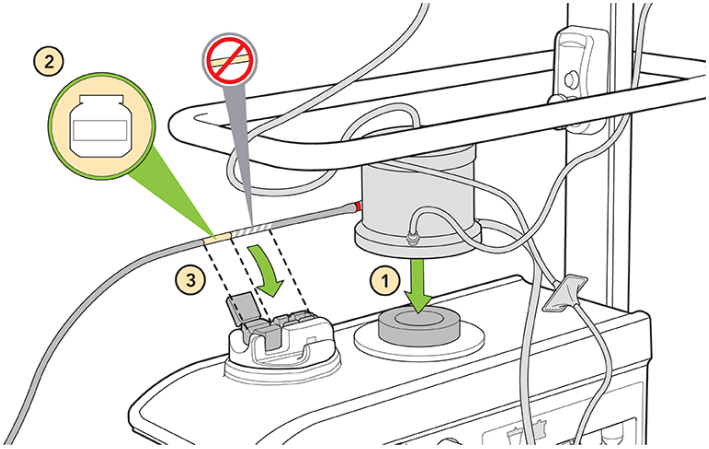
2 Tap the line to assist in this process if needed.

STEP 16 **Check System for Air**



Visually inspect the entire circuit for air bubbles. If air bubbles are found in the circuit, guide them into the recirculation bag.

STEP 17 **Apply Petroleum Jelly, Install Cartridge and Tubing**



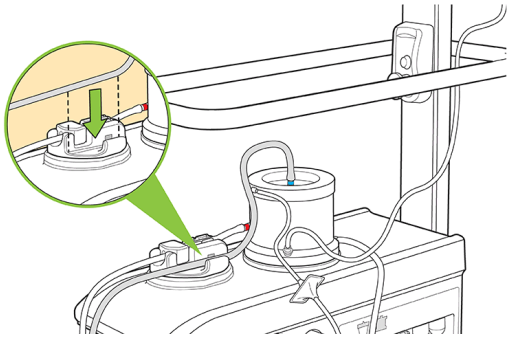
1 Place the Cartridge on the Controller as shown.

2 Apply a small amount of petroleum jelly to the area of the tubing that sits in the blood flow sensor.

3 Place the tubing into the bubble detector and blood flow sensor, and close the blood flow sensor door.

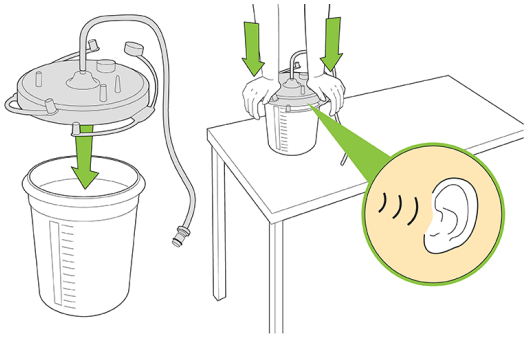
CAUTION: Do not place petroleum jelly on the section of tubing that is placed into the bubble detector

STEP 18 **Place Blue Tube in Strain Relief**



Place the blue tubing into the strain relief next to the Cartridge. Ensure the tubing is not kinked and has adequate slack to allow proper blood flow.

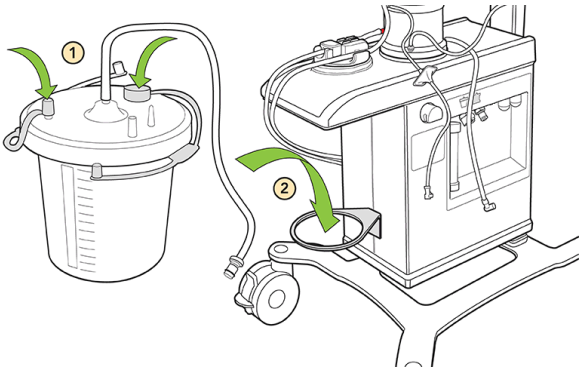
STEP 19 **Assemble the Vacuum Canister**



Place the lid on top of the vacuum canister and apply pressure around the circumference of the lid to secure it. Several "clicks" will be heard when the canister lid is properly secured. Visually inspect the canister lid for proper securement.

CAUTION: The vacuum canister lid must be firmly attached to the canister to form a vacuum. Failure to do so will result in a low sweep gas flow alarm.

STEP 20 **Cap Ports and Place Canister**

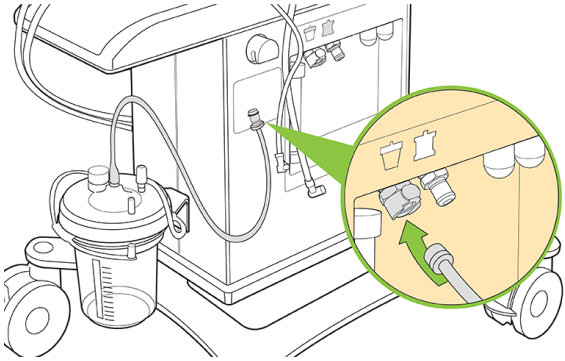


1 Cap the large port labeled "ACCESSORY" and the small port labeled "TANDEM". These ports will not be used.

2 Hang the vacuum canister on the Controller using the bracket.

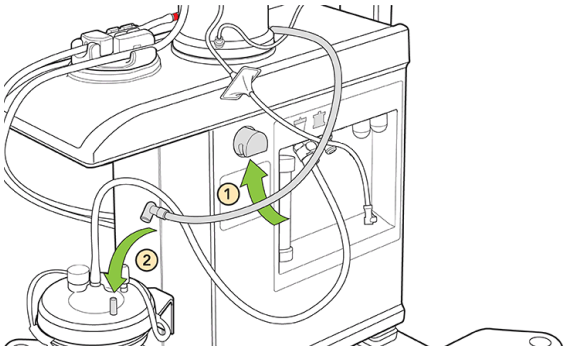
NOTE: Routinely replace the vacuum canister every 24 hours to ensure the integrity of the canister and overall system performance.

STEP 21 **Connect Tube to Port**



Connect the free end of the sweep gas vacuum tube to the vacuum canister port on the side panel of the Controller.

STEP 22 **Install Tube in Purge Valve and Connect to Canister**

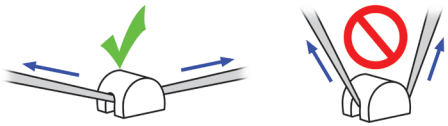


1 Install the silicone sweep gas tube coming from the Cartridge into the purge valve by pulling it upwards into the valve.

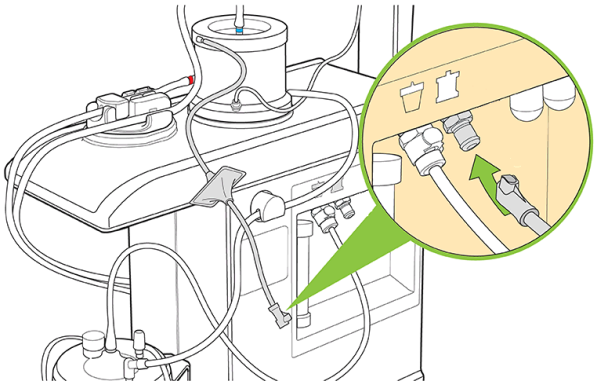
2 Connect the elbow on the end of the tube to the vacuum canister port labeled "PATIENT".

CAUTION:

- Use care when placing the silicone tubing into the purge valve. Using too much force or excessive stretching can cause damage to the tubing.
- Do not apply excessive upward force to the silicone tubing when inserting it into the purge valve.

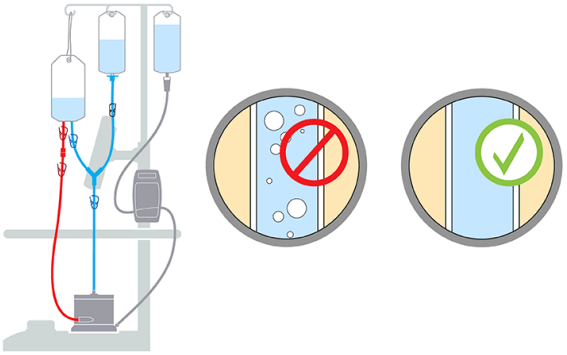


STEP 23 **Connect Sweep Gas Supply Tube**



Connect the sweep gas supply tube (with bacterial filter) to the sweep gas port on the Controller as shown.

STEP 24 **Check Tubing Connections and Check for Air**



Check all tubing connections. Inspect the entire circuit for signs of fluid leakage. If a leak is found, do not use the device. Check the circuit for air bubbles. Small air bubbles can be removed during recirculation. If large air bubbles are present, guide them into the recirculation bag before starting recirculation.

STEP 25 **Start Recirculation**

Press the **NEXT** button to start the recirculation sequence.

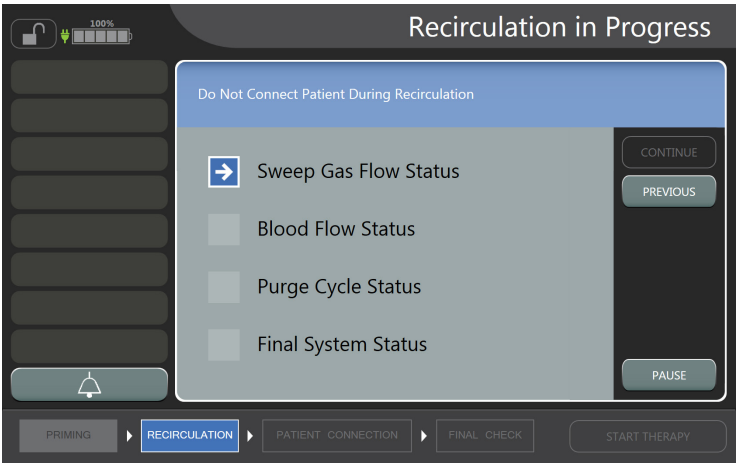
5.4 Recirculation

The purpose of recirculation is to remove any remaining air bubbles in the blood circuit. The pump will circulate the priming solution through the blood circuit to remove any remaining air bubbles. The system will also conduct several self-checks to ensure proper sweep gas flow rates and blood flow rates. A test purge cycle will be performed to ensure that the vacuum canister and purge valve are operating correctly.

WARNING: The user is responsible for ensuring that no air bubbles are left in the circuit before continuing.

Procedure

STEP 1 **Enter Recirculation Mode**

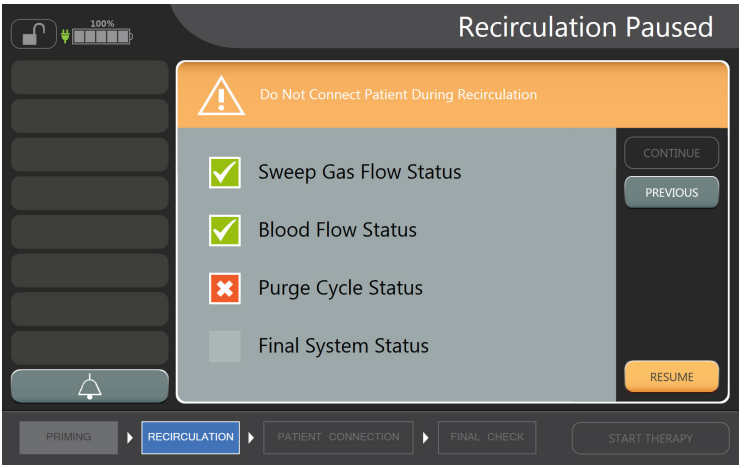


Pressing **NEXT** on the previous screen starts the recirculation sequence. The pump and system checks will start automatically.

WARNING: Ensure that the patient is not connected to the Hemolung RAS before starting recirculation. Running the system in recirculation mode with the patient connected may result in an air embolism or unmonitored therapy.

STEP 2 **Allow the System to Self-test**

Errors

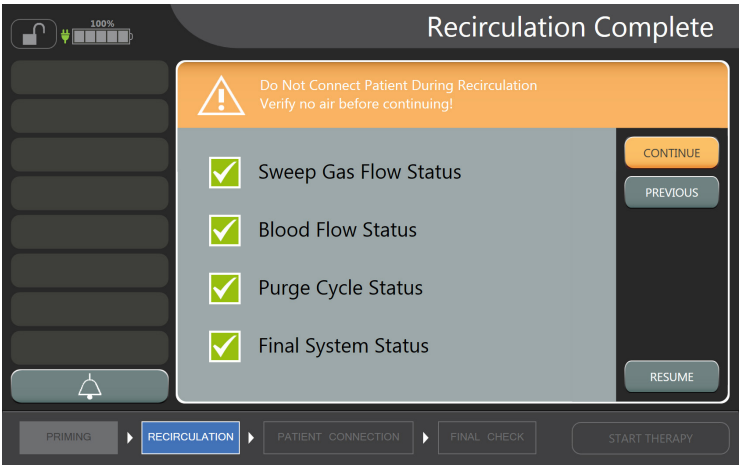


If an error is found in the system during Recirculation, the pump will stop, the failed step will be indicated, and the screen will display possible courses of action to correct the problem. Once the problem has been addressed, press the **RESUME** button to restart the system checks. The Recirculation checks will restart from the beginning any time the pump is stopped and then resumed.

When the system successfully completes all Recirculation checks, it will stop the pump to allow the user to check the circuit for signs of air bubbles. If any air is present, press the **RESUME** button to restart recirculation. Recirculation may be repeated until all air is removed.

The user must inspect the inlet (blue connector) to the Cartridge. If air is found at the inlet, guide it up the tube into the recirculation bag. Repeat recirculation until all air is clear.

Successful Completion



When all recirculation checks have passed, and air has been removed from the circuit, press the **CONTINUE** button to proceed to the next screen.

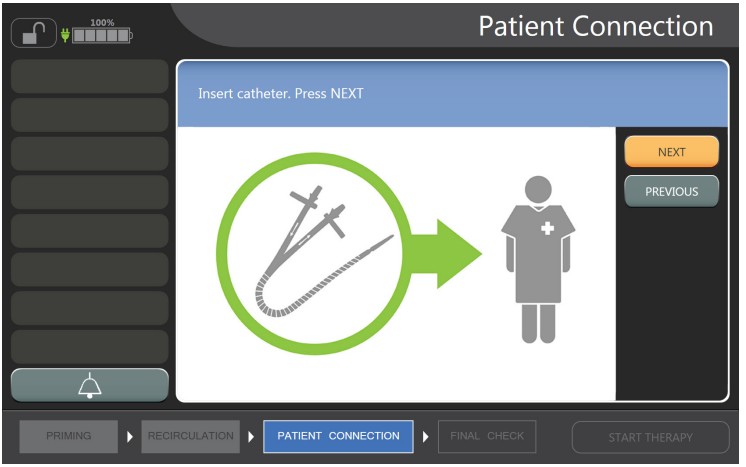
5.5 Sweep Gas

The Hemolung RAS is operated with room air as the sweep gas. Room air will be entrained through the white air inlet filter.

5.6 Wait for Catheter Connection

Procedure

STEP 1 **No Immediate Action Required on Controller**



Once the Patient Connection screen is entered, the pump will run continuously until ready to connect the patient. Only press **NEXT** when ready to begin the patient connection procedure. Pressing **NEXT** will stop the pump and display instructions and graphics for connecting to the patient. The following chapters will focus on catheterizing the patient and connecting the Catheter to the Hemolung Cartridge.

6

CATHETER PREPARATION

6.1 Catheter Insertion

Procedure

STEP 1 **Prepare Catheter and Insertion Supplies**

Fill three (3) 20 mL syringes with 20 mL each of sterile saline for injection.

