

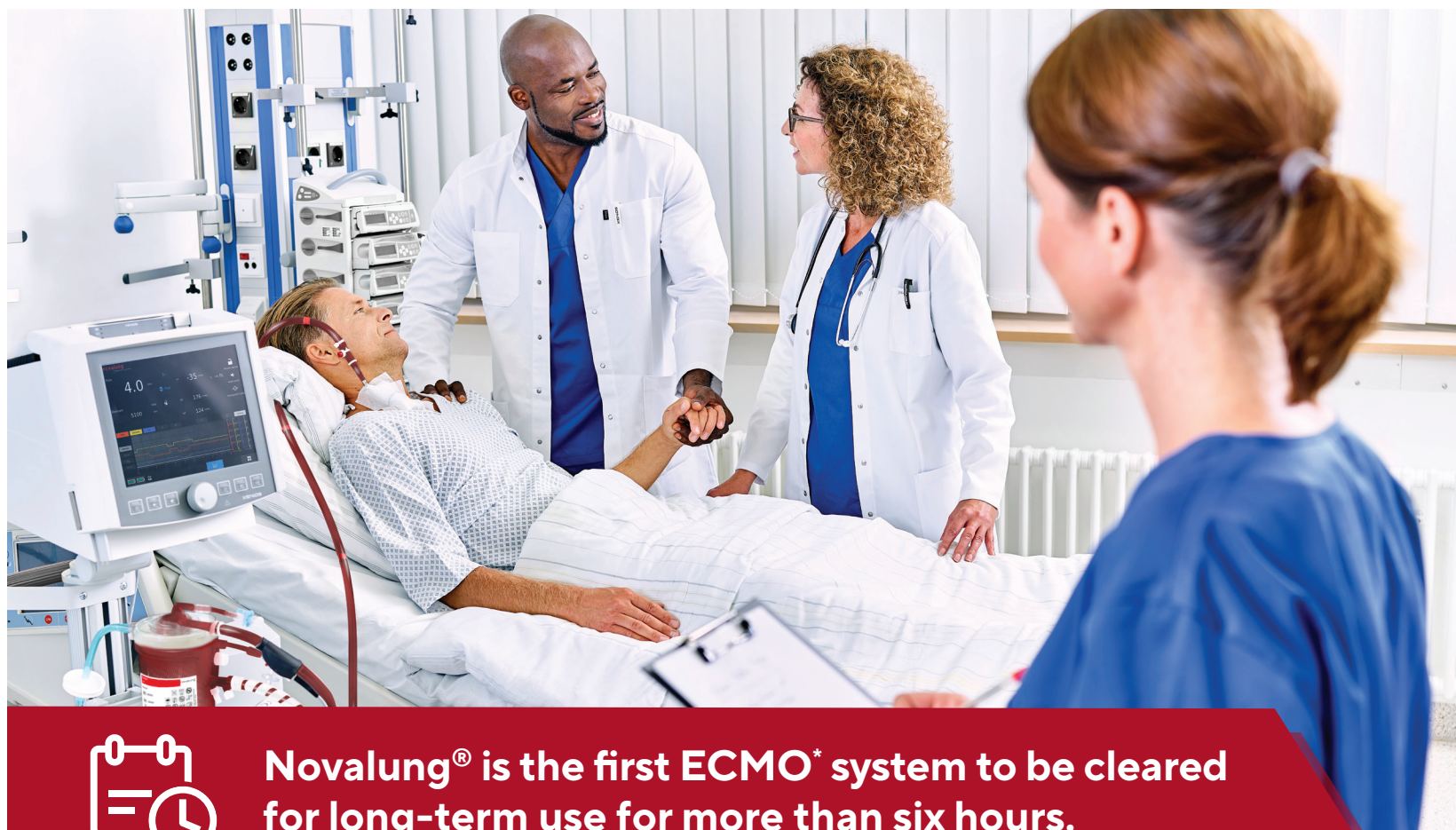
novalung

HEART AND LUNG THERAPY SYSTEM



**FRESENIUS
MEDICAL CARE**

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 by Fresenius Medical Care 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

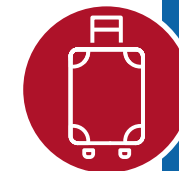
- The device supports life-threatening conditions
- Provides oxygenation
- Removes CO₂ (ECCO₂R)*

