



System One™ S with NxView™

at the heart of
renal care



OVERVIEW

SIMPLICITY

FLEXIBILITY

**TECHNICAL
SPECIFICATIONS**



Nxview is currently used by **leading U.S. hospitals** including the majority of the **top renal care hospitals** as ranked by *U.S. News & World Report*.¹

Reference: 1. *U.S. News & World Report*. Top-Ranked Hospitals for Nephrology. <http://health.usnews.com/best-hospitals/rankings/nephrology>. August 2020.



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It's not just what we've added to kidney care—it's what we took away.

▶ **NO SCALES**

With a uniquely designed volumetric fluid balancing system, fluid accuracy is achieved without the need for scales. Dealing with scale-based alarms is completely eliminated, reducing staff workload.

▶ **NO WASTE BAGS**

Effluent flows to an open drain line, eliminating interruptions in therapy due to emptying waste bags.

▶ **NO COMPLEX CONTROLS**

Simple, intuitive controls designed for ease of use and to simplify user training.

▶ **NO SPECIAL ELECTRICAL OR PLUMBING REQUIREMENTS**

Eliminates the need for cumbersome equipment and water treatment systems so you can use it virtually anywhere in your facility.

▶ **NO BLOOD-AIR INTERFACE**

Disposable cartridge is specifically designed to eliminate blood-air interfaces, which may reduce the risk of filter clotting and related therapy interruptions.¹

Reference: 1. Polaschegg, HD. Mechanical Aspects of Dialysis; The Extracorporeal Circuit. *Seminars in Dialysis* Vol. 8, No 5 (Sep-Oct) 1996 pp 299-304.



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OVERVIEW: System One S with NxView

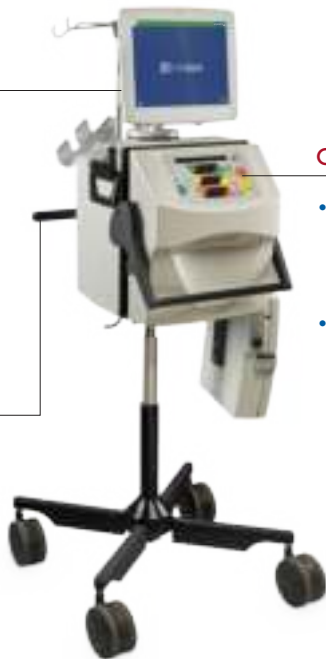
The System One S with NxView is designed to simplify delivery of therapy with features including:

NXVIEW MONITOR

- Intuitive touch screen navigation for simple instruction for operating, monitoring, and troubleshooting
- Real-time treatment information
- 96 hours of therapy graphing
- EMR connectivity with Wi-Fi capability

ERGONOMIC STAND

- Easy transport with push/pull handle
- Conveniently hang fluid bags at shoulder height
- Hang up to 29 L of fluid at once



CYCLER

- Compact design takes up minimal space in the already crowded ICU
- No special electrical or plumbing needs so the System One S can virtually be used anywhere in your facility



EMR INTEGRATION



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OVERVIEW: EMR Integration With the NxStage System One S

The System One S with NxView includes wireless capability to access EMR records from any place in the ICU or hospital using integrated Wi-Fi technology.

The System One S offers:



SAFETY

Treatment data is permanently stored and retrievable, even in the event of a power loss or if the EMR system goes down.



SECURITY

Microsoft® Windows® 10 with built-in Windows Defender Antivirus is embedded on a locked drive, providing protection for the System One S from viruses, malware, spyware, and other threats.



COMPATIBILITY

The System One S can be integrated with Epic®, Cerner®, and other EMR providers.



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The System One S with NxView was designed with the user in mind.

- Compact system
 - Easy to transport
 - Frees up valuable real estate in the ICU
- NxView monitor provides user-friendly instructions, real-time monitoring, and troubleshooting assistance
- Volumetric fluid balancing provides convenient fluid management
- Simple streamlined cartridge design makes it easy to set up



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SIMPLICITY: Volumetric Balancing Technology

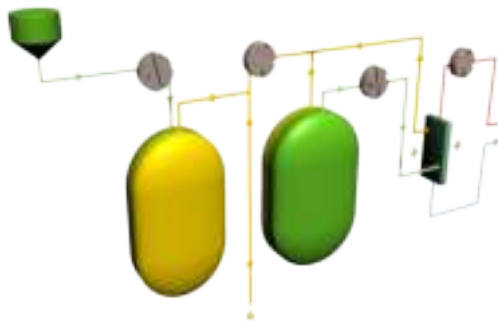
The System One S with NxView has a unique volumetric fluid balancing system, allowing for accurate fluid balancing without the need for scales.

Our simplified fluid management system allows the connection of up to 9 fluid bags at once and direct-to-drain effluent disposal, helping to reduce staff workload.

The volumetric balancing technology of the system also eliminates the need for scales.

- No waste bags or waste bag changes needed
- No scale-related alarms
- No scale calibration
- No splash or injury risk due to bag changes

In addition, there is no need for system recalibration, other than regularly scheduled preventative maintenance.



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- Simple drop-in cartridge for easy setup
- Easily switch between modalities without changing the cartridge
- Cartridges are designed to eliminate blood-air interface, which may reduce the risk of filter clotting¹
- The Purema H™ filter technology allows for high clearances running in either hemofiltration or hemodialysis modes^{2,3}
- The cartridges include several ports to customize and support anticoagulation
- Integrated drain line



The CAR-505 includes a SecureClip™ pre-attached to the arterial and venous lines, designed to strengthen patient connection and minimize access tubing disconnects.