Fill one (1) 10 mL syringe with 3 mL of sterile saline for injection.

Using a sterile technique, insert the stylet with RED priming adapter into the Infusion Lumen (RED), placing the priming adapter over the barb connector.

Unscrew the stylet from the RED priming adapter and remove it from the Catheter.

Connect one of the 20 mL syringes to the RED priming adapter. Hold the catheter with the tip up, and flush the Infusion Lumen (RED) with approximately 10 mL of saline. Remove the syringe and replace the stylet into the Infusion Lumen (RED).

CAUTION: Do not clamp the Infusion Lumen (RED) with the stylet in place.

Connect one of the 20 mL syringes to the Drainage Lumen (BLUE) priming adapter. Hold the Catheter with the tip up and flush the Drainage Lumen (BLUE) with approximately 10 mL of saline. Clamp the Drainage Lumen (BLUE) using the attached slide clamp. Remove the syringe.

NOTE: The Catheter cannot be heparin/saline locked. Be cautious that after Catheter insertion that all air is fully aspirated to prevent air embolism.

STEP 2 **Prepare Insertion Site**

Prepare the insertion site according to your institution's protocol. Ensure that proper sterile precautions are taken to prevent infections.

NOTE: For jugular insertion, position the patient in a slight Trendelenburg position.

STEP 3 **Puncture Vessel**

With a sterile scalpel blade, nick the skin over the target vessel.

Attach a 10 mL syringe to the introducer needle and insert the needle into the target vessel using appropriate imaging technology. Aspirate to ensure proper placement.

NOTE: Free blood flow indicates vessel entry. If the blood is bright red or a pulsating return is encountered, withdraw and redirect the needle. If no blood flow is observed, the needle is not inside of the blood vessel and must be redirected.

Remove the syringe and place a thumb over the end of the introducer needle to prevent blood loss or air embolism.

Once blood has been aspirated, slide the flexible "J" tip end of the guidewire back into the advancer so that only the tip of the guidewire is visible.

Insert the advancer's distal end into the needle hub.

Advance the guidewire with a forward motion into and past the needle hub so that it reaches the target vessel. Insertion length depends on the patient's size. Do not allow the guidewire to enter the right atrium.

Securely holding the guidewire, remove the needle.

WARNING: Do not force the guidewire, as doing so can kink it.

WARNING: Cardiac arrhythmias can result if the guidewire and or catheter is allowed to enter the right atrium. Place the patient on a cardiac monitor to detect any arrhythmias.

CAUTION: The use of appropriate imaging guidance is recommended to ensure proper guidewire insertion and placement.

CAUTION: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and guidewire as a unit to prevent the needle from damaging the guidewire.

STEP 4 Anticoagulate the Patient

After the guidewire is placed in the target vessel, anticoagulate the patient. See *Section 3 Anticoagulation* for anticoagulation recommendations.

Proceed to Step 5 while the Heparin circulates through the patient.

STEP 5 Dilate Vessel

Slide the vessel dilator onto the guidewire. Advance the dilator through the skin and into the vessel. Use a shallow angle approach to reduce the potential risk that the guidewire kinks or a vessel is punctured.

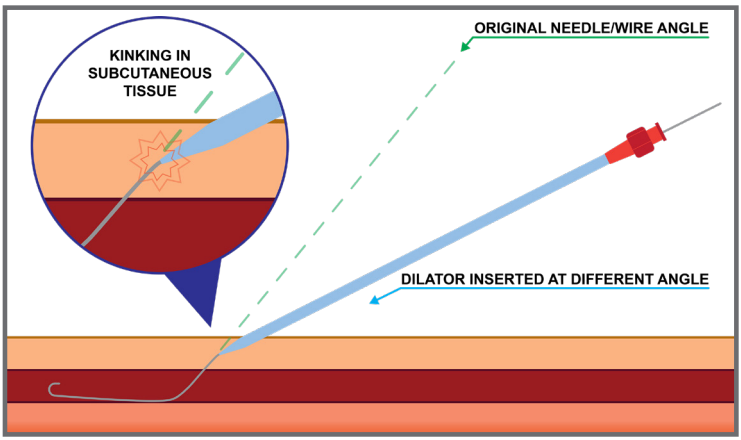
If a larger dilator is needed, remove the first one and thread a larger dilator over the guidewire and into the vessel. Repeat this process until the tissue is sufficiently dilated.

Next, remove the dilator, leaving the guidewire in place.

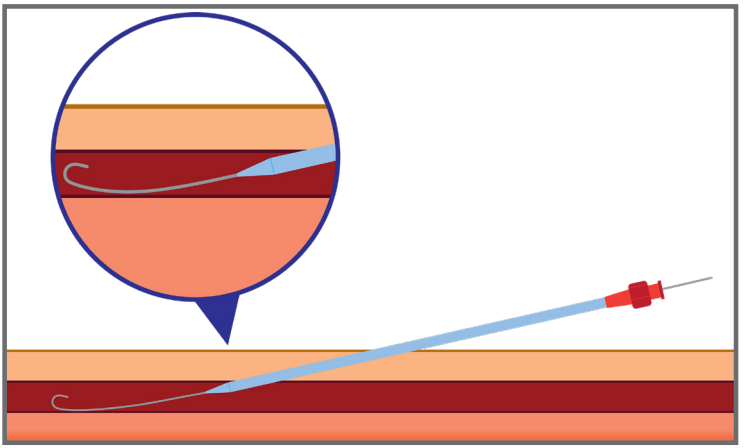
Guidewire and Dilator Insertion Tips

The following tips are provided to minimize guidewire kinking:

1. Position the patient to create a "straight shot" through the tissue and into the target vessel.
2. Insert the introducer needle, and subsequently the guidewire, at a shallow angle (more parallel to the target vessel than a standard 45° approach).
3. If resistance is encountered while inserting the guidewire through the introducer needle, the guidewire should not be advanced. Withdraw the guidewire and needle as an assembly to prevent cutting and shearing of the wire by the sharp needle tip.
4. Pass the dilators over the guidewire at the same angle the needle/guidewire was placed. Forcing the dilator in a direction that diverges from the path of the guidewire can result in kinking the guidewire.
5. Maintain adequate tension of the guidewire taking care to always control the end of the guidewire.
6. Ensure adequate tissue relaxation with each dilation step. Consider repeatedly inserting/retreating the dilator at each step until the tissue is fully relaxed and resistance to insertion is minimal. Utilize rotational motion to gently advance the dilators through the tissue



Incorrect: Dilator inserted at a different angle than the guidewire resulting in kinking in the subcutaneous tissue.



Correct: Dilator inserted at a shallow insertion angle to avoid guidewire kinking.

STEP 6 **Insert the Catheter**

Feed the distal section of the stylet over the guidewire.

Proper Catheter location will be indicated by free blood flow.

Verify the advancement, positioning, and placement of the Catheter using appropriate imaging guidance.

For JUGULAR insertion, advance the Catheter tip to the junction of the superior vena cava and right atrium.

For FEMORAL insertion, advance the Catheter tip into the inferior vena cava.

WARNING: Do not place the Catheter into or allow it to remain in the right atrium or right ventricle. Failure to follow these instructions can result in patient injury or death.

After Catheter placement verification, withdraw the guidewire from the stylet.

Remove the stylet from the Catheter by unscrewing it from the priming adaptor and withdrawing.

STEP 7 **Check Catheter Patency**

Check Catheter patency and remove all air.

Attach a 20mL syringe filled with 15mL sterile normal saline to the priming adaptor of each Catheter lumen.

Release each Catheter clamp and aspirate blood through each lumen. Blood should aspirate easily through both lumens.

If either lumen exhibits excessive resistance to blood aspiration, rotate or reposition the Catheter to obtain adequate blood flow.

NOTE: Do not suture Catheter into place until proper Catheter placement has been verified and adequate blood flow is present.

STEP 8 **Irrigate Lumens**

Irrigate both lumens with saline-filled syringes (20 mL) using a quick bolus technique.

Be sure that the lumen clamps are open during the irrigation procedure.

After flushing, use the attached RED and BLUE slide clamps to clamp the lumens.

WARNING: Failure to clamp the lumens before connecting the blood tubing to the patient can lead to air embolism.

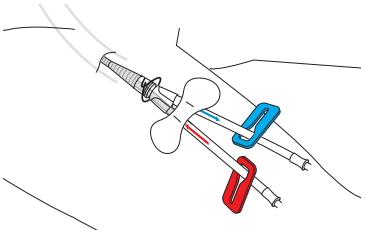
After flushing the lumens with saline, immediately connect the blood tubing and start extracorporeal blood flow. If a delay occurs in establishing extracorporeal blood flow, the Catheter lumens should be flushed continuously with a saline infusion to prevent clotting.

STEP 9 **Proceed to the Next Step**

Once the patient has been catheterized, the Controller will provide steps to connect the circuit to the catheter. From the "Catheter Connection" screen, press the **NEXT** button to stop the pump and proceed to the connection sequence.

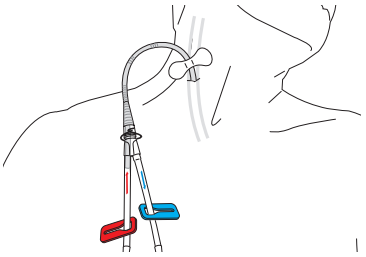
STEP 10 **Secure the Catheter**

Femoral Catheter Securement



Secure the Catheter hub to the skin using a strong suture. The suture should be placed in the groove of the Catheter hub and must be securely tightened. Place the lumens in the Grip-Lok device. Secure the Grip-Lok device to the skin per the Grip-Lok IFU. Grip-Lok devices are provided in the Catheter kit.

Jugular Catheter Securement



The jugular Catheter must be secured at both the exit site and the Catheter hub for maximum stability. Place the Catheter body in the Grip-Lok device at the point where it exits the skin. Secure the Grip-Lok device to the skin per the Grip-Lok IFU. Secure the Catheter hub to the skin using a strong suture. The suture should be placed in the groove of the Catheter hub and must be securely tightened.

WARNING: If the suture is not positioned properly, it can damage or cut the Catheter. Sharp objects may puncture or cut the lumen and cause Catheter failure.

WARNING: Always ensure the Catheter is adequately secured using the provided Grip-Lok securement device and sutured utilizing the available suture groove. If mobilizing the patient, continuously monitor the Catheter and avoid excessive tension to the blood tubing to prevent Catheter dislodgement during mobilization.

WARNING: Position the Hemolung Controller directly adjacent to the patient's bed to ensure the security of the blood tubing. Application of excessive tension to the blood tubing may result in its accidental disconnection or catheter dislodgement, resulting in cessation of therapy and bleeding risk.

NOTE: If a sufficiently long portion of the femoral Catheter resides outside of the body, an additional Grip-Lok device can be used to secure the Catheter at the point where it exits the skin.

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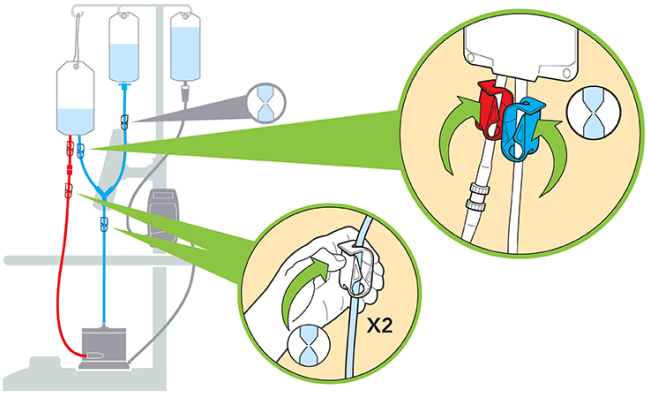
7
STARTING THERAPY

7.1 Connect Tubing to Catheter

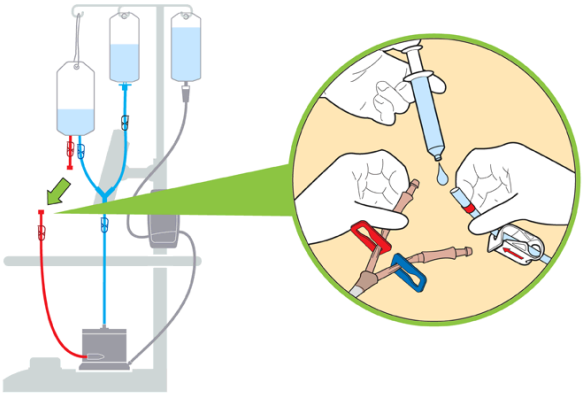
Procedure

STEP 1 **Close All Clamps**



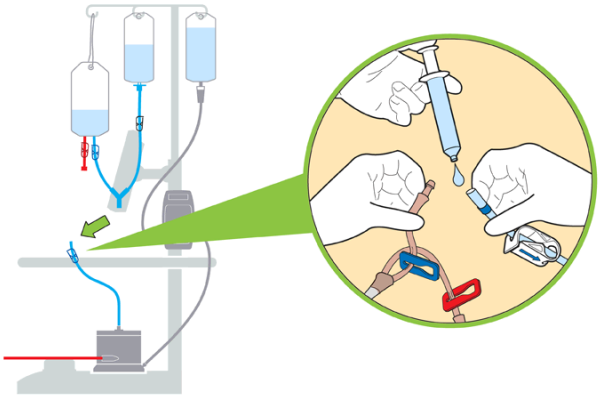
Close all clamps in the circuit. Ensure clamps are closed near the end of each blood tube to minimize the introduction of air.

STEP 2 **Connect TO PATIENT (Red) Tubing Set to Catheter**



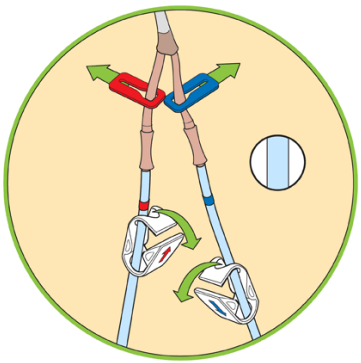
Disconnect the TO PATIENT (Red) Tubing Set from the recirculation bag. Using a wet-to-wet technique, connect the tube to the red lumen on the Catheter. Ensure that the tubing is placed completely over the connector for a secure connection.

STEP 3 **Connect FROM PATIENT (Blue) Tubing Set to Catheter**



Disconnect the FROM PATIENT (Blue) Tubing Set from the Y-connector. Using a wet-to-wet technique, connect the tube to the blue lumen on the Catheter. Ensure that the tubing is placed completely over the connector for a secure connection.

STEP 4 **Open All Clamps**



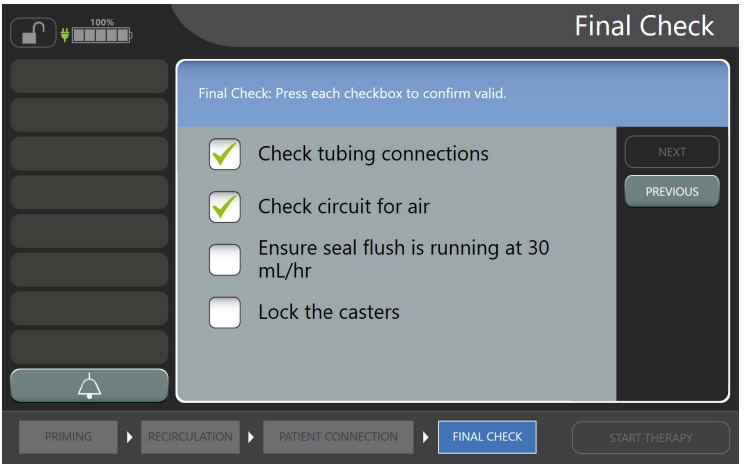
Open all clamps before starting the blood pump. Then Press **NEXT** to proceed to the Final Checklist.