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

*Extracorporeal carbon dioxide removal

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



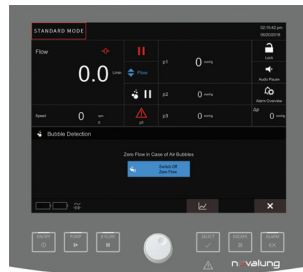
- Pressure-limiting flow control
- Low-flow precision
- Auto set alarm limits
- Visual parameter trending

Features That Help You Work Smarter



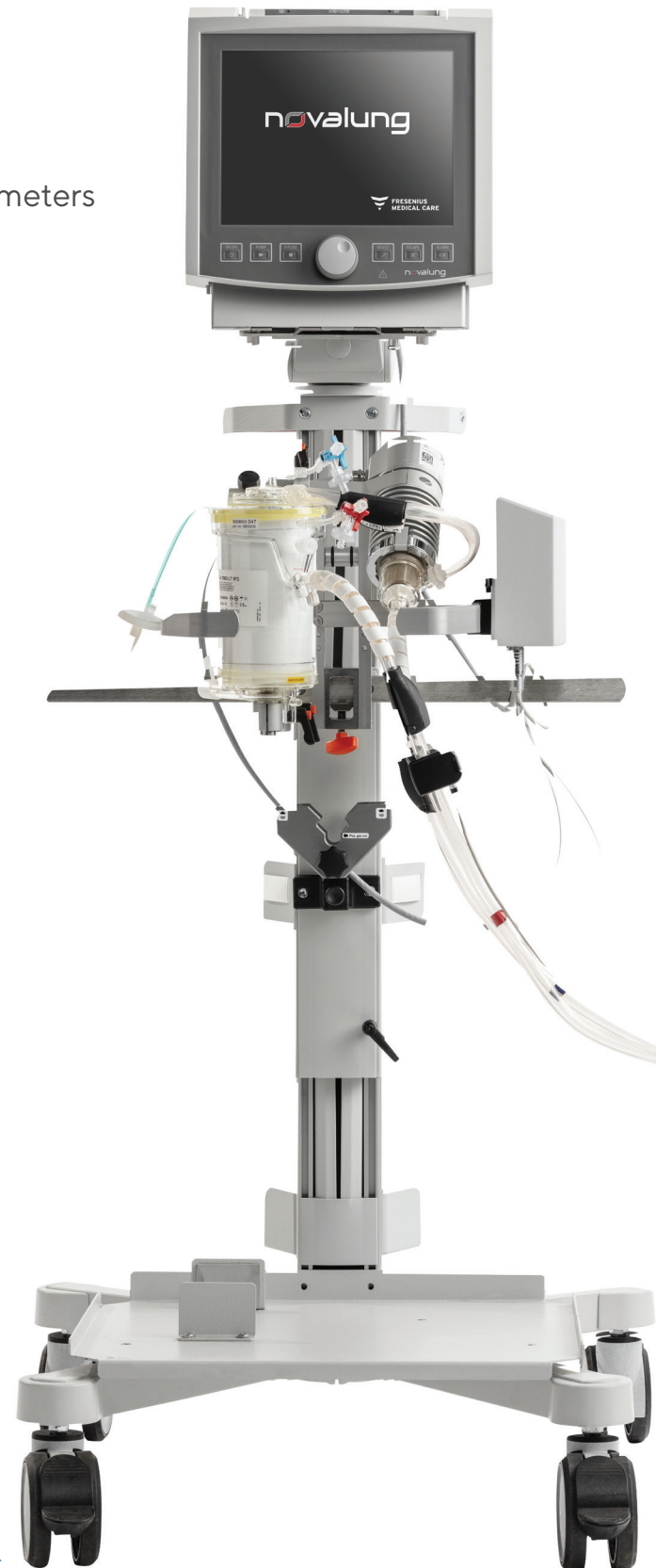
Intuitive Interface

- 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
800-405-1321



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

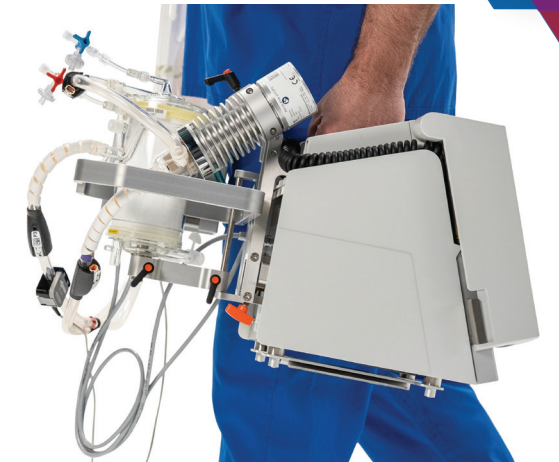
Helping to protect your investment and supporting device performance is our priority. Our trusted technicians take pride in serving our customers.