Reference:

1. Polaschegg HD. The extracorporeal circuit. *Semin Dial.* 1995;8(5):299-304.

2. Filter Membrane Webinar, part 1, nxstage.com. Data on file, Membrana GmbH, membrana.com. February 2010.

3. Filter Membrane Webinar, part 2, nxstage.com. Data on file, Membrana GmbH, membrana.com. May 2010.



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Kidney Replacement Therapy (KRT)

The System One S allows you to use one simple system for kidney replacement therapy in the ICU throughout the continuum of patient care.

Slow Continuous Ultrafiltration (SCUF)

The System One S allows you to switch to Isolated Ultrafiltration without having to change the cartridge.

Therapeutic Plasma Exchange (TPE)

The System One S brings a well-established, simple membrane technology to TPE procedures.



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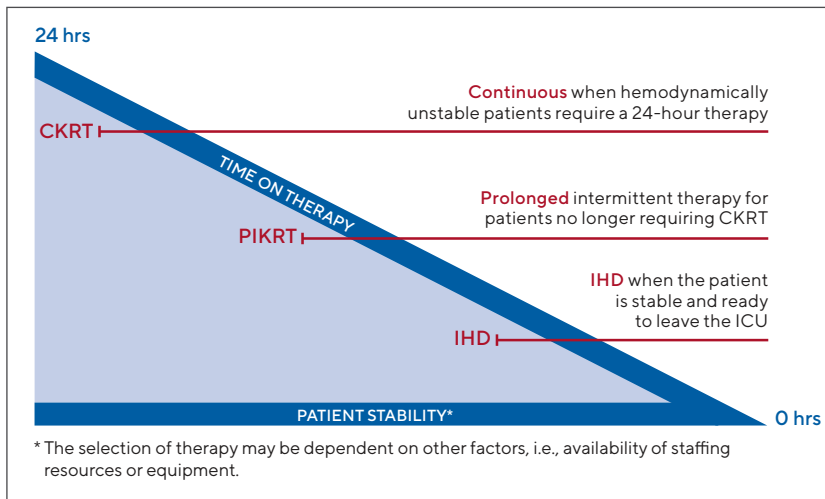
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FLEXIBILITY: KRT

With a broad range of flow rates, the System One S allows you to individualize the therapy based on the condition of the patient, including Continuous Kidney Replacement Therapy (CKRT), Prolonged Intermittent Kidney Replacement Therapy (PIKRT), or Intermittent Hemodialysis (IHD).

System One S Flow rates:

- **Blood:** Up to 600 mL/min
- **Prescription fluid:** Up to 12 L/hr
- **UF/Fluid removal:** Up to 2.4 L/hr



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With the System One S, you can easily transition from KRT to SCUF using the same cartridge.

A low-volume CAR-125-B with Renaflo® filter is also available.

All Cartridge Express products allow a broad range of flow rates:

- Blood flow rates: 10-600 mL/min
- Fluid removal rate: up to 2.4 L/hr

Low-volume CAR-125-B with Renaflo filter:

- Blood flow rates: 10-200 mL/min
- Fluid removal rate: up to 2.4 L/hr
- Total extracorporeal blood volume:
 - HF-400: 83 mL
 - HF-700: 108 mL
 - HF-1200: 138 mL



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The System One S brings a well-established, simple technology to TPE procedures. As membrane-based TPE becomes more popular, an increasing number of physicians are using this therapy.

The NxStage TPE cartridge with Asahi Plasmaflo™ Plasma Separator is designed to provide:

SAFETY

- Low extracorporeal blood volume (110 mL)
- Needleless luer-activated valves maintain their microbial barrier properties based on test results of 140 activations, when used with an adequate disinfection procedure¹

EFFECTIVENESS

- Up to 4.0 L of plasma exchange per hour
- No blood-air interface in cartridge, designed to reduce risk of filter clotting²

SIMPLICITY

- Volumetric control eliminates the need for scales and waste bags
- Unique drop-in cartridge design for quick TPE setup
- Up to nine connections for replacement fluid

References:

1. Robertsite 7-day Microbial Challenge Evaluation, P Miller, December 2007. Halkey-Roberts Corporation.
2. Polaschegg HD. The extracorporeal circuit. *Semin Dial.* 1995;8(5):299-304.



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TECHNICAL SPECIFICATIONS: System One S with NxView

THERAPY OPTIONS

Hemodialysis
Pre- or post-dilution Hemofiltration
Isolated Ultrafiltration
TPE

FLOW RATES

Blood	10–600 mL/min
UF/Fluid Removal	Up to 2.4 L/hr
Prescription Fluid	Up to 12 L/hr

WEIGHT AND DIMENSIONS

HxWxD (cm)	39x37x46
Weight	~30 kg (35 kg with warmer)
System Height Adjustable	119 cm = lowest 146 cm = highest

OPTIONAL FW-200 COMFORTMATE™ FLUID WARMER

Ambient Operating Temperature	15 °C to 37 °C (59 °F to 98 °F)
Input Voltage	100–130 VAC and 200–240 VAC, auto-ranging
Frequency	50/60 Hz
Current	5 A @ 100–130 VAC, 2.5 A @ 200–240 VAC

CARTRIDGE CONFIGURATION

With or without preattached filter, low volume, and TPE

SAFETY AND CONTROL SYSTEMS

Arterial pressure, venous pressure; effluent pressure; air detection in venous, arterial, and therapy fluid lines; temperature; blood leak; balance chamber and TMP with TPE, TMPa

POWER REQUIREMENTS (CYCLER)