WARNING: Have a back up Hemolung Cartridge Kit available during therapy.

7.2 Final Checklist

After pressing **NEXT** on the final Patient Connection screen, the Final Check screen will be displayed. All items must be completed and checked off before the Start Therapy button becomes accessible.

Procedure



Check each box after completing the task.

STEP 1 **Check Tubing Connections**

Check all tubing connections to make sure they are properly connected.

STEP 2 **Check Circuit for Air**

Check the entire circuit for air bubbles. If air is present in the circuit, it must be removed before proceeding.

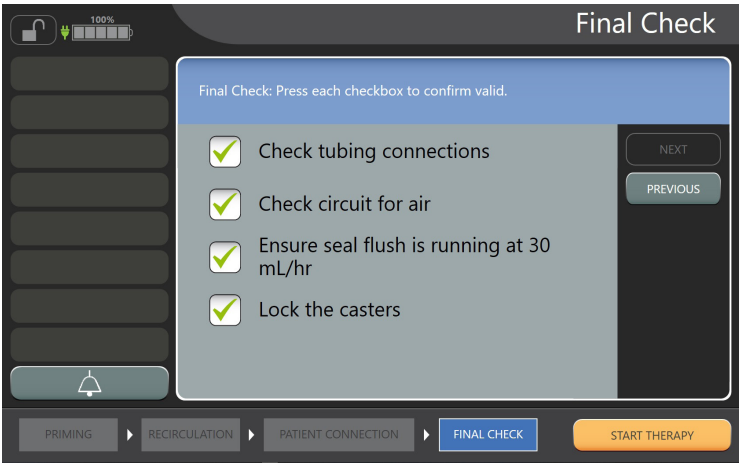
STEP 3 **Check Seal Flush**

Ensure that the seal flush is flowing at a rate of 30 mL/hr.

STEP 4 **Lock the Casters**

Lock the Controller's wheel casters to prevent movement while in use.

STEP 5 **Press START THERAPY**



Press **START THERAPY** to start the blood pump.

7.3 Start Blood Pump

After connecting the primed extracorporeal circuit to the Catheter, Therapy is initiated by pressing Start Therapy after the final checklist. The pump will start automatically, which causes blood to flow through the extracorporeal circuit and sweep gas to pass through the Cartridge membranes. The Hemolung Cartridge will initially operate at the default pump speed (500 RPM) and sweep gas flow rate (1 L/min). The pump speed and sweep gas flow rate can then be slowly adjusted to the desired settings while carefully monitoring the patient. See Section 8 Managing Therapy for more details on changing Therapy parameters.

8

MANAGING THERAPY

8.1 Theory of Operation

Control of CO_2 removal is dependent on three fundamental factors. These are:

- Patient pCO_2
- Sweep gas flow rate
- Blood flow rate (determined by motor RPM)

CO_2 removal is achieved by running the sweep gas through the center of the hollow fibers in the Cartridge while blood is circulated around the outside of the fibers. The sweep gas flow is determined by the programmed sweep gas flow rate and the blood flow rate is determined by the pump speed.

The difference in CO_2 concentration between the patient's blood (high) and the sweep gas (low) will cause CO_2 to diffuse from the blood, across the fiber boundary, and into the sweep gas. The CO_2 will then be exhausted from the Hemolung.

Increasing either the blood flow rate via the motor RPM or the sweep gas flow rate will result in a higher CO_2 removal rate. With low flow ECCO2R, however, blood flow should be maintained at its maximum achievable level throughout therapy and should not be used to control or wean from therapy. Reducing blood flow may increase risk of clotting.

As the patient's pCO_2 drops, the partial pressure difference of pCO_2 in the blood versus CO_2 in the sweep gas will be reduced, resulting in a lower CO_2 exchange rate.

CO_2 removal rate should not be used as a primary indicator of patient condition. In addition to using CO_2 removal rate, monitor the patient's condition and make appropriate use of arterial blood gas.

The blood passing through the Cartridge is oxygenated by using room air as the sweep gas. However, the amount of oxygen delivered to the patient is predominantly a function of the blood flow rate, and at the flows which the Hemolung operates, which are approximately 10% of cardiac output, the amount of oxygen provided is not clinically meaningful. The Hemolung is not intended to provide oxygenation support.

8.2 Managing Initial Therapy

Managing the initial Therapy using the Hemolung RAS should be based on the patient's status and the desired therapy goals. Factors to consider include hemodynamic status, ventilatory status, pH pCO_2 level, and distress level, as well as the patient's general overall condition.

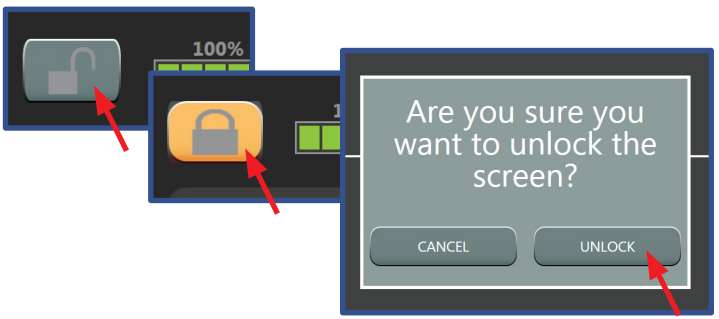
When determining initial pump speed settings, consideration should be given to reaching a minimum blood flow (350 mL/min) as quickly as possible to reduce the chances of thrombus formation. However, changing blood flow rates too quickly or setting them too high may result in hemodynamic instability.

When determining initial sweep gas flow settings, one should take into account that CO_2 removal when starting Therapy is nearly instantaneous. The impact to the patient varies based on pCO_2 level and patient status. Raising the sweep gas flow setting too quickly could result in the patient becoming hypocapnic or in cerebral blood flow vasoconstriction.

During initial Therapy, Hemolung CO_2 removal, ventilator status, and arterial blood gasses should be monitored closely and managed for the desired therapeutic outcome. Continued monitoring of these parameters throughout ongoing Therapy is recommended.

Screen Lock

To avoid accidental button presses, it is recommended to lock the screen during therapy. Press the lock icon in the upper left corner of the screen to lock it. The screen will lock automatically after 2 minutes of inactivity. To unlock the screen press it again and then press **UNLOCK** on the popup message.



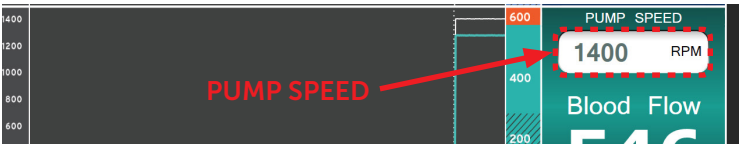
8.3 Controlling Pump Speed

Increasing the blood flow rate will increase CO_2 removal. The blood flow rate is adjusted by varying the pump speed using the Controller. The pump speed can be set between 500 and 1400 RPM to achieve the desired blood flow rate. Pump speed can only be changed from Therapy Mode.

The recommended blood flow rate is 350 to 550 mL/min. Higher blood flows will result in greater CO_2 removal and reduce the risk of thrombus formation in the extracorporeal circuit. Consult *Section 13 Alarms and Troubleshooting* for details.

To adjust the pump speed:

STEP 1 Press the white area where the set pump speed is displayed.



STEP 2 Using the displayed number pad, enter the desired pump speed in increments of 10 RPM.

STEP 3 Press **OK** to accept changes or **CANCEL** to return to the Therapy screen.

NOTE: Maximum blood flow should be achieved using the minimal amount of RPMs to reduce risk of hemolysis. The maximum pump speed will not always generate the greatest blood flow. Negative pressure generated by the pump at maximum speed can also cause the Catheter to lodge against the vessel wall.

If inadequate blood flows are obtained, increase the pump speed. If increasing the pump speed does not increase the blood flow rate, consider the following:

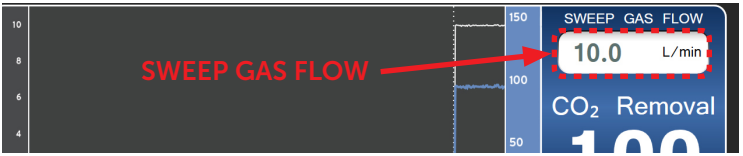
- Check the blood circuit and Catheter for kinks and/or thrombus.
- Consider repositioning the Catheter and/or patient if a vessel obstruction is suspected.
- Consider the patient's volume status and adjust as necessary. A hypovolemic patient may experience lower blood flows, while a hypervolemic patient may experience increased blood flows.

8.4 Controlling Sweep Gas Flow

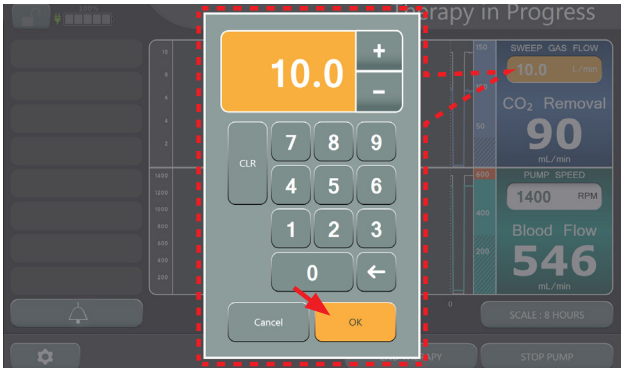
Increasing the sweep gas flow rate will increase CO_2 removal. The sweep gas flow rate can be set to 0 L/min, or be adjusted between 1.0 and 10.0 L/min. The sweep gas flow rate can only be changed from Therapy Mode.

To adjust the sweep gas flow rate:

STEP 1 Press the white area where the set sweep gas flow rate is displayed.



STEP 2 Using the displayed number pad, enter the desired flow rate in increments of 0.1 L/min.

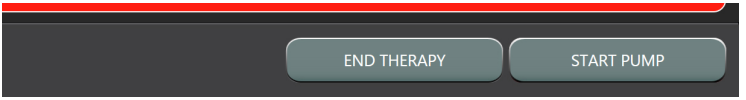


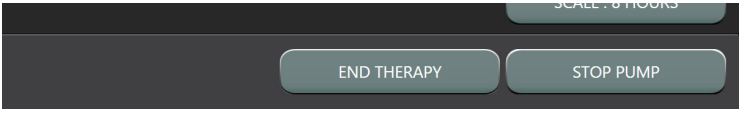
STEP 3 Press **OK** to accept changes or **CANCEL** to return to the Therapy screen.

CAUTION: The sweep gas flow rate should be set at the lowest setting that produces an adequate level of carbon dioxide removal. High sweep gas flow rates can cause patient heat loss from evaporation of water vapor across the Cartridge membranes. Patient temperature should be closely monitored during Hemolung therapy.

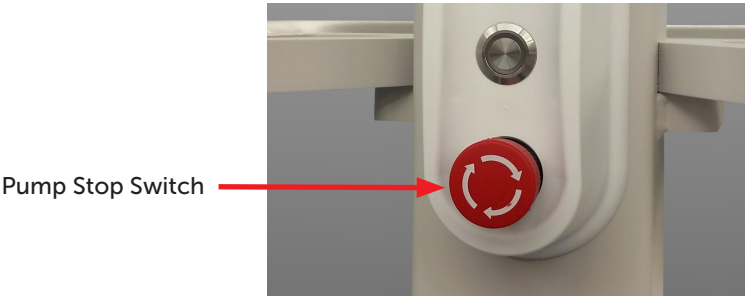
8.5 Start/Stop Blood Pump

The pump can be turned on and off with the on screen Start/ Stop Pump button.





The pump may also be shut off using the Pump Stop Switch. This will immediately stop the pump and display an E-Stop Engaged alarm. Twist the Pump Stop Switch clockwise to disengage the switch and press the Start Pump button to resume.



8.6 Operation During Purge

During Therapy Mode, the Hemolung Controller enters a purge cycle every 15 minutes. The purpose of the purge cycle is to remove moisture from the fiber membrane. The purge cycle occurs automatically and does not require any action by the user. During the purge cycle, the purge valve first closes for 30 seconds, occluding the sweep gas outlet tubing and creating a vacuum in the vacuum canister. The speed of the sweep gas vacuum pump increases during the purge cycle, causing it to become temporarily louder. The purge valve then opens and allows the system to recover for 30 seconds, causing a large flow of sweep gas that purges moisture from the membranes.

During the purge cycle, carbon dioxide removal is not measured and is displayed on the screen as "---". The *Low Sweep Gas Flow* and *Running on Air* alarms are disabled, and sweep gas cannot be adjusted.

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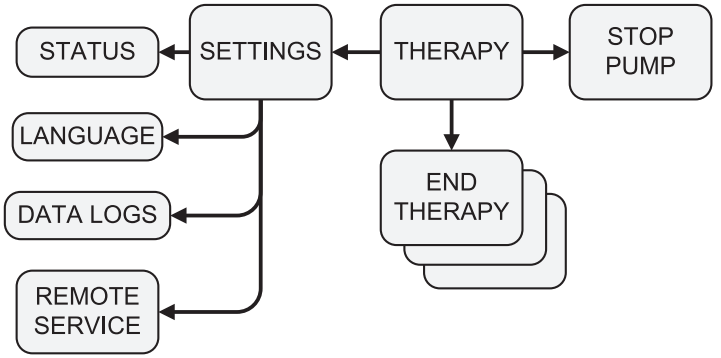
9 USING THE SYSTEM

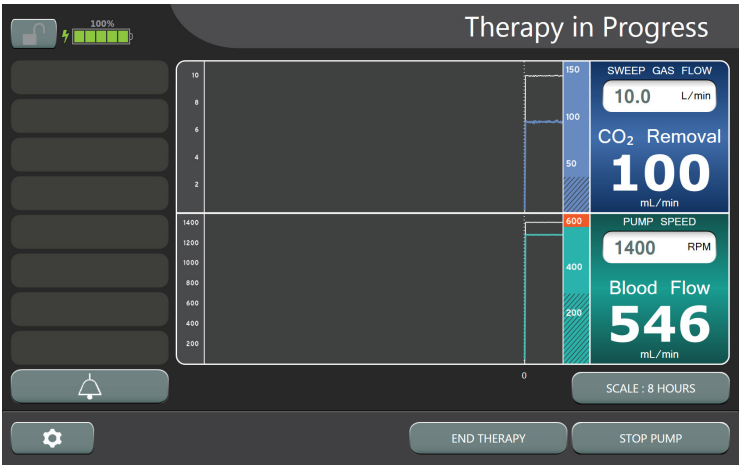
9.1 Therapy Operation

The "Therapy Screen" is the primary screen used while providing patient Therapy. From this screen, the user can control all Therapy parameters, monitor Therapy trends, and manage alarms. The diagram for the Therapy screen workflow is shown below:



NOTE: To ensure safe operation, any screen that does not display patient therapy parameters will automatically return to the main Therapy screen after 60 seconds.