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

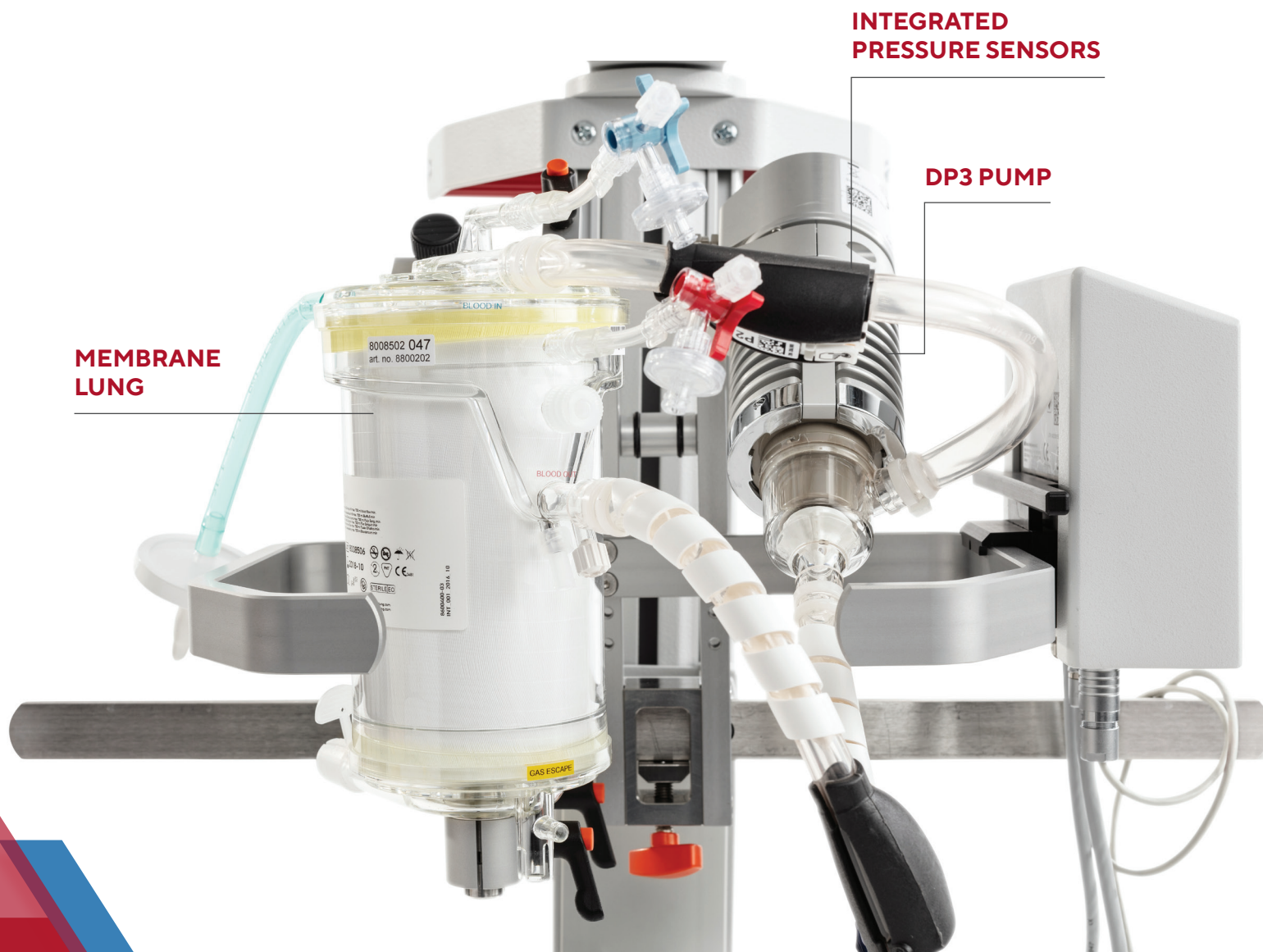
Reliable Connections

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

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- Hughes, Ronson et al., "Extracorporeal Membrane Oxygenation in Traumatic Injury: An Overview of Utility and Indications." *In Tech* (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.

Fresenius Medical Care North America

920 Winter Street | Waltham, MA 02451 | 781-699-9000 | fmcna.com/novalung

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