Input Voltage	100-120/230 VAC, auto-ranging
Frequency	50/60 Hz
Input Power	600 VA (200 VA for cyclers; 400 VA for AC outlet)

OPERATING SYSTEM

Embedded Microsoft® Windows® 10

STANDARDS

Safety	UL-60601-1:2003; ANSI/AAMI ES60601-1:2005 IEC 60601-1:2005; CAN/CSA-C22.2 No. 60601-1:2008 IEC 60601-2-16:2008 and 2012
EMC	IEC 60601-2:2007

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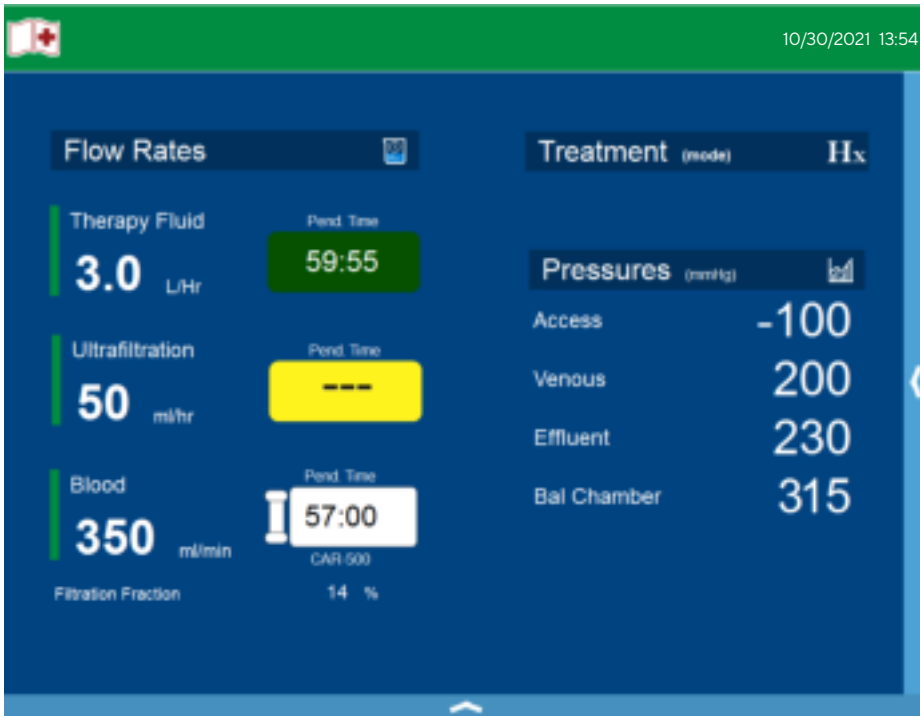
DEMO

DEMONSTRATION: System One S with NxView



NxView User Guide. NC23088 Rev. B, 2021-10.

DEMONSTRATION: System One S with NxView



NxView User Guide. NC23088 Rev. B, 2021-10.



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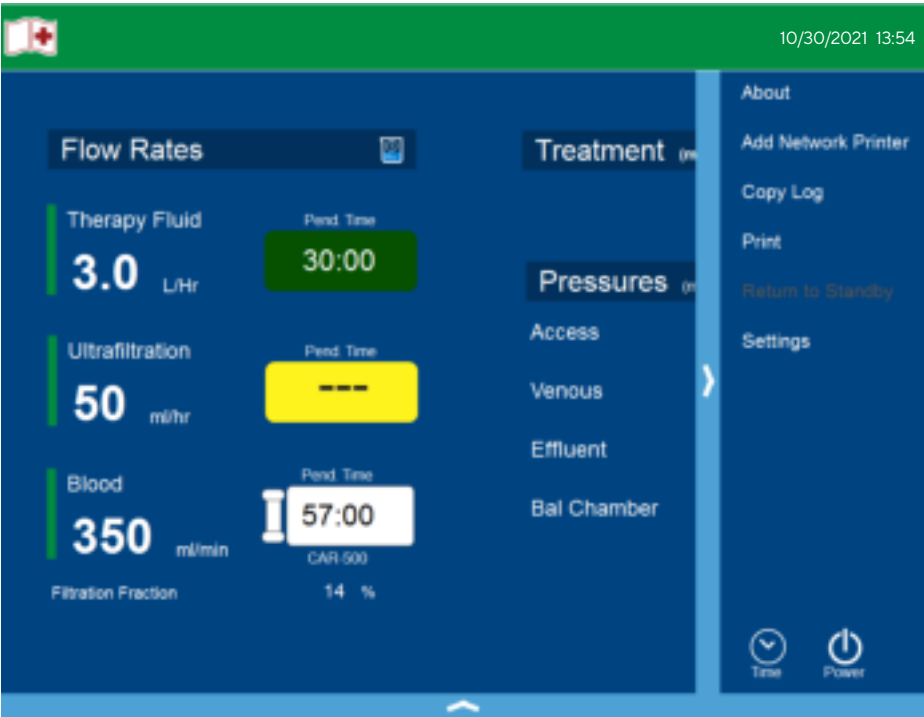
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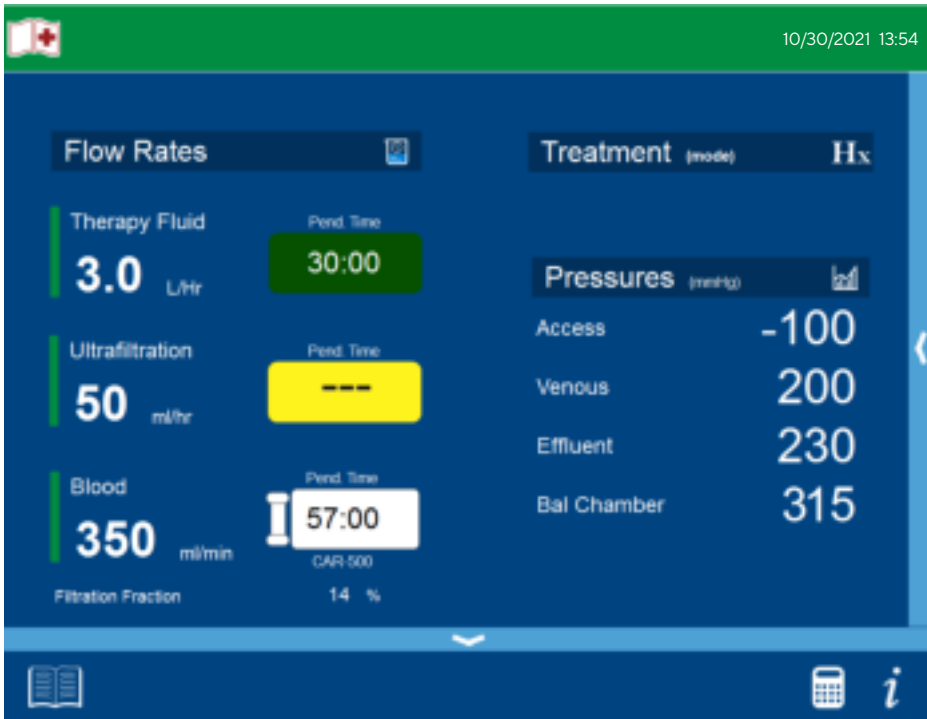
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DEMONSTRATION: System One S with NxView