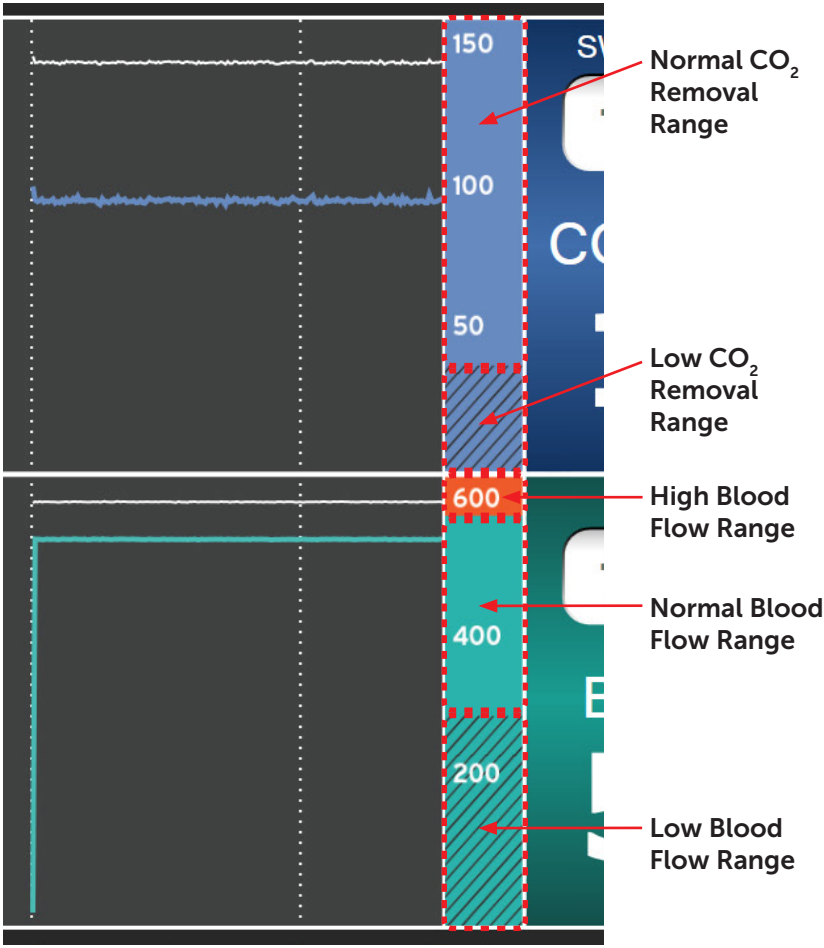
Therapy (Main) Screen



This is the primary screen used while the Hemolung is providing Therapy. This screen will allow the user to:

- View and control sweep gas flow and pump speed settings
- View CO_2 removal rate and blood flow rate
- Evaluate Therapy trending data
- Obtain Help on system operation and alarms

Normal Operating Range

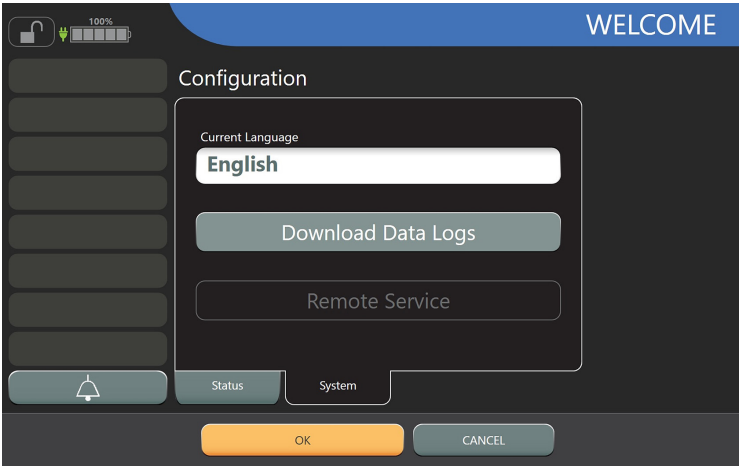


The normal operating range for CO_2 Removal and Blood Flow are marked on the scale by solid colors. Low CO_2 Removal and Blood Flow are marked with a slash pattern. And high Blood Flow is marked in Orange.

Settings Menu

The **Settings Button** (⚙) opens tabs for system configuration and performance information. The Status Tab shows the following system parameters:

Pressing the Settings Icon and then the System Tab shows the following options:



Press **OK** to accept any changes made and return to the Therapy screen. Or press **CANCEL** to return to the Therapy screen without any changes.

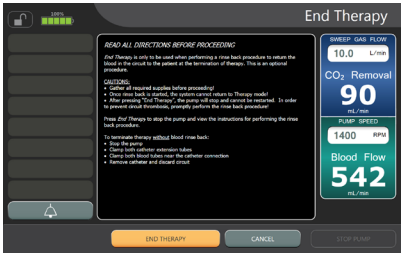
Status Screen

The Status screen displays all patient therapy parameters, as well as system parameters.

System Screen

The System screen is used to change the language, download system data, and access remote service for diagnostics.

End Therapy Screens

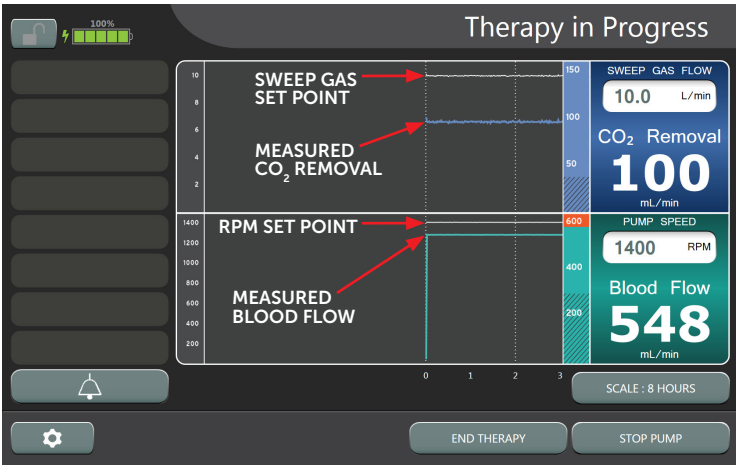


The End Therapy screen will provide guidance to the user for determining whether it is appropriate to end therapy. The screen provides guidance and will not cause the system to leave Therapy mode. Once the user selects **END THERAPY** on the screen to continue with End Therapy, the pump motor will stop and the system will no longer provide patient therapy. See *Section 12 Ending Therapy* for more details on ending therapy.

WARNING: Once End Therapy has been confirmed, Hemolung operation can only be resumed by restarting the system.

9.2 Monitoring Trends in Therapy

While in Therapy mode, the system displays plot lines for the user set sweep gas flow and blood pump RPM as well as the measured CO_2 removal and blood flow rate to detect trends.



The white line in each graph represents the user set point for sweep gas flow and blood pump RPM. The blue line in the top graph represents the measured CO_2 removal. The green line in the bottom graph represents the measured blood flow rate.

Press the **SCALE** button to change the displayed time scale on the graph. Press the button multiple times to cycle between the following time scales:

- 8 hours
- 24 hours
- 7 days
- 14 days

To reduce the chance of misinterpreting trends, the time scale will automatically return to the default 8 hour display after two minutes.

NOTE: Therapy is validated for 7 days. The 14 day trending graph is available if therapy continues for longer than 7 days, at the discretion of the treating physician. Directions for Cartridge change out are provided in section 11.4.

NOTE: When evaluating trends, it is important to remember that the CO_2 removal rate and blood flow rate shown on the graphs are a function of device settings (sweep gas flow rate and pump speed), as well as patient condition.

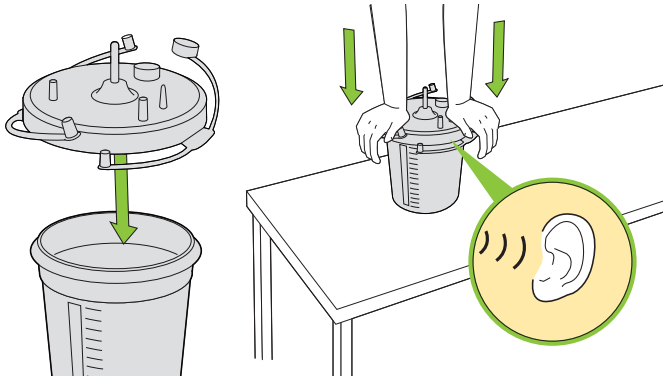
10 ROUTINE TASKS

10.1 Vacuum Canister Replacement

NOTE: The sweep gas vacuum canister must be changed daily to ensure adequate sweep gas flow. No changes or operations to the therapy parameters or blood pump are necessary to complete this task.

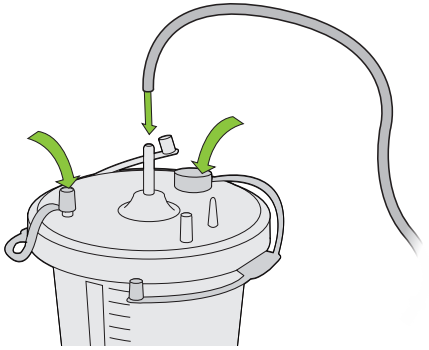
Procedure

STEP 1 **Assemble New Vacuum Canister**



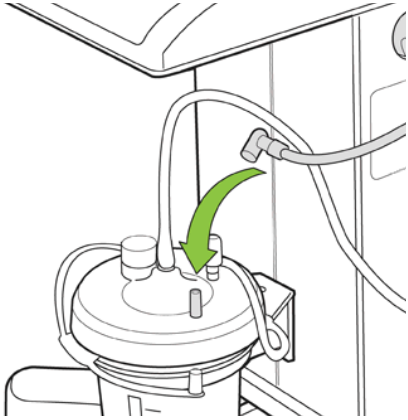
Place the lid on top of the new vacuum canister and apply pressure around the circumference of the lid to secure it. Several "clicks" will be heard when the canister lid is properly secured. Visually inspect the canister lid for proper securement.

STEP 2 **Close Unused Ports and Attach Vacuum Tubing**



Cap the large port labeled "ACCESSORY" and the small port labeled "TANDEM". These ports will not be used. Disconnect the vacuum tube from the center port labeled "VACUUM SOURCE" from the old canister and attach it to the same port on the new vacuum canister.

STEP 3 **Attach Sweep Gas Elbow**



Disconnect the sweep gas elbow from the vacuum canister port labeled "PATIENT" and attach it to the same port on the new vacuum canister.

NOTE: Alarms will temporarily appear on the display screen during and following the vacuum canister change and should clear within approximately 1 minute. Monitor the device following canister replacement to ensure that the system is properly functioning.

NOTE: After changing the vacuum canister, if the system is unable to reach the desired set point, verify that the top is properly attached to the canister. Also, verify tubing connections to ensure that a proper vacuum is present.

10.2 Inspect Circuit

Routinely inspect the entire circuit, including the Hemolung Cartridge, Catheter, and blood tubing, for signs of failure such as:

- Blood leaking from the circuit
- Blood leaking into sweep gas
- Damage to the sweep gas circuit
- Bubbles in the blood
- Excessive vibration
- Thrombus formation

If any of the above conditions are found, replace the faulty component at the discretion of the physician.

10.3 Clean Magnetic Fan Cover

The case fan located at the bottom of the Hemolung Controller will need to be periodically cleaned

To remove and clean the fan cover:

Procedure

STEP 1 Remove the magnetic cover by hand.

STEP 2 Rinse with water to remove any built up debris.

STEP 3 Dry completely.

STEP 4 Place back into the groove on the bottom of the Controller.

10.4 Change Seal Flush Fluid

Replenish seal flush fluid according to hospital procedures using normal saline. Refer to *Quick Reference Guide* or *Instructions for Use* for the infusion pump.

10.5 Catheter Maintenance

Catheter maintenance and insertion site care is recommended per your institutional protocol.

Acceptable cleaning solutions and disinfectants include:

- Aqueous based povidone iodine (Betadine®)
- Chlorhexidine Gluconate (Hibiclens®)
- Chlorhexidine patches (Biopatch®)
- Bacitracin and Neosporin® Ointments
- Aqueous chlorhexidine topical solutions (ChloraPrep®)

CAUTION: Do not use acetone or alcohol on any part of the Catheter tubing. Exposure to these liquids may damage the Catheter.

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11 SPECIAL CASES

11.1 Patient Transport

The Hemolung RAS can be utilized in transport situations. Before transporting a patient, ensure that the battery is fully charged. A properly maintained and fully charged battery will provide up to 1 hour of run time. Secure the display and only use the handle to push the Controller. Take extra precaution not to strike the vacuum canister during transportation. Immediately connect the Controller to an AC power outlet following transport.

11.2 Pump Stopped During Therapy

Any time the pump is stopped during Therapy, either manually or because of an error or alarm condition, the system will revert to the main Therapy screen and will display a large "Pump Off" message. The "Pump Off" message will include a timer, indicating the time in minutes and seconds that the pump has been stopped.

WARNING: DO NOT restart the pump and continue Hemolung Therapy before performing a COMPLETE evaluation of the patient and RAS, including but not limited to: (1) evaluating the individual patient's condition and anticoagulation status, (2) considering the length of time since the pump was stopped, (3) checking the system for signs of thrombus formation, and (4) considering any local or institutional procedures for continuing therapy. Failure to properly evaluate patient and system conditions before reinitiating therapy may result in thromboembolism.

If it is deemed appropriate to restart Therapy after evaluating the patient and device, press the START PUMP button to restart the pump.

Controller Powered Off

If the power is cycled on the Controller while providing Therapy to a patient, Recover Mode should be used to skip the initial setup procedures and immediately resume Therapy.

WARNING: DO NOT restart the pump and continue Hemolung Therapy before performing a COMPLETE evaluation of the patient and RAS, including but not limited to: (1) evaluating the individual patient's condition and anticoagulation status, (2) considering the length of time since the pump was stopped, (3) checking the system for signs of thrombus formation, and (4) considering any local or institutional procedures for continuing therapy. Failure to properly evaluate patient and system conditions before reinitiating therapy may result in thromboembolism.

WARNING: DO NOT perform Priming or Recirculation while connected to a patient.

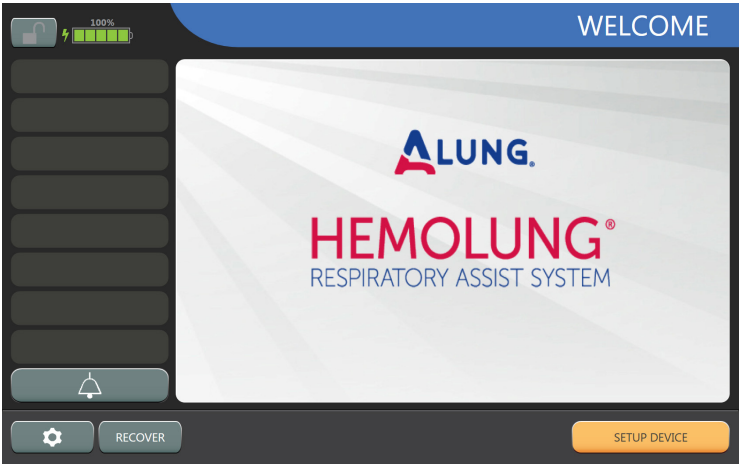
Procedure

STEP 1

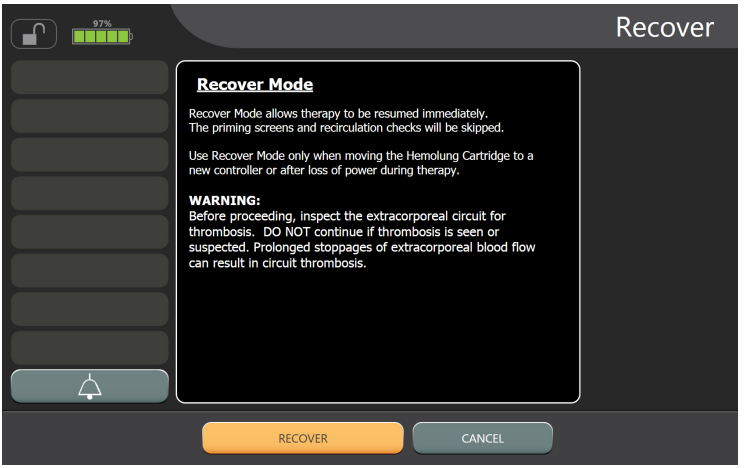
Ensure that the Controller is plugged into an AC outlet if possible.

STEP 2

Turn on the system using the power switch located on the column below the monitor. Once the Controller has completed the Power On Self Test, the Setup Screen will appear.



STEP 3
Press the **RECOVER** button. The following screen will appear.



STEP 4
Review the warnings and press the **RECOVER** button again to continue to Therapy Mode. Press **CANCEL** to return to the Setup screen.

STEP 5
After entering Therapy Mode, restart the pump by pressing the **PUMP START** button.

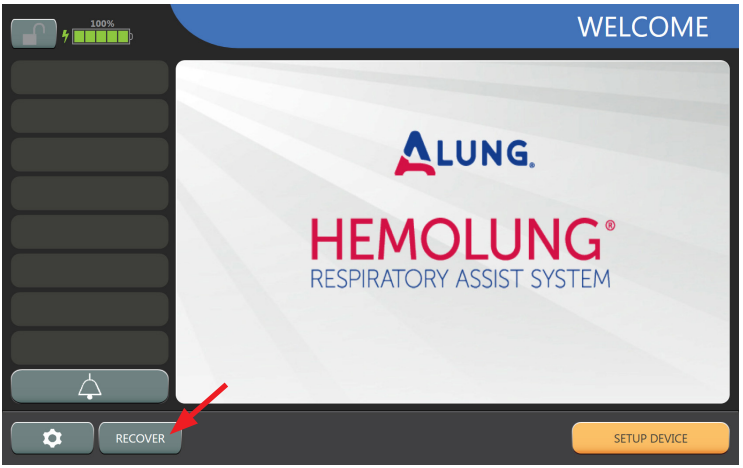
11.3 Changing a Controller

The Hemolung RAS has the ability to skip the initial setup procedures and immediately restart therapy if a Cartridge being used in therapy needs to be switched to a new Controller.

Procedure

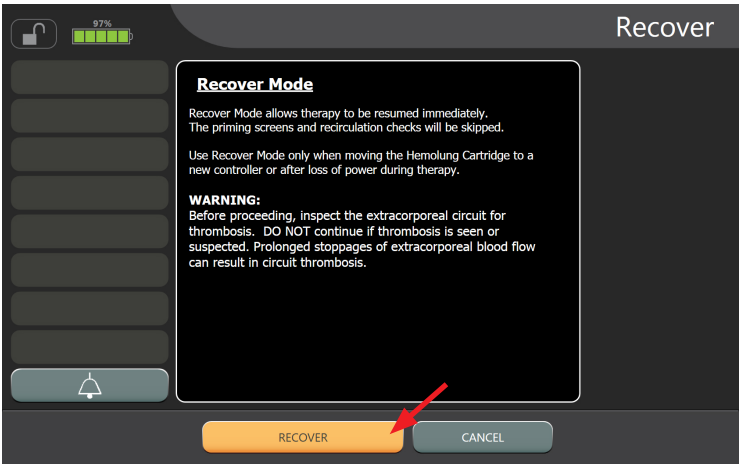
STEP 1

Press the **RECOVER** button on the replacement Controller.



STEP 2

Review the warnings and press the **RECOVER** button again.



STEP 3

Disconnect sweep gas tubes from the old Controller.

STEP 4
Release infusion line from infusion pump.

STEP 5
Release TO PATIENT (Red) Tubing from flow sensor.

STEP 6
Move the Cartridge, vacuum canister soda lime column, and blood tubing/sweep gas tubing to the new Controller.

STEP 7
Install TO PATIENT (Red) Tubing in flow sensor with a layer of petroleum jelly. Only place petroleum jelly in area that sits in the blood flow sensor.

STEP 8
Install infusion line and connect sweep gas tubes.

STEP 9
Restart therapy by pressing the **PUMP START** button.

11.4 Cartridge Change

Supplies Required

Sterile Precautions	Disinfectant Solution	Hemolung Cartridge Kit
Sterile Scissors	Hemolung Rinseback Kit	500 mL bag of saline

Procedure

NOTE: If blood rinse back is desired, follow the procedures in Section 12.2 End Therapy: With Blood Rinse Back. Blood should only be returned to the body if there are no signs of clotting or thrombosis.

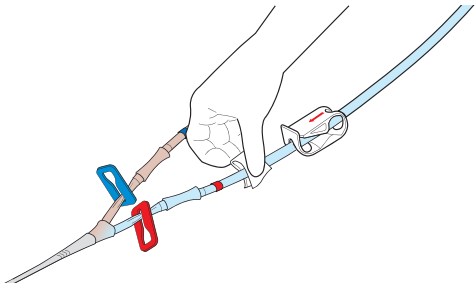
STEP 1 **Prime Hemolung Cartridge**

Assemble, prime, and recirculate a new Hemolung Cartridge (with new blood tubing). See Section 5.3 Circuit Priming and Section 5.4 Recirculation for instructions.

STEP 2 **Prepare Syringes**

Fill the 30 mL syringes with normal saline. They will be used to provide irrigation during tubing connections.

STEP 3 **Disinfect Blood Tubes**



Clean and disinfect a 12 in length of each blood tube, starting at the catheter barb connector and moving toward the Hemolung Cartridge. Use one of the following approved solutions.

Aqueous based povidone iodine (Betadine®)
Chlorhexidine Gluconate (Hibiclens®)
Aqueous chlorhexidine topical solutions (ChloraPrep®)

STEP 4 **Reduce Pump Speed**

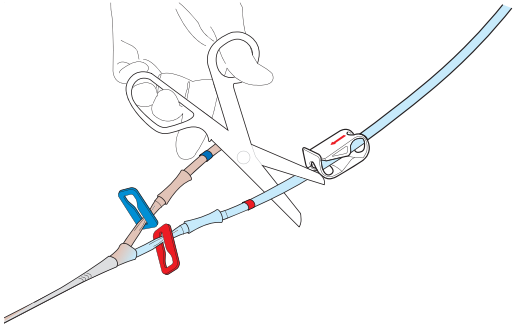
Reduce the Hemolung Cartridge pump speed to approximately 500 RPM.

STEP 5 **Stop Pump**

Press the **PUMP STOP** button to stop the Hemolung Cartridge pump. Because stopping the blood flow increases the risk of clotting, the remaining steps should be completed as quickly as possible.

STEP 6 **Close All Four (4) Clamps**

STEP 7 **Cut Blue and Red Tubings**

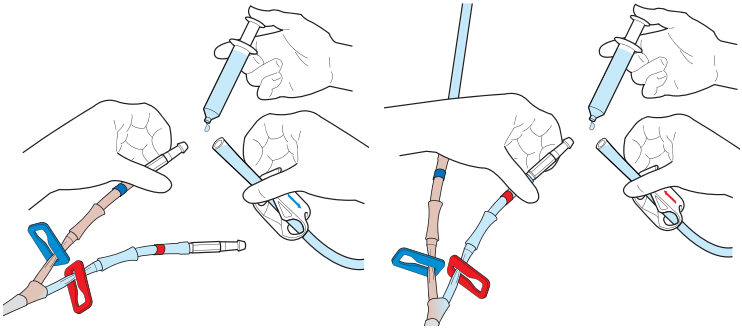


Cut the tubing between the tubing clamp and the Catheter barb in the area that was previously cleaned.

STEP 8 **Insert Barb-Barb Connector**

Attach the barb-barb connectors to the tubing remaining on the Catheter.

STEP 9 **Connect New Cartridge**



Using a wet-wet technique, connect the new Cartridge to the Catheter.

11.5 Performance Changes

The performance of the Hemolung RAS must be continuously monitored. The primary and secondary indicators of device performance are the CO_2 removal rate and blood flow rate, respectively. In the event of reduced CO_2 removal, carefully monitor the patient for changes to respiratory status. If the CO_2 removal rate is inadequate or the blood flow rate is continuously below 350 mL/min, consider replacing the Hemolung Cartridge. Low blood flow rates can lead to decreased CO_2 removal and circuit thrombosis.

WARNING: If circuit and/or Catheter thrombosis is suspected, do not rinse back the blood to the patient at the conclusion of therapy or when replacing the Hemolung Cartridge.

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12
ENDING THERAPY

12.1 Weaning

Weaning from Therapy is done by progressively reducing the amount of CO_2 removal while closely monitoring the patient.

To reduce the level of CO_2 removal, reduce the sweep gas flow rate. After reducing the sweep gas flow rate, the new CO_2 removal rate will display on the screen after approximately 2 minutes.

The sweep gas flow rate can be reduced to zero while circuit blood flow is maintained to evaluate the patient's response to withdrawing Therapy.

"Weaning mode" will appear on the display screen at sweep gas flows below 5 L/min. The "Low CO_2 Removal" alarm is disabled in weaning mode.

Do not use blood flow for weaning as this may increase the risk of clotting. Maintain blood flow 350-550 mL/min until the pump is stopped.

12.2 End Therapy: With Blood Rinse Back

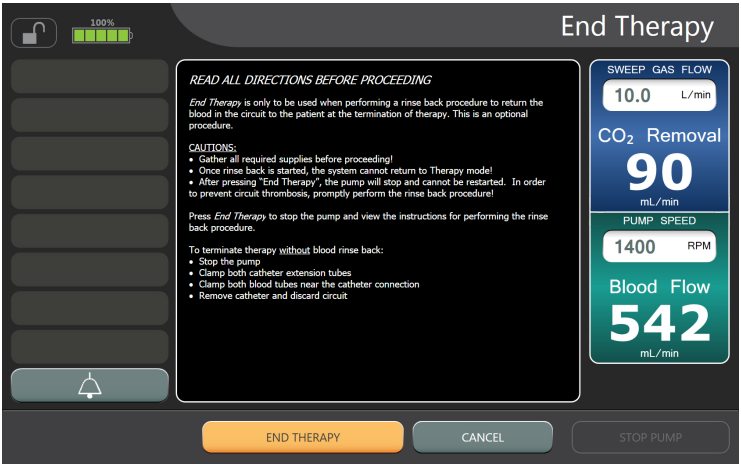
Following Hemolung therapy, the attending physician may decide to return blood from the circuit back to the patient using the Hemolung Rinse Back Kit. Prior to rinse back, prepare all necessary supplies.

Additional Supplies Required

Sterile precautions	Sterile scissors
Disinfectant solution	500 mL bag of saline
Irrigation syringe	Saline for syringe

Procedure

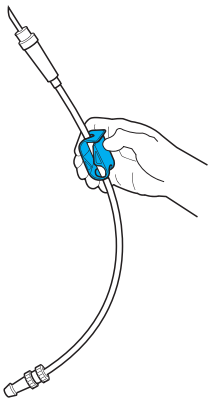
STEP 1 **Enter Rinse Back Mode on Controller**

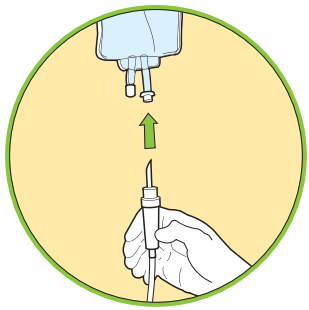


From the main Therapy screen press **END THERAPY**. After reading all warnings, press **END THERAPY** again to begin the on screen instructions.

WARNING: Once the rinse back procedure is initiated, the pump will stop and the user cannot restart therapy without power cycling the Controller. In case of accidental initiation of the rinse back procedure, power cycle the Controller and use the Recovery option to immediately restart therapy. See Section 11.2 Pump Stopped During Therapy for instructions on recovery mode

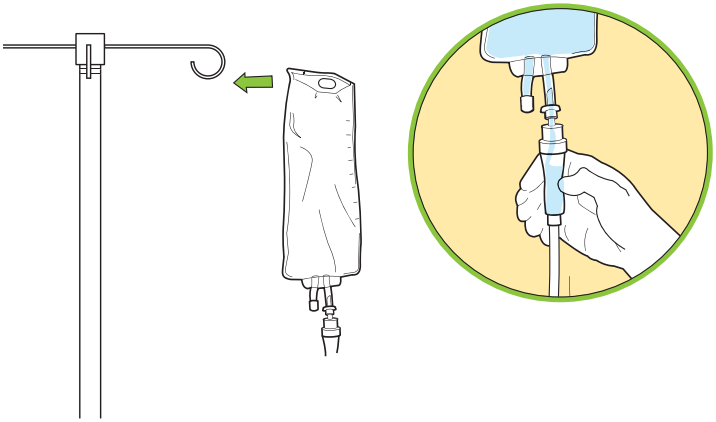
STEP 2 **Close Blue Clamp and Spike Saline Bag**





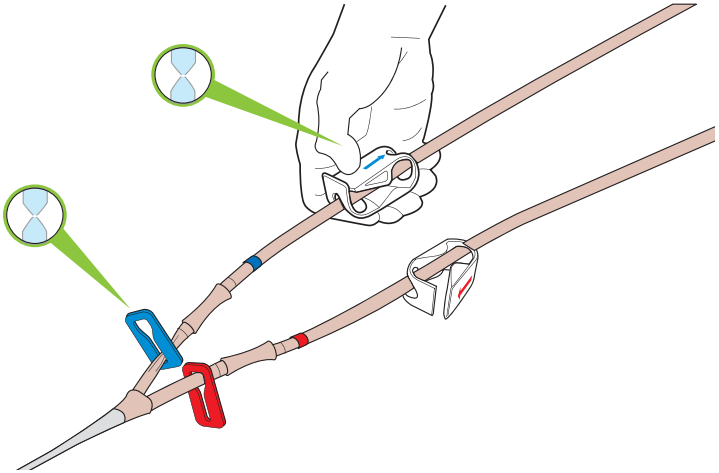
Close the blue clamp on the IV tubing and spike the saline bag.

STEP 3 **Hang the Saline Bag and Prime Drip Chamber**



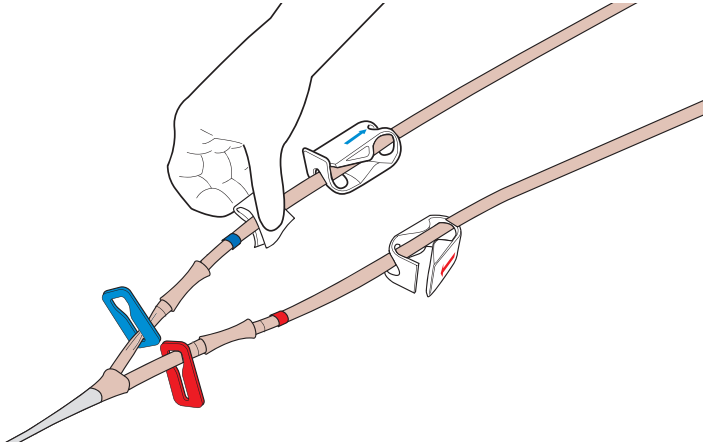
Hang the saline bag on the Controller. Squeeze the plastic chamber to prime the IV tube.