NxView User Guide. NC23088 Rev. B, 2021-10.

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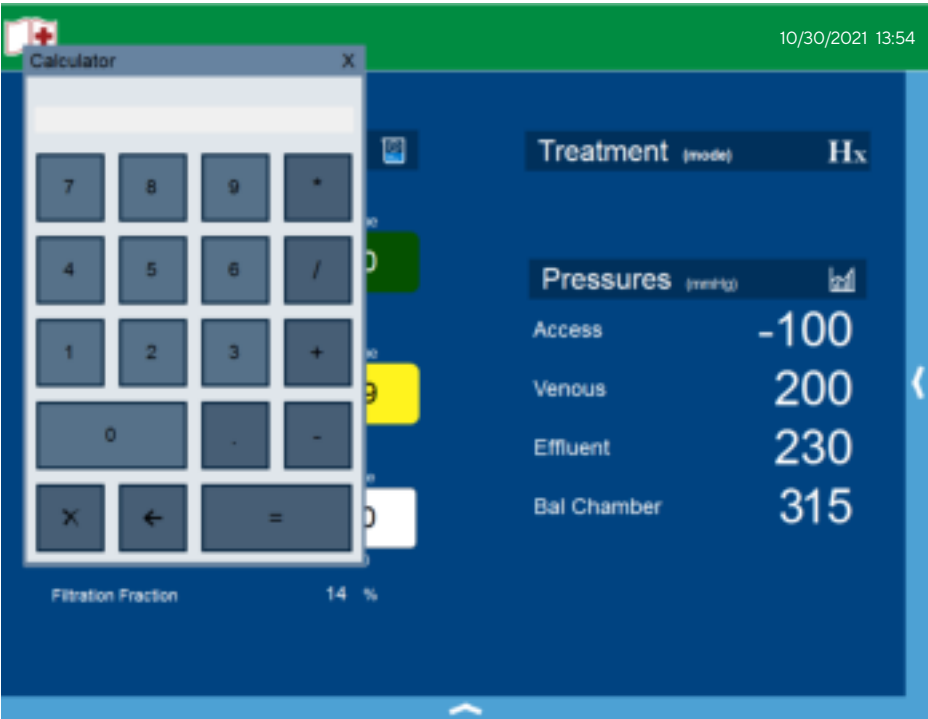
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NxView User Guide. NC23088 Rev. B, 2021-10.



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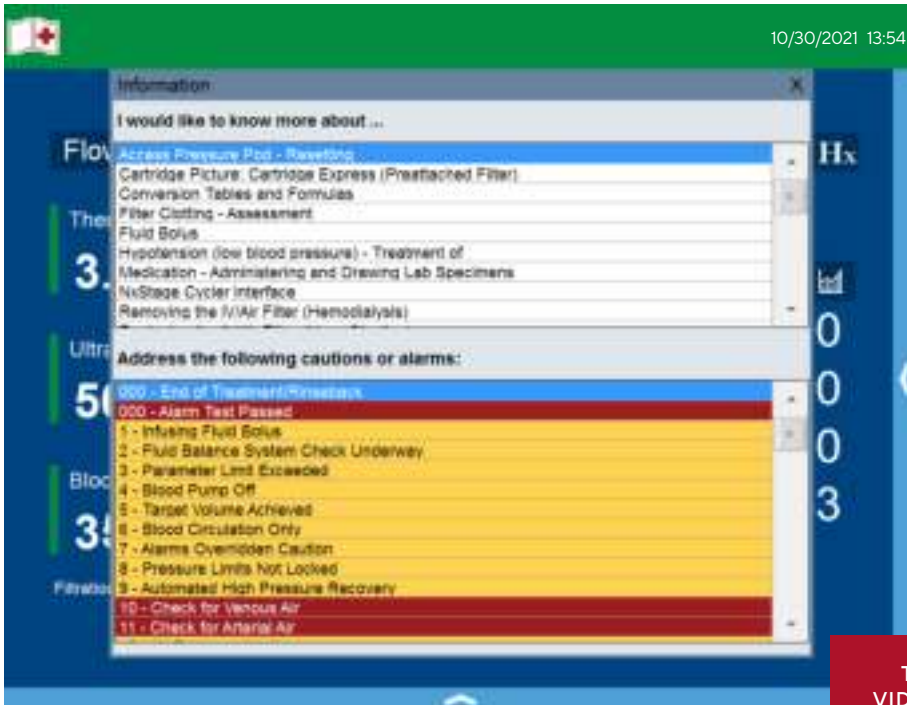
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NxView User Guide, NC23088 Rev. B, 2021-10.