STEP 4 **Clamp Blue Tubing and Lumen**



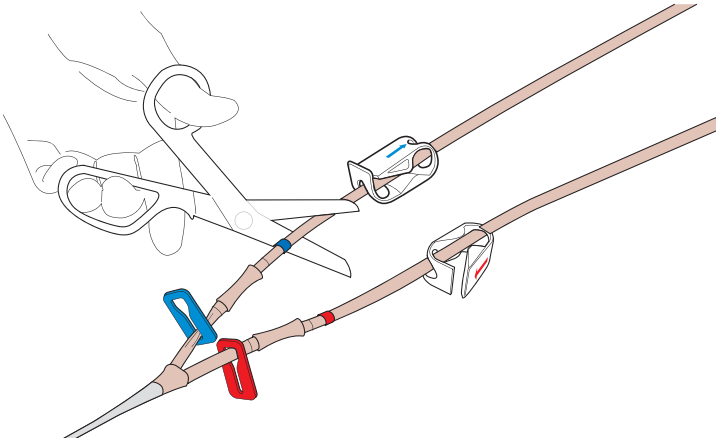
Clamp the FROM PATIENT (Blue) Tubing approximately 8 in from the Catheter connection using the attached ratchet clamp or another tubing clamp.

STEP 5 **Sterilize FROM PATIENT (Blue) Tubing**



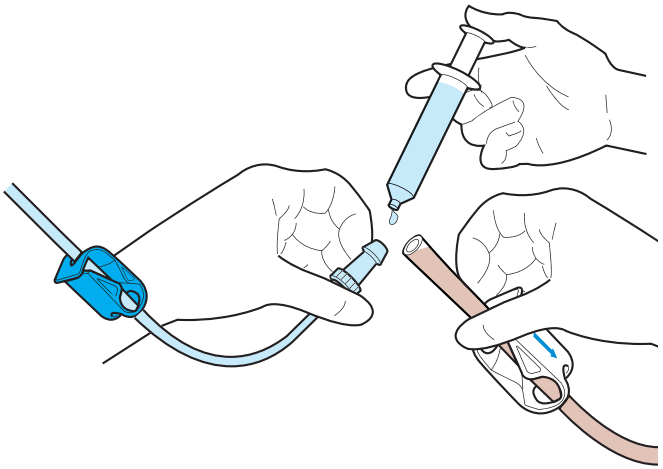
Clean and disinfect a 12 in length of each blood tube, starting at the Catheter barb connector and moving toward the Cartridge. Use one of the following approved solutions:
Aqueous based povidone iodine (Betadine®)
Chlorhexidine Gluconate (Hibiclens®)
Aqueous chlorhexidine topical solutions (ChloraPrep®)

STEP 6 **Cut FROM PATIENT (Blue) Tubing**



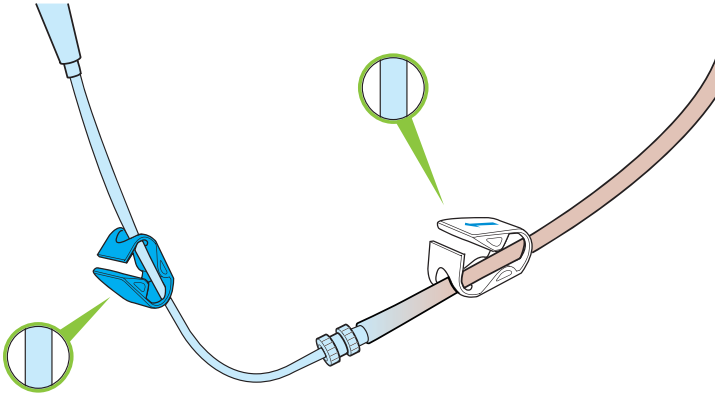
After ensuring that the clamps are closed, cut the FROM PATIENT (Blue) Tubing between the tubing clamp and the Catheter barb connector in the area that was previously cleaned.

STEP 7 **Connect FROM PATIENT (Blue) Tubing to IV Tube**



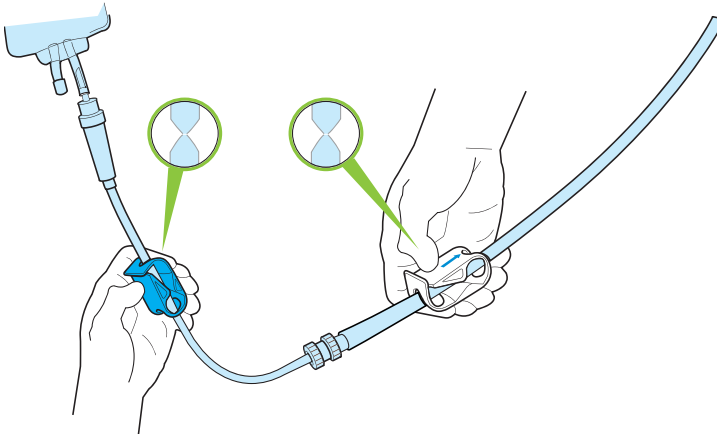
Using a wet-to-wet technique, connect the priming spike barb connector to the FROM PATIENT (Blue) Tubing, ensuring no air is trapped in the tubing. Use a 30 mL saline-filled syringe to provide irrigation for connection.

STEP 8 **Release Blue Clamps**



Release the clamp on the FROM PATIENT (Blue) Tubing and the blue clamp on the priming spike barb connector. Saline will begin to flow by gravity through the Cartridge, rinsing the blood back to the patient.

STEP 9 **Close Blue Clamps**



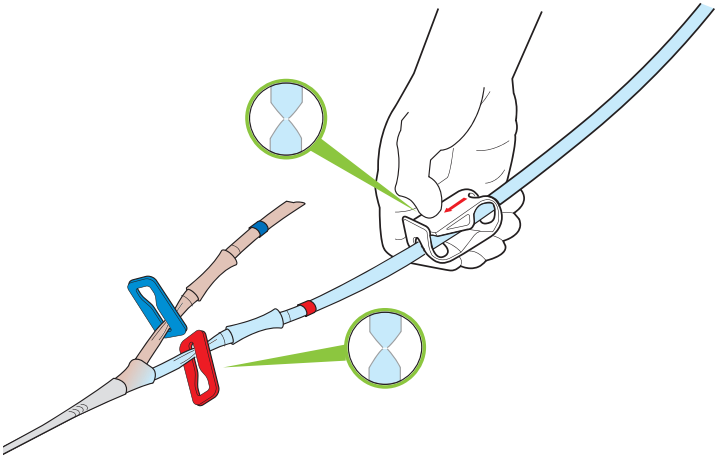
Once the blood is returned, close the clamp on the FROM PATIENT (Blue) Tubing and the priming spike barb connector.

STEP 10 **Alternatives to Removing Catheter**

If the physician decides to discontinue therapy but wants to leave the Catheter in place, cut the TO PATIENT (Red) Tubing using the same method as the FROM PATIENT (Blue) Tubing (Steps 3–5). Barb to Luer connectors can be used to connect a continuous infusion line to prevent clotting.

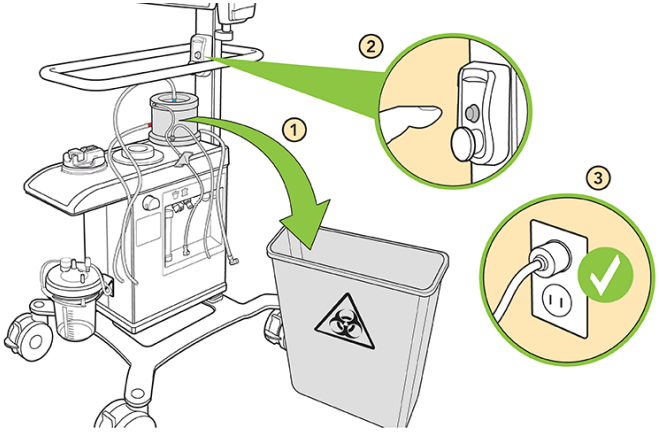
Locking the Catheter is not recommended. If deemed necessary, caps provided in the rinse back kit may be used. If treatment is to be resumed, follow steps for changing Cartridges in *Section 11.4 Cartridge Change*, using the provided barb-to-barb connectors to splice the new tubing set.

STEP 11 **Clamp Red Tubing and Remove Catheter**



Close the TO PATIENT (Red) Tubing and remove the Catheter in the same manner as any other large bore central venous Catheter.

STEP 12 **Dispose of Tubing, Power Off, Store Plugged In**



Dispose of the Catheter and blood circuit following hospital procedures for biological wastes. Power off the Controller and store it while plugged in.

12.3 End Therapy: Without Blood Rinse Back

The attending physician may decide that returning blood to the patient is not necessary and discard the entire circuit.

Procedure

STEP 1 **Turn Off Cartridge Pump**

Press the **STOP PUMP** button to stop the Hemolung Cartridge pump..

STEP 2 **Clamp Catheter Lumens**

Clamp both Catheter lumens with the attached slide clamps.

STEP 3 **Clamp Blood Tubes**

Clamp both blood tubes approximately 6 in from the Catheter connection using the attached ratchet clamps or other tubing clamps.

STEP 4 **Remove Catheter**

Remove the Catheter using standard clinical procedures for removal of large-bore central venous catheters.

STEP 5 **Dispose Catheter and Circuit**

Dispose of the Catheter and blood circuit following hospital procedures for biological wastes. Power off the Controller and store it while plugged in.

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13

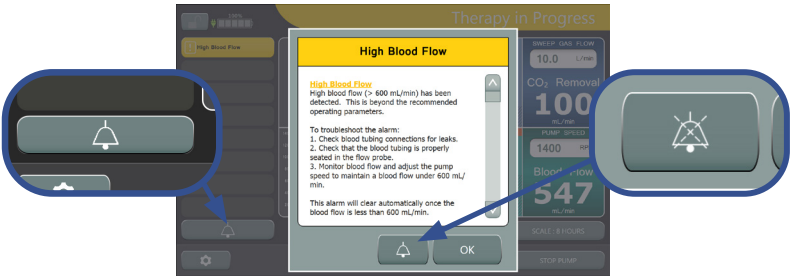
ALARMS & TROUBLESHOOTING

13.1 Overview

The Hemolung Controller has an intelligent alarm system to indicate abnormal operation and to warn the operator of potential hazards to the patient from the device. The Hemolung Controller provides audible and visible warnings for both critical errors and alarms.

13.2 Silencing Audible Alarms

Audible alarms can be paused either using the **Audible Alarm Icon** at the bottom of the alarm list or within the alarm help screen. Pressing the alarm opens the help screen. To individually silence the alarm press the 🔔 button and the press **OK**. The occurrence of a new alarm condition or pressing the button again will result in reactivation of the audible alarm.



13.3 Alarm Levels

The device prioritizes alarm notifications. The alarms are displayed in the notification area on the left side of the screen. If multiple alarms occur, the highest priority alarm will be listed at the top. The alarms will appear individually in their corresponding color code.

High Priority Pump stopped/Pump not stopped
High priority alarms notify the user of an urgent safety hazard, diminished therapy delivery, or loss of therapy. An immediate response is required from the user. In certain cases, the pump is stopped to prevent harm to the patient.

Medium Priority
Medium priority alarms notify the user that the device is operating in an unexpected state. A prompt response by the user is required to prevent diminished performance of the system. The pump always continues to run in the event of a medium priority alarm.

Low Priority
Low priority alarms notify the user that the device is operating in an unexpected state. Alarms in this category include CALL SERVICE alarms caused by component failures. The pump always continues to run in the event of a low priority alarm.

Power on Self Test (POST) Errors
POST errors are failure conditions that present after the initial power-on of the Controller. If an error has occurred during POST, the system is non-operational and the user is notified when possible with onscreen text. The error must be corrected and the power cycled for the system to become operational again. Contact technical support.

Critical Errors
Critical errors are failure conditions that render the equipment status undetermined or unreliable. When a critical error occurs, system operation is suspended and the user is notified if possible. This results in a non-operational interface. The error must be corrected and the power cycled for the system to become operational again.

13.4 Alarm Indicators

Alarm descriptions are presented on the screen in conjunction with an audible alarm and an indicator light. The alarm also has a background color to represent its priority. The single LED indicator light will illuminate red, yellow, or green based on alarm priority. The LED illuminates green when no alarms are present. The following chart shows a summary of the alarm types and user notifications.

Alarm Priority	Visual Indication	Audible Indication	On-Screen
High Pump Stops	Red LED Flash at 2 Hz 50% Duty Cycle	10 repeating beeps	Red Notification
High Pump Runs	Red LED Flash at 2 Hz 50% Duty Cycle	10 repeating beeps	Red Notification
Medium Pump Runs	Yellow LED Flash at $^{1}/_{2}$ Hz 50% Duty Cycle	3 repeating beeps	Yellow Notification
Low Pump Runs	Yellow LED Solid On	None	Yellow Notification
Critical Error Pump Stops	Red LED Flash at 2 Hz 50% Duty Cycle	10 repeating beeps	Message with special instructions

13.5 Definitions

Soak Time Indicates the amount of time an alarm condition must persist before it is asserted.

Reset Time Indicates the amount of time an alarm condition must no longer exist before the alarm automatically clears.

Latched
Yes – Alarm persists even if the alarm condition no longer exists.
No – Alarm will clear automatically after the reset time.

Resettable
Yes – Alarm can be reset by restarting the pump or performing a corrective action.
No – Alarm cannot be reset.

13.6 High Priority Alarm - Pump Stops

Description

Air Detection Alarm

Problem Air has been detected in the outflow blood tubing.
Solution Check all blood tubing connections. If air cannot be removed, set up a new circuit. Once cleared, press **START PUMP** to resume. Pump stoppages can result in circuit clotting. The pump should not be restarted if circuit clotting is suspected.

Soak Time	Immediate	**Reset Time**	Manually Reset
Latched	Yes	**Resettable**	Yes

Blood Flow Invalid

Problem A flow sensor error has been detected.
Solution Check that the blood tubing is properly seated in the flow sensor and the sensor door is properly closed. Restart the pump by pressing the **START PUMP** button. Pump stoppages can result in circuit clotting. The pump should not be restarted if circuit clotting is suspected. Monitor the blood flow. The alarm will clear automatically when the problem is resolved. If the problem persists, contact technical support.

Soak Time	3 sec	**Reset Time**	Manually Reset
Latched	Yes	**Resettable**	Yes

Battery Depleted

Problem The battery is completely discharged.
Solution Immediately connect the controller to AC power immediately. Restart the pump by pressing the **START PUMP** button. Pump stoppages can result in circuit clotting. The pump should not be restarted if circuit clotting is suspected.

Soak Time	15 sec	**Reset Time**	Manually Reset
Latched	Yes	**Resettable**	Yes

13.7 High Priority Alarm - Pump Continues to Run

Description

CO_2 Removal Low

Problem A low carbon dioxide removal rate has been detected (< 45 mL/min).
NOTE: This alarm is disabled when the sweep gas flow is less than 5 L/min.
Solution Increase sweep gas flow rate and/or blood flow rate. If the level of CO_2 removal remains low, consider replacing the Hemolung Cartridge. See *Section 11.4 Cartridge Change* for more details.

Soak Time	15 sec	**Reset Time**	5 sec
Latched	No	**Resettable**	Automatic

CO_2 Sensor Failure

Problem If either a CS 10 or CS13 alarm is active, the system shall issue a CO2 Sensor Failure Alarm.
Solution Contact technical support.

Soak Time	Immediate	**Reset Time**	Manually Reset
Latched	No	**Resettable**	No

E-Stop Engaged

Problem If the E-stop switch is engaged, this alarm is active.
Solution Twist the Pump Stop Switch clockwise to disengage the switch and press the Start Pump button to resume.

Soak Time	Immediate	**Reset Time**	Immediate
Latched	No	**Resettable**	Automatic

Low Blood Flow

Problem A low blood flow has been detected (< 315 mL/min). Low blood flow can increase the risk of clotting.
Solution Check the blood tubing for blood clots and kinks. Reposition the patient if necessary. Increase the blood flow rate by increasing the pump speed.

Soak Time	15 sec	**Reset Time**	5 sec
Latched	No	**Resettable**	Automatic

Pump Stopped

Problem The pump is stopped. Therapy cannot begin or resume until the pump is started.
Solution Start the pump by pressing the **START PUMP** button. Pump stoppages can result in circuit clotting. The pump should not be restarted if circuit clotting is suspected.

Soak Time	Immediate	**Reset Time**	Immediate
Latched	No	**Resettable**	Automatic

No Sweep Gas Flow

Problem The sweep gas flow is zero while in therapy and the set point is not zero.
Solution Check the sweep gas tubing for kinks, loose connections, and liquid. Replace the vacuum canister. The alarm will clear automatically once the problem is resolved. If the problem persists, contact technical support.

Soak Time	3 sec	**Reset Time**	5 sec
Latched	No	**Resettable**	Automatic

13.8 Medium Priority Alarms

Description

No Battery Operation

Problem If CS14 or CS15 are active, this alarm shall be made active.
Solution When this alarm is active, the battery icon shall depict that the battery is unavailable for use. If the condition persists, contact technical support.

Soak Time	Immediate	**Reset Time**	N/A
Latched	No	**Resettable**	Automatic

High Cabinet Temperature

Problem The internal cabinet temperature of the Controller is above 50°C (122 F).
Solution Contact technical support.

Soak Time	30 sec	**Reset Time**	30 sec
Latched	No	**Resettable**	Automatic

Low Sweep Gas Flow

Problem The sweep gas rate is less than 0.3 L/min below the set point.
Solution Check the sweep gas tubing for kinks, loose connections, and liquid. Replace the vacuum canister. The alarm will clear automatically once the problem is resolved. If the problem persists, contact technical support.

Soak Time	15 sec	**Reset Time**	5 sec
Latched	No	**Resettable**	Automatic

No Vacuum During Purge

Problem No vacuum developed during the purge cycle, which may make CO_2 removal ineffective.
Solution Check the sweep gas tubing for proper placement in the purge valve. Ensure that there are no leaks in the sweep gas tubing. This alarm can be manually reset by the user or if the system completes a purge successfully the alarm will be reset automatically. If the condition persists, contact technical support.

Soak Time	10 sec	**Reset Time**	Immediate
Latched	Yes	**Resettable**	Automatic/Manual

Running on Battery

Problem The Hemolung Controller is running on battery power.
Solution The Hemolung Controller will operate on a properly maintained and fully charged battery for up to 1 hour. When the battery is depleted, the system will shut off. Monitor the battery life using the battery icon on the display and reconnect to AC power before battery depletion to ensure uninterrupted system operation.

Soak Time	5 sec	**Reset Time**	3 sec
Latched	No	**Resettable**	Automatic

13.9 Low Priority Alarms

Description

High Blood Flow

Problem A high blood flow has been detected (> 600 mL/min).
Solution Check blood tubing connections for leaks and proper placement in the flow sensor. Adjust the pump speed to obtain a flow less than 600 mL/min. The alarm will clear automatically once the condition is resolved. Contact technical support if the problem persists.

Soak Time	15 sec	**Reset Time**	5 sec
Latched	No	**Resettable**	Automatic

Clean Fan Filter

Problem If the case temperature is > 40 C and < 50 C the system shall issue this alarm.
Solution Clean the fan filter to allow proper system ventilation. See Section 10.3 Clean Magnetic Fan Cover for instructions. The alarm will clear automatically once the condition is resolved. Contact technical support if the problem persists.

Soak Time	3 sec	**Reset Time**	3 sec
Latched	No	**Resettable**	Automatic

CALL SERVICE: CS1 *(Data Recorder Failure)*

Problem A data log error has occurred. Data logging has been disabled and no data will be available for download.
Solution This alarm cannot be cleared. Contact technical support.

Soak Time	Immediate	**Reset Time**	N/A
Latched	Yes	**Resettable**	No

CALL SERVICE: CS2 *(Purge Valve Failure)*

Problem The sweep gas purge valve has failed. This will prevent the successful completion of the purge cycle and will degrade CO_2 removal performance over time.
Solution This alarm will clear automatically once the condition is resolved. Restarting the system will cause POST to fail and result in an inoperable system. Contact technical support.

Soak Time	5 sec	**Reset Time**	N/A
Latched	No	**Resettable**	No

CALL SERVICE: CS3 *(Case Fan Failure)*

Problem A Controller fan is not working. This can lead to increased system operating temperature.
Solution This alarm will clear automatically once the condition is resolved. Restarting the system will cause POST to fail and result in an inoperable system. Contact technical support.

Soak Time	3 sec	**Reset Time**	N/A
Latched	No	**Resettable**	No

CALL SERVICE: CS7 *(Communication Error)*

Problem A communication error has occurred between the Supervisor and Controller.
Solution Check the connection between the Supervisor and the Controller. The alarm will automatically clear if the condition is resolved. If the condition persists, contact technical support.

Soak Time	Immediate	**Reset Time**	N/A
Latched	Yes	**Resettable**	No

CALL SERVICE: CS10 *(CO_2 Monitor Failure)*

Problem The CO_2 monitor has a high out of range value.
Solution Contact technical support. Use other methods of determining CO_2 removal.

Soak Time	3 sec	**Reset Time**	N/A
Latched	Yes	**Resettable**	No

CALL SERVICE: CS13 *(CO_2 Analyzer Communication Failure)*

Problem A communication error has occurred between the CO2 analyzer and the Controller.
Solution The alarm will clear automatically once the condition is resolved. Contact technical support.

Soak Time	0 sec	**Reset Time**	N/A
Latched	No	**Resettable**	No

CALL SERVICE: CS14 *(Battery Monitor Failed)*

Problem The battery monitor and charger has failed. Battery charge status and run time cannot be determined. Do not remove AC power.
Solution Please contact your authorized service representative.

Soak Time	5 sec	**Reset Time**	N/A
Latched	Yes	**Resettable**	No

CALL SERVICE: CS15 *(Battery Dead)*

Problem The battery has failed. The system will not operate if AC power is removed or fails because of a power outage.
Solution This alarm cannot be cleared. Restarting the system during this alarm will cause the POST to fail and result in an inoperable system. Contact technical support immediately.
Note: Potentially after power up or upon AC charge completion the system may display the Battery Dead alarm. Disregard if the alarm clears after a few minutes. Contact technical support if the alarm persists.

Soak Time	3 sec	**Reset Time**	N/A
Latched	Yes	**Resettable**	No

CALL SERVICE: CS16 *(High Sweep Gas Flow)*

Problem The sweep gas flow rate is greater than 0.3 L/min above the set point
Solution This alarm may occur as a result of a sweep gas tubing occlusion being removed. The alarm will automatically clear once the condition is resolved. If the problem persists, contact technical support.

Soak Time	30 sec	**Reset Time**	N/A
Latched	Yes	**Resettable**	No

13.10 Critical Error

Description

Main Bus Voltage Exceeded (Error Code 101)

Problem The main bus voltage has exceeded 32 volts.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	3 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Blood Pump Motor Current Exceeded (Error Code 103)

Problem The pump motor current has exceeded 3.0 amperes.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	5 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Motor Speed Exceeded (Error Code 104)

Problem The pump motor speed is above 1700 RPM.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	3 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Stack Overrun (Error Code 106)

Problem The stack guard band value was overwritten.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	Immediate	**Reset Time**	Never
Latched	Yes	**Resettable**	No

PCB Voltage Exceeded (Error Code 107)

Problem PCB logic voltage has gone outside the specifications.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	30 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Blood Pump Failed (Error Code 110)

Problem The blood pump speed has dropped below 50 RPM during Therapy or Recirculation.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	15 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Bubble Detector Failure (Error Code 111)

Problem The bubble detector input reading is high during self-test.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	Immediate	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Temperature Sensor Failure (Error Code 116)

Problem The temperature sensor has stopped responding to the Controller.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	5 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Display Not Responding (Error Code 117)

Problem A communication error has occurred between the display and Controller.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	30 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Blood Flow Sensor Communication Failure (Error Code 118)

Problem A communication error has occurred between the blood flow sensor and Controller.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	5 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Controller Processor Failure (Error Code 121)

Problem A problem has occurred with the Controller's processor.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	3 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Sweep Gas I2C Communication Failure (Error Code 122)

Problem The sensor inside the Hemolung Controller has stopped responding or is reporting an abnormal number.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	15 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Battery Monitor Communication Failure (Error Code 124)

Problem The sensor inside the Hemolung Controller has stopped responding or is reporting an abnormal number.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	5 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

Emergency Stop Sensor Failure (Error Code 125)

Problem The sensor inside the Hemolung Controller has failed.
Solution The Hemolung Controller has failed and was placed in a safe state (pump stopped). Power must be cycled for the system to become operational again. Contact technical support.

Soak Time	5 sec	**Reset Time**	Never
Latched	Yes	**Resettable**	No

13.11 Unexpected System Behavior

In the event the system displays an unexpected behavior and one of the following conditions exist, therapy should be discontinued.

- The system has become inoperable due to an overall system failure as indicated by the alarm status LED blinking red and a high priority audible alarm.
- The system is unresponsive to user inputs (e.g. changes to therapy parameters).

Discontinue use of the Hemolung Controller and contact ALung Service in the event of an unexpected system behavior.

The Hemolung CR4 is rated as Defibrillation Proof Type CF Applied Part. During a defibrillation procedure the device may experience the loss of touch screen function, while the display remains active. In this case the touch screen function can be restored by cycling power to the display. Press the power on/off button located on the bottom edge of the right side of the display to turn the display off. Press it again to turn the display on.

13.12 Unexpected System Restart

An "unexpected system restart" occurs when a system in operation unexpectedly returns to the Power On Self Test (POST) or Setup Screen.

This indicates that the Hemolung Controller has suffered a significant failure. Discontinue use of the Hemolung Controller and contact ALung Service in the event of an unexpected system restart.

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14

DEVICE MAINTENANCE

14.1 Battery

The battery should be tested on a monthly basis. With the Hemolung Controller turned on, unplug the Controller from the AC power and observe the battery charge indicator. If it does not indicate a full charge, contact ALung Service or an ALung authorized distributor.

CAUTION: The battery only charges when the Hemolung Controller is plugged into an active AC power source. Failure to leave the Controller plugged into an active AC power source will result in battery failure, making power unavailable during patient transport or AC power failure.

CAUTION: Do not remove the instrument covers on the Hemolung Controller. The Hemolung RAS does not have any user serviceable parts and the battery cannot be replaced by the user. Contact ALung or your medical equipment distributor for service or repairs.

14.2 Cleaning

Clean the Hemolung Controller with a damp sponge and a mild soap solution and/or a 10% bleach solution. DO NOT USE organic solvents or abrasive cleansers. Standard institutional procedures regarding cleaning and infection control should always be observed.

Clean the Hemolung Controller screen carefully to prevent scratches. Dust and dirt particles can be blown off or brushed off using a soft cloth. Fingerprints and stains may be removed by using a liquid cleaner and a soft cloth. DO NOT wipe a dry screen. DO NOT USE alcohol or chlorinated hydrocarbon solvents.

14.3 Storage

Check the power cord and display cable between each use. Replace any damaged cords.

Keep the Hemolung Controller plugged into an AC outlet at all times.

CAUTION: Only use power cords provided by ALung. Failure to do so may result in diminished or unsafe performance.

14.4 Preventative Maintenance

There are no user serviceable parts. The Hemolung Controller requires an annual calibration and safety check by a certified technician.

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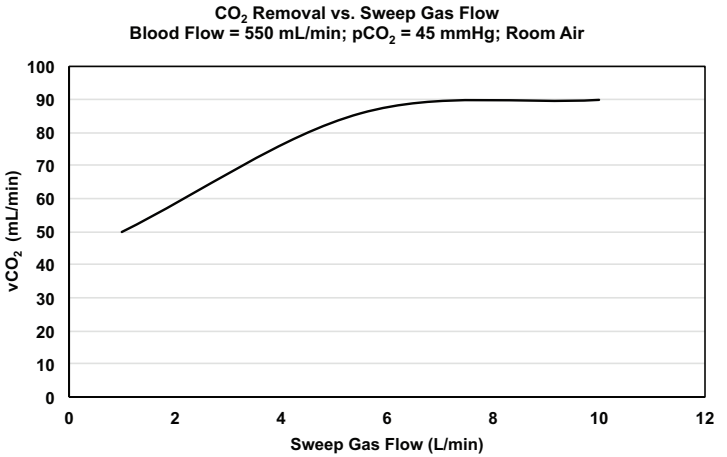
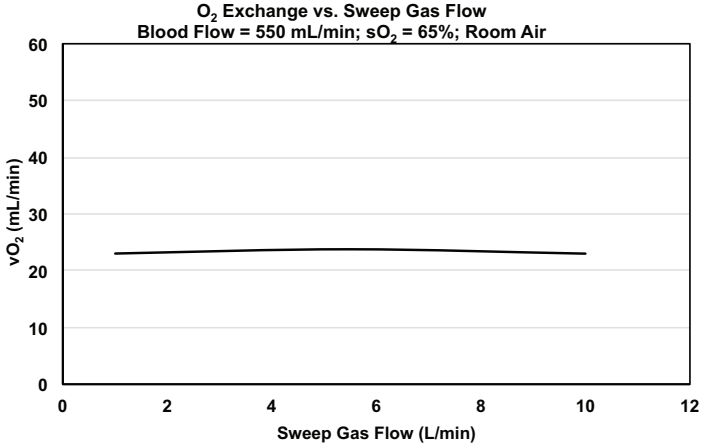
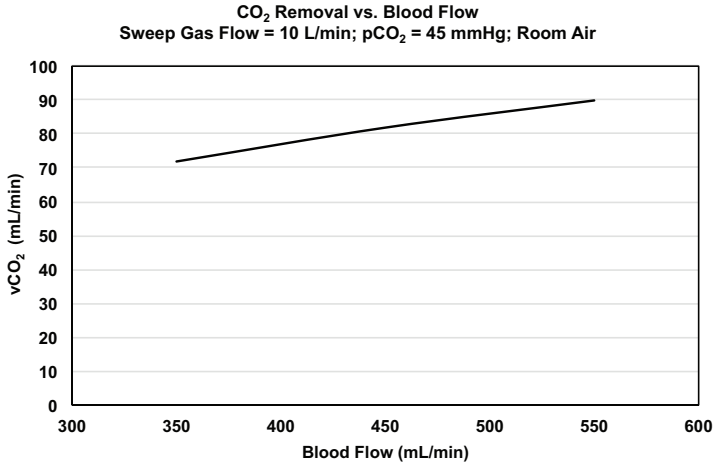
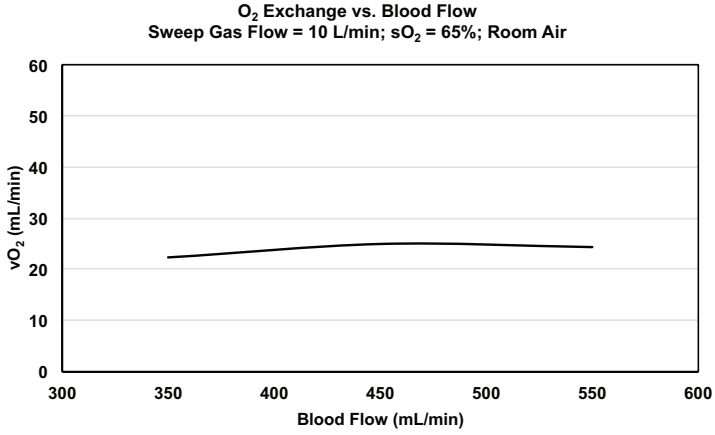
15 SPECIFICATIONS