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11/30/2020 14:58


24 Hr Help Line 1-866-897-8243

Emergency return of the blood (emergency rinseback)






For cartridge CAR-500

Emergency rinseback can be performed when it is necessary to return the blood quickly, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient lines.

1. Make sure 300-500 ml of saline is available to rinseback the blood. 



- If there is not enough saline remaining, hang a new bag of saline.
- To prevent air from entering the blood circuit, ensure that the saline line is primed.

NxView User Guide, NC23088 Rev. B, 2021-10.



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DEMONSTRATION: System One S with NxView

10/30/2021 13:54

Date / Time	Therapy Fluid (L)	Ultrafiltration (ml)	AP	VP	EP	Description
14:23			-100	100	230	Therapy Rate: 1.2 L/Hr UF Rate: 0.26 L/Hr Blood Rate: 200 ml/min
14:22 - 14:23	0.02	0.00	-100	100	230	
14:26						Target Volume Therapy: 15.00 L, UF: 0.00 L
14:28			-100	100	230	Therapy Rate: 1.2 L/Hr UF Rate: 10 ml/hr Blood Rate: 200 ml/min
14:28			-100	100	230	YELLOW CAUTION 4 Blood Pump Off
15:07						Target Volume Therapy: 14.00 L, UF: 9.99 L
15:41			-100	100	230	YELLOW CAUTION 4 Blood Pump Off
15:43			-100	100	230	RED ALARM 10 Check for Venous Air
15:44			-100	100	230	YELLOW CAUTION 12 Air Recovery Underway
15:57			-100	100	230	YELLOW CAUTION 14 Check Fluid Line Inlet: Air Detected in Fluid Line Inlet
15:04 - 16:00	2.48	41	-100	100	230	

Cartridge	2.70	43
Total	2.10	0

Show Totals
 Show All Vp/Rate Changes
 Show All Other Events

Total Duration: 12 Hours (???) Hrs

NxView User Guide. NC23088 Rev. B, 2021-10.




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RED ALARM 10 - Check for Venous Air

24 Hr Help Line 1-866-697-8243

6/13/2021 13:54

10 – CHECK FOR VENOUS AIR (RED ALARM)

Probable Causes





Air is detected in the Cartridge tubing after the *filter* and before the *venous (return) patient line (blue clamp)*. Potential causes include:

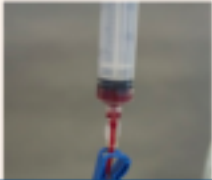
- Air entering the blood circuit
- Arterial connection loose (between the patient and Blood Pump)
- Arterial access dislodged or disconnected
- Air in saline for priming, bolus, rinseback
- Air in Therapy Fluid (hemofiltration therapy only)
- Residual air from Cartridge during prime






All pumps stop and air must be removed before continuing.

Corrective Measures

Perform venous air recovery.

1. Press **MUTE**.  
 - Identify the source of air and eliminate, as possible.
2. Press **STOP**. 
3. Attach a 20ml syringe to the *post filter cap port*, unclamp, then slowly pull back on syringe and remove air. 





NxView User Guide. NC23088 Rev. B, 2021-10.



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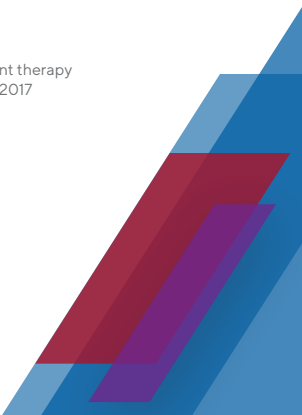
Kidney replacement therapy, as with any medical therapy, is not without risks. The decision of which therapy and medical device to use should be made by the physician, based on previous experience, and on the individual facts and circumstances of the patient.

There is no literature demonstrating that one CKRT is clinically better than the other.¹

The use of anticoagulation is at the discretion of the prescribing physician.

NxView is contraindicated as the sole method of monitoring a patient during treatment.²

References:

1. D. M. Nash, S. Przech, R. Wald, and D. O'Reilly, "Systematic review and meta-analysis of renal replacement therapy modalities for acute kidney injury in the intensive care unit," *Journal of Critical Care*, vol. 41, pp. 138-144, 2017
 2. NxStage System One User Guide, NC4921 Rev. K2021-10.
- 