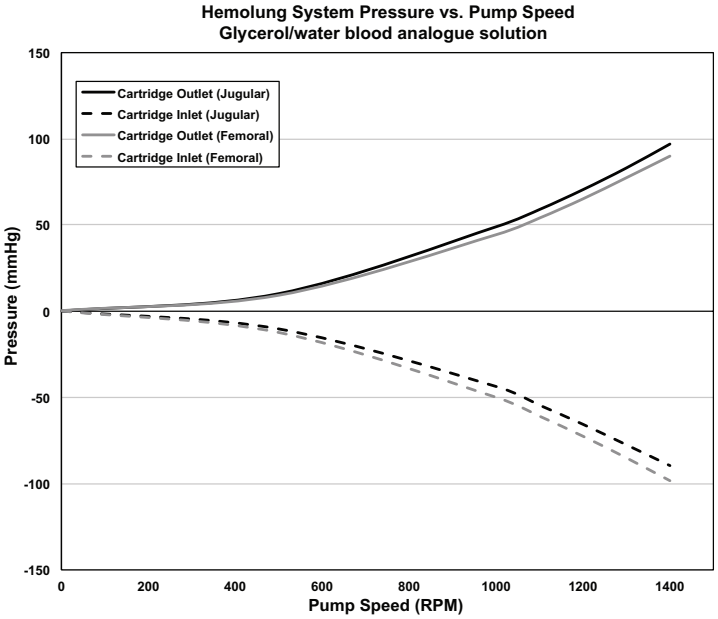
15.1 Performance Charts






CO_2 Removal vs. Blood Flow
Sweep Gas Flow = 10 L/min; pCO_2 = 45 mmHg; Room Air
vCO_2 (mL/min)
100
90
80
70
60
50
40
30
20
10
0
300
350
400
450
500
550
600
Blood Flow (mL/min)


O_2 Exchange vs. Blood Flow
Sweep Gas Flow = 10 L/min; sO_2 = 65%; Room Air
vO_2 (mL/min)
60
50
40
30
20
10
0
300
350
400
450
500
550
600
Blood Flow (mL/min)


Hemolung System Pressure vs. Pump Speed
Glycerol/water blood analogue solution
Cartridge Outlet (Jugular)
Cartridge Inlet (Jugular)
Cartridge Outlet (Femoral)
Cartridge Inlet (Femoral)
Pressure (mmHg)
150
100
50
0
-50
-100
-150
0
200
400
600
800
1000
1200
1400
Pump Speed (RPM)

15.2 Hemolung 15.5 Fr Catheters

Catheter Material	Polyurethane/silicone blend with stainless steel wire reinforcement
Lumens	Inner - Infusion (to patient, RED) Outer - Drainage (from patient, BLUE)
Nominal Outer Diameter	15.5 Fr (5.17 mm)
Connectors	¼ in (0.64 cm) Barb
Minimum Pressure	-220 mmHg
Maximum Pressure	220 mmHg
Implant Length	Femoral: 26 cm (10.24 in) Jugular: 17 cm (6.69 in)
Guidewire Compatibility	Stylet fits 0.038 in. (0.97 mm) guidewire

Lumen Volumes (with priming adapters)	Femoral	Jugular
Infusion (RED)	6.1 mL	7.1 mL
Drainage (BLUE)	8.1 mL	9.7 mL

Transportation/Storage Conditions-Disposables	
Temperature Range	Avoid exposure to temperatures below 50 °F or above 104 °F
Relative Humidity	Store in a dry location at room temperature

15.3 Hemolung Cartridge

Membrane Type	Microporous polypropylene hollow fibers coated with siloxane and heparin
Membrane Surface Area	0.59 m^2
Static Priming Volume	144 mL (Cartridge) + 115 mL (blood tubing) = 259 mL (entire circuit)
Blood Flow Range	350–550 mL/min
Sweep Gas Flow Rate Range	0–10 LPM
Venous Inlet Port	¼ in (0.64 cm) barb connector
Arterial Outlet Port	¼ in (0.64 cm) barb connector
Gas Inlet Port	3⁄16 in (0.48 cm) barb connector
Gas Outlet Port	Pre-connected 3⁄16 in (0.48 cm) silicone tubing
Blood Tubing	¼ in (0.64 cm) ID x 3⁄32 in (0.24 cm) Wall Tygon ND-100-65, two 6 ft lengths DEHP-FREE
Transportation/Storage Conditions-Disposables	
Temperature Range	Avoid exposure to temperatures below 50 °F or above 104 °F
Relative Humidity	Store in a dry location at room temperature

15.4 Hemolung Controller

Operating Conditions	
Temp Range	50 °F to 95 °F
Relative Humidity	20% to 90%, non-condensing, steady state
Transportation/Storage Conditions-Controller	
Ambient Temperature	–20 °C to +50 °C (-4 °F to +122 °F)
Relative Humidity (non-condensing, steady state)	15% to 95%
Cable Lengths	Maximum length
Power Cord	98 in
Display Cable	36 in
Dimensions (L x W x H)	27 in x 20 in x 48 in
Weight	140 lbs
Power Requirements	100 to 240 V, 50–60 Hz, 480 VA

Hemolung Controller Display

Dimensions (L x W x H)	34.3 cm x 7.6 cm x 26.7 cm 13.5 in x 3.0 in x 10.5 in
Type	Liquid crystal display (LCD)
Viewing Area	18.4 cm x 24.8 cm 7.25 in x 9.75 in
Resolution	800 pixels by 600 pixels

Hemolung Controller Battery

Battery Type	Sealed lead acid, 2 x 12 V/10.5 A-hr
Run Time	1 hour minimum (1400 RPM and 10 LPM)
Recharge Time from battery cutoff threshold	12 hour maximum to fully recharge
Battery Low Threshold	23 V Yellow battery bar
Battery Cutoff Threshold	21 V Red battery bar, low battery alarm Thrapy will be stopped. 18 V Controller will shut down.

Hemolung Controller: Sensors

Carbon Dioxide Analyzer	0.0% to 5.0% (± 0.1%) Warm-up 15 min 0-50000 PPM, Accuracy +/- 1000PPM
Mass flow Sensor	0.0 to 20.0 LPM (± 0.3 LPM)
Blood Flow Meter	0 to 1000 mL/min (± 10 %)
Bubble Detector	0.5 mL bubble detection at all flow rates

Hemolung Controller: Safety & Regulatory

Regulatory Specifications	CE Mark. European Conformity. This symbol means that the device fully complies with European Council Directive 93/42/EEC (June 14, 1993, concerning medical devices).
Intended Use	See Intended Use in the manual above.
Safety Standards	IEC 60601-1:2005:/A1:2012, EN 60601-1:2006/A1:2013 "Medical Electrical Equipment, Part 1: General Requirements for Safety" IEC/EN 60601-1-2:2014
Classifications	
Type of protection, shock	Defibrillation Proof Type CF Applied Part
Degree of protection, fluid ingress	System: IPX1
Flammable mixtures	Not for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous
Leakage/Auxiliary Currents	
Maximum allowable patient leakage current	10 µA normal condition 50 µA single fault condition
Alarm Signal Sound Pressure Range	59–70 dB measured at 1 m from all sides

Potential Equalization

A potential equalization connector provides a direct connection between the equipment and the potential equalization busbar of the electrical installation. The connector is marked with symbol IEC 60417-5021 per IEC 60601-1

Disposal EU Countries

This product contains electronic and other components (such as batteries) that may contain materials that, if disposed of with general household waste, could be damaging to the environment. In accordance with Directive 2002/96/EC Waste Electrical and Electronic Equipment, ALung Technologies requires that residents of the European Union return this product for proper disposal at the end of its useful life. Contact ALung Technical Support or your Authorized ALung Distributor for further directions.

Disposal Other Countries

When disposing of the Hemolung RAS, its batteries, or any of its accessories, ensure that any negative impact on the environment is minimized. Contact your local waste disposal service and use local recycling or disposal schemes. Separate any other parts of the equipment where arrangements can be made for their recovery, either by recycling or energy recovery. The main batteries are potentially harmful and will require separate disposal according to manufacturer's instructions or local regulations.

Hemolung Controller: Electrical Specifications

System Power Input-AC	IEC 320 power inlet receptacle
Line Input Voltage	100 to 240 V, 50–60 Hz, 480 VA
Internal Battery Fuse	5 x 20 mm, 6.3 A, 250 V Fast Blow Fuse, F6.3AL 250 V
Power Entry Module Fuse	5 x 20 mm, 6.3 A, 250 V, High Breaking Capacity, Time Delay Fuse, T6.3A H 250 V

Electromagnetic Compatibility (EMC)

The ALung Hemolung RAS is intended for use in the electromagnetic environment specified below. The customer or user of the Hemolung RAS should assure that the controller is used in such an environment. Mains power quality should be that of a typical commercial or hospital environment.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A), except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The Hemolung CR4 has not been tested in the EMC environment generated by diathermy devices. The Hemolung CR4 has not been tested in the EMC environment generated by CT devices. Avoid interference when used with CT devices by keeping the Hemolung CR4 outside of the primary x-ray beam of the CT scanner. The Hemolung CR4 has been tested in the EMC environment generated by RFID devices only in the range shown in the Proximity Field section of the EMC immunity table.

WARNING: The Hemolung CR4 has not been tested for compatibility with an MR environment and should therefore be considered "MR Unsafe".

WARNING: It is not possible to assure IMMUNITY from Electromagnetic Interference under all possible conditions. Exposure to Electromagnetic Interference at levels and ranges beyond those tested may result in the degradation of performance of the following essential device functions:

- A degradation of performance of the sweep gas flow sensor could result in the inability to control the sweep gas flow.
- A degradation of performance of the blood flow sensor could result in an inaccurate display of blood flow.
- A degradation of performance of the blood pump motor could result in the inability to control the blood pump motor to the desired RPM.
- A degradation of performance of the detection of bubbles in the blood tubing could result in a false activation of the bubble detector or the inability to detect a bubble.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Hemolung RAS, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Electromagnetic disturbances such as Electrostatic Discharge (ESD) or bursts of interference pulses on the AC power lines may cause the display to go blank momentarily. Should this occur the controller will continue to operate normally, and the display will self-recover when the electromagnetic disturbance is removed.

The Electromagnetic Emissions and Immunity Compliances for the CR4 Hemolung Respiratory Assist System are shown in the following tables. The CR4 Hemolung Respiratory Assist System must undergo preventive maintenance at the recommended service intervals to maintain Electromagnetic Emissions and Immunity Compliance.

Electromagnetic Emissions

Test Description	Specification	Notes (Class, Test Range, Etc)	Results
Conducted Emissions	IEC 55011:2009 + A1:2010	Class A 150kHz – 30MHz	Complied
Radiated Emissions	IEC 55011:2009 + A1:2010	Class A 30MHz – 1GHz	Complied
Harmonic Current	IEC 61000-3-2:2014	230 VAC / 50 or 60 Hz	Complied
Voltage Fluctuations & Flicker	IEC 61000-3-3:2013	230 VAC / 50 Hz	Complied

Electromagnetic Immunity

Test Description	Specification	Notes (Class, Test Range, Etc)	Results
Electrostatic Discharge Immunity	IEC 61000-4-2:2008	+/- 2kV (Air) +/- 4kV (Air) +/- 8kV (Air) +/- 15kV (Air) +/- 8kV (Contact) Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.	Complied
Radiated Electromagnetic Field Immunity	IEC 61000-4-3:2010	10 V/m (80MHz-2.7GHz) 80% AM at 1kHz	Complied

Proximity Fields **IEC 61000-4-3:2010**

Frequency (MHz)	Service	Modulation Type	Modulation Frequency	Field Strength (Volts/ meter)	Results
385	TETRA 400	Pulse	18 Hz	27	Complied
450	GMRS 460, FRS 460	Pulse	18 Hz	28	Complied
710 745 780	LTE Band 13, 17	Pulse	217 Hz	9	Complied
810 870 930	GSM 800/900 TETRA 800, iDEN 820 CDMA 850 LTE Band 5	Pulse	18 Hz	28	Complied
1720 1845 1970	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25 UMTS	Pulse	217 Hz	28	Complied
2450	Bluetooth, WLAN, 802.11 b/g/n RFID 2450 LTE Band 7	Pulse	217 Hz	28	Complied
5240 5500 5785	WLAN 802.11 a/n	Pulse	217 Hz	9	Complied

Electromagnetic Immunity (continued)

AIM 7351731 Immunity to RFID Readers

Frequency	Modulation Type	Modulation Frequency	Field Strength	Results
134 KHz	AM	1 KHz	65 A/m	Complied
13.56 MHz	AM	1 KHz	12 A/m	Complied
433 MHz	AM	1 KHz	3 A/m	Complied
860-60 MHz	AM	1 KHz	54 A/m	Complied
2.45 GHz	AM	1 KHz	54 A/m	Complied

Test Description	Specification	Notes (Class, Test Range, Etc)	Results
Fast Transient/ Burst Immunity	IEC 61000-4-4:2012	+/- 2kV (power) +/- 1kV (I/O)	Complied
Surge Immunity	IEC 61000-4-5:2014	+/- 0.5kV, +/- 1kV & +/- 2kV (L-PE & N-PE) +/- 0.5kV & +/- 1kV (L-N)	Complied
Conducted RF Immunity	IEC 61000-4-6:2013	3 Vrms 150kHz to 80Mhz 6Vrms 150kHz to 80MHz 80% AM to 1kHz	Complied
Magnetic Field Immunity	IEC 61000-4-8:2009	30A/m @ 50Hz or 60Hz Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.	Complied
Voltage Dips, Short Interruptions & Variations	IEC 61000-4-11:2010	100% / 0.5 Cycle 60% / 5 Cycles 30% / 25 Cycles 100% / 5 Seconds.	Complied

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SUPPORT & WARRANTY

16.1 Warranty

Warranty details are provided in the Terms and Conditions of sale or your purchasing contract.

16.2 Training

All users are required to complete product training prior to using the Hemolung RAS. A comprehensive training program is offered by ALung Technologies and its distributors. Product training includes a combination of classroom and hands-on activities related to the proper setup, use, and maintenance of the Hemolung RAS. Refresher training is also available by request. Institutions using the device are encouraged to develop on-going training programs for their staff.

16.3 Technical Support

Before requesting service, ALung Technologies, Inc. recommends performing a complete operational check to verify proper control settings on the Hemolung. If problems persist, contact the ALung Service or an ALung authorized distributor.

Please have available the model and serial numbers along with a description of the problem when placing a service request.

16.4 Accessories and Replacement Parts

Use only accessories and replacement parts supplied by ALung or an ALung authorized distributor. Failure to do so may adversely affect system performance and EMC compliance, and will void your warranty.

Contact ALung Technologies, Inc. or an ALung authorized distributor to order accessories and replacement parts for the Hemolung Respiratory Assist System.

16.5 Contact Information

Dedicated 24/7 Support
1-866-GO-ALung (462-5864)

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