InterMed Resources
TENNESSEE

1-800-224-6113
support@intermedtn.com
www.intermedtn.com



 InterMed Resources
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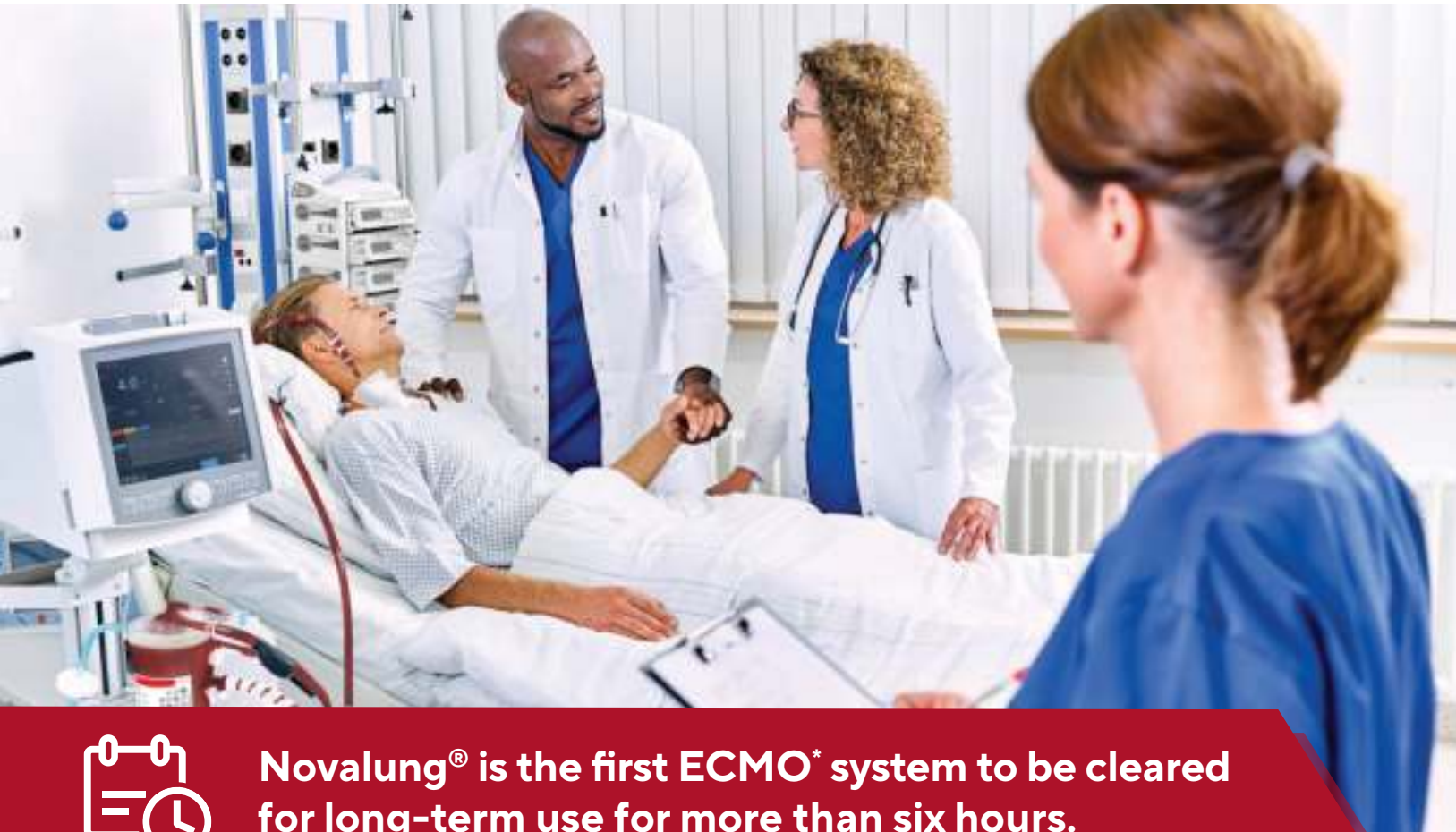
novalung

HEART AND LUNG THERAPY SYSTEM





Solutions for Acute Respiratory or Acute Cardiopulmonary Failure



Novalung® is the first ECMO* system to be cleared for long-term use for more than six hours.

Treating critically ill patients with acute respiratory or cardiopulmonary failure can be challenging at best. And often your most promising treatment efforts may fail. Now there is an option that gives your patient more time to heal. Novalung is an extracorporeal life support (ECLS) system that provides extracorporeal circulation and physiologic gas exchange for long-term support. When you need a time-sensitive and simple solution, choose Novalung for lifesaving support for your most critical patients.

**Extracorporeal membrane oxygenation*

▼

Insist on safety. Deliver accuracy. Choose Novalung.



One Integrated Heart and Lung Therapy Platform

Acute Cardiopulmonary Failure

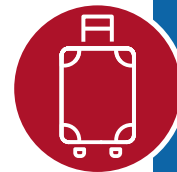
- ECMO-assisted cardiopulmonary resuscitation (ECPR)
- Failure to wean from cardiopulmonary bypass (CPB)

Acute Respiratory Failure

- The device supports life-threatening conditions
- Provides oxygenation
- Removes CO₂ (ECCO₂R)*

Focused on Improving Patient Care

- Reduces the need for intubation¹
- Minimizes invasive ventilation¹
- Allows mobilization²
- Enables spontaneous breathing³
- Improves survival for patients in cardiac arrest^{4,5}
- Impacts post-operative recovery⁶
- Supports complex interventions^{7,8}
- Limits the extent of multi-organ injuries⁸



PORTABLE THERAPY

- Intensive care units
- Operating rooms
- Cardiac cath labs
- Emergency rooms



SAFETY-FOCUSED

- Pre-connected standard set
- Rapid priming
- Pressure sensor technology
- Integrated bubble trap



ACCURATE DELIVERY

- Pressure-limiting flow control
- Low-flow precision
- Auto set alarm limits
- Visual parameter trending

*Extracorporeal carbon dioxide removal

Features That Help You Work Smarter



Intuitive Interface

- Colorful and bright display
- Data trending up to four parameters
- Optional hard key navigation



Pressure and Alarm Management

- Negative pressure limiter
- Zero flow mode
- Bubble and flow alarms



CONTACT US
800-224-6113



CLINICAL SUPPORT

Our specialists are experts at ECLS. They provide on-site assistance for our equipment with instruction, training, and guidance on its use for patient support.



TECHNICAL SERVICE

Helping to protect your investment and supporting device performance is our priority. Our trusted technicians take pride in serving our customers.



Convenient and Responsive

PORTABLE CONSOLE

On the Move

The Novalung offers remarkable flexibility to support critically ill patients. The system can be deployed in all approved treatment areas of your healthcare center.



HOT SWAPPABLE BATTERY PACKS

Power When You Need It

Two independent battery packs provide up to seven hours of backup power when you need it. This functionality is essential when AC power or DC power is not available, or during backup operation. Additionally, the batteries have direct pump drive connections to provide added support.

SENSOR BOX

Reliable Connections

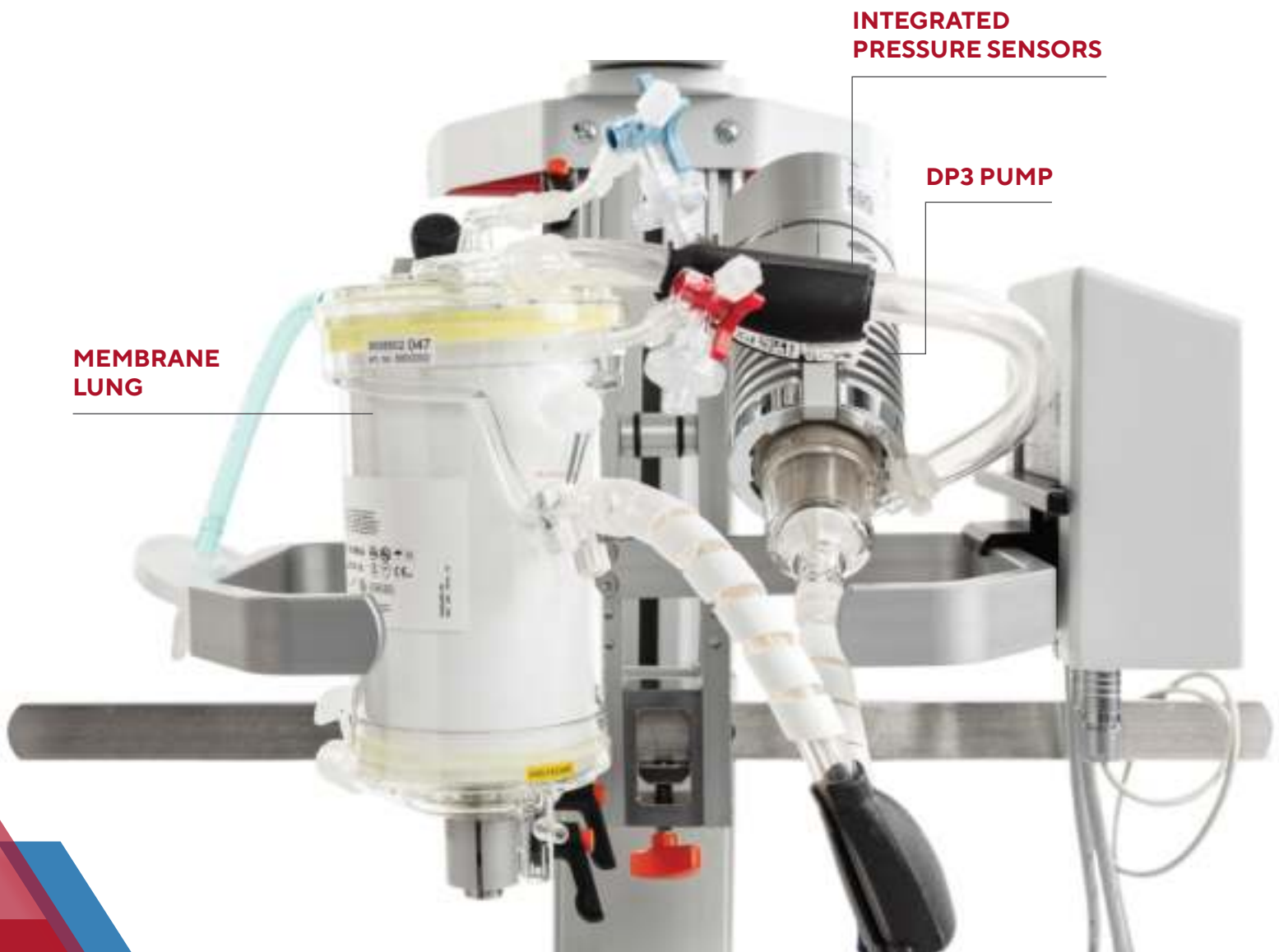
The sensor box is a central control unit that contains connectors for the pressure sensors, flow sensor, and pump drive.





Power and Precision When You Need It Most

The Novalung system, combined with the innovative XLung™ Patient Kit, may replace mechanical ventilation by enabling extracorporeal gas exchange. The therapy provides clinicians with a robust solution that allows a patient's lungs time to heal. The patient kit includes a membrane lung, DP3 pump head, and integrated pressure sensors.



XLung Patient Kit



MEMBRANE LUNG

Powerful Oxygenation

- Features x.ellence® heparin coating
 - Provides hemocompatibility for long-term applications
- Includes PMP fiber technology
- Integrated pressure sensors
- Oxygenator with integrated bubble trap

DP3 PUMP

Accurate Flow Delivery

- Features diagonal pump design for minimal prime volume
- Dissipates unwanted heat through innovative design
- Offers precise control for low- and high-flow delivery
- Easy-to-change backup drive included



INTEGRATED PRESSURE SENSORS

Reduced Risk

- Enhances safety by eliminating pressure measurement lines
- Eliminates risk of air aspiration
- Simple connection, no calibration needed

Technical Specifications

OXYGENATOR SPECIFICATIONS	
Blood Flow Rate ¹	1-7 L/min
Maximum Gas flow	0-14 L/min
Maximum Blood Side Pressure	600 mmHg (80 kPa)
Maximum Gas Side Pressure	25 mmHg
Maximum Recommended Water Pressure	750 mmHg (100 kPa)
Surface Area of the Gas Exchange Membrane	1.9 m ² (20.45 ft ²)
Total Priming Circuit	605 mL ± 10%
Oxygenator Static Prime	320 mL
Inlet Tubing Length	182 cm (71.65 in)
Outlet Tubing Length	187 cm (73.62 in)
Gas Fiber Material	Polymethylpentene (PMP)
Hex Material	Polyethylene (PE)
Hex Surface Area	0.45m ²

DELTASTREAM DP3 PUMP HEAD SPECIFICATIONS	
Speed	0-10,000 rpm
Pressure Difference	0-600 mmHg (0-80 kPa)
Tubing Fitting	3/8"
Static Prime Volume	17 mL

NOVALUNG SPECIFICATIONS	
Measurement Range	Novalung
Dimensions Width x Height x Depth	290 x 300 x 369mm 11 x 12 x 15 inches
Weight	26 lb. (12Kg) incl. batteries
Power Supply	100-240 VAC, 50-60Hz 11-28 VDC
Battery Pack	10.8 VDC, 8.64 Ah, 93.3 Wh
Operation Time/Battery	120-420 min (120 min @10,000 rpm)
Display	10.4 Touchscreen TFT, Resolution 1024 x 768
Measurements	1 Flow (-2 to +8 L/min) 3 Pressures (-400 to +400) 1 Air Bubble
Flow Rate	0-1 L/min; ±0.1L/min 1.01-8.0 L/min; ± 8% of displayed value

INTEGRATED PRESSURE SENSOR SPECIFICATIONS	
Measurement Range	-400 mmHg to +400 mmHg
Accuracy	± 1% (-50 mmHg to +50 mmHg) ± 3% (-400 mmHg to -51 mmHg; + 51 mmHg to +400 mmHg)

Ordering Information

Description	Part Number
Novalung Console	F30000162 Novalung Sensor Box Novalung Power Supply Novalung Control Panel Novalung Battery Pack (2) Novalung Pump Drive (2) AC Power cord
Trolley	F30000169
Compact Holder	F30000175
Flow Sensor 3/8"	F38400010
IPS Pressure Sensor Connecting Cable	F38350001
Infusion Stand	F35350001
Support for Backup Drive	F38350400
Battery Pack	F30000166
XLung Kit	F32000004

References

1. Kluge, Stefan et al., "Avoiding Invasive Mechanical Ventilation by Extracorporeal Carbon Dioxide Removal in Patients Failing Noninvasive Ventilation." *Intensive Care Medicine* 38, no. 10 (October 2012): 1632-1639.
2. Abrams, Darryl et al., "Extracorporeal Membrane Oxygenation in Cardiopulmonary Disease in Adults." *Journal of the American College of Cardiology* 63, no. 25 (July 2014): Part A 2769-2778.
3. Maclaren, Graeme et al., "Contemporary Extracorporeal Membrane Oxygenation for Adult Respiratory Failure: Life Support in the New Era." *Intensive Care Medicine* 38, no. 2 (February 2012): 210-220.
4. Shin, TG et al., "Extracorporeal Cardiopulmonary Resuscitation in Patients with In-hospital Cardiac Arrest: A Comparison with Conventional Cardiopulmonary Resuscitation." *Crit Care Med* 39, no. 1 (January 2011): 1-7.
5. Alsoufi, Bahaaldin MD et al., "Survival Outcomes After Rescue Extracorporeal Cardiopulmonary Resuscitation in Pediatric Patients with Refractory Cardiac Arrest." *The Journal of Thoracic and Cardiovascular Surgery* 134, no. 4 (October 2007): 952-959.e2.
6. Khorsandi, Maziar et al., "Extra-Corporeal Membrane Oxygenation for Refractory Cardiogenic Shock After Adult Cardiac Surgery: A Systematic Review and Meta-Analysis." *Journal of Cardiothoracic Surgery* 12, no. 55 (July 2017).
7. Arlt M, Philipp A, Voelkel S, Rupprecht L, Mueller T, Hilker M, Graf BM, Schmid C., "Extracorporeal Membrane Oxygenation in Severe Trauma Patients with Bleeding Shock." *Resuscitation* 81, no. 7 (July 2010): 804-809.
8. Hughes, Ronson et al., "Extracorporeal Membrane Oxygenation in Traumatic Injury: An Overview of Utility and Indications." *InTech* (September 2016).

Indications for Use

The Novalung System is indicated for long-term (>6 hours) respiratory/cardiopulmonary support that provides assisted extracorporeal circulation and physiologic gas exchange (oxygenation and CO₂ removal) of the patient's blood in adults with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. These may include:

- Failure to wean from cardiopulmonary bypass following cardiac surgery in adult patients
- ECMO-assisted cardiopulmonary resuscitation in adults

Caution: Federal (US) law restricts these devices to sale by or on the order of a physician.

Note: Read the Instructions for Use for safe and proper use of these devices. The Indications for Use for this device can be found at fmcna.com/products/indications-safety-and-warnings.