

THE MOST GENTLE SAFE AND VERSATILE SOLUTION FOR ECMO AND ECLS

OECMOLI



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The most **gentle**, **safe** and **versatile** solution for ECMO (Extracorporeal Membrane Oxygenation) and ECLS (Extracorporeal Life Support) enabling all HCPs (Health Care Providers) to easily manage any situation in different environments



GENTLE

Features state of the art technology for optimal biocompatibility



SAFF **Designed for optimal** patient safety

VERSATILE Portable and flexible to address a variety of different practices

Magnetic levitating pump technology for **minimized hemolysis**

Phosphorylcholine coated circuit for **reduced platelets consumption**

Up to 14 days disposable validation for **long term procedures**

Non invasive sensoring system for **optimal patient monitoring**

Integrated back-up system for extra safety in case of failure

Auxiliary external battery for **extra procedural time** in case of emergency

Compact design for **easy transport**

Optimized circuits for ECMO and ECLS

Proprietary Leonardo trolley for convenient transportability across different hospital facilities





GENTLE

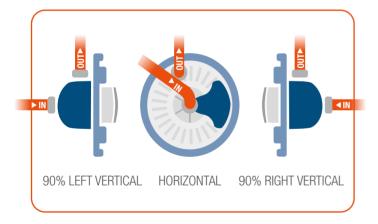
Features state of the art technology for optimal biocompatibility

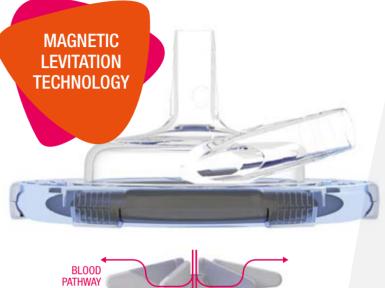


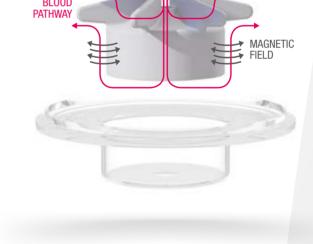
MAGNETIC LEVITATING PUMP TECHNOLOGY FOR MINIMIZED HEMOLYSIS

The impeller's contact-free environment ensures:

- Optimal flow dynamics
- Reduced blood stagnation areas
- Minimal friction and shear stress







Precise rotor control and stability is guaranteed by 32,000 controls every second.

The magnetic field is automatically adjusted to compensate for external movements and bumps.



Technical Features

Limitations

Blood flow range: Centrifugal pump speed: Blood pathway volume: Max blood pathway pressure Patient weight: 0-10 I/min 0-5000 rpm 39 ml 800 mmHg (107 kPa) ≥20 kg

3/8" (9.53 mm)

3/8" (9.53 mm)

Female Luer Lock ISO 594-2

Ports

Blood inlet: Blood outlet: P_{drain} pressure monitoring port (on dedicated configuration only):

Materials in contact with blood

Housing:	Polycarbonate (PC)
Rotor:	Polycarbonate (PC)
Luer cap:	Polyethylene (PE)
Biocompatible coating:	Phosphorylcholine (PC)

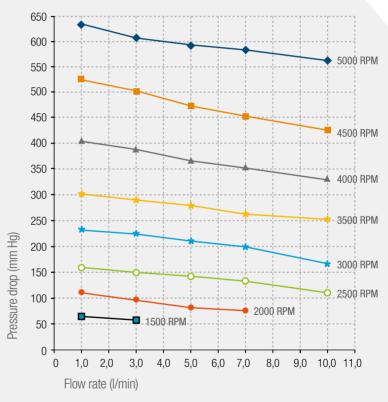
Hydraulic performance data: PERFORMANCE GRAPH

Data gathered from test in accordance with ISO 18242 standard. Conditions: Anticoagulated Bovine Blood,

$$Hb = 12 \pm 1 \text{ g/dL},$$

Temp. 37±1°C.

PERFORMANCE GRAPH



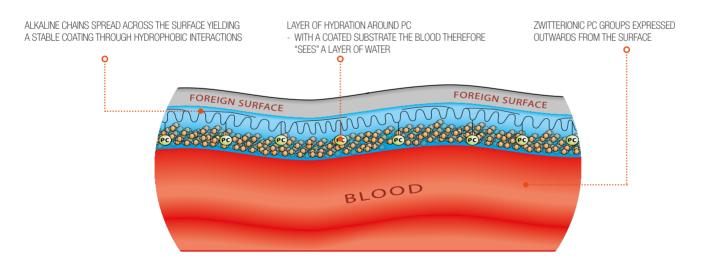


PHOSPHORYLCHOLINE COATED CIRCUIT FOR REDUCED PLATELETS CONSUMPTION

Phosphorylcoline is the predominant lipid headgroup found within the outer layer of cell membranes.

Phosphorylcoline has a natural affinity for water and binds water tightly around itself.

- Reduces platelet consumption remarkably.¹
- Phosphorylcoline coating is suitable for patients with acute HIT (Heparine Induced Thrombocytopenia)².



REFERENCES

 R. Lorusso et al. Effects of phosphorylcholine coating on extracorporeal circulation management and postoperative outcome: a double-blind randomized study. Interactive CardioVascular and Thoracic Surgery 8 (2009) 7–11.
F.Pappalardo et al. Bioline® heparin-coated ECMO with bivalirudin anticoagulation in a patient with acute heparin-induced thrombocytopenia: the immune reaction appeared to continue unabated. Perfusion 2009; 24: 135–137



UP TO 14 DAYS DISPOSABLE VALIDATION FOR LONG TERM PROCEDURES

The optimized circuits for ECMO and ECLS are validated for 14 days, ensuring **optimal performance throughout the entire period**.





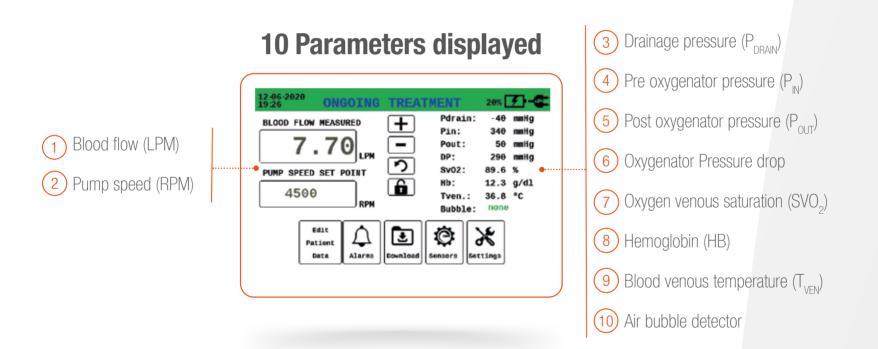
SAFE

Designed for optimal patient safety



NON INVASIVE SENSORING SYSTEM FOR OPTIMAL PATIENT MONITORING

The ECMOLIFE system is equipped with 5 non invasive sensors ensuring continuous monitoring of 10 parameters displayed simultaneously and in real time, providing the operator with **full control of the procedure**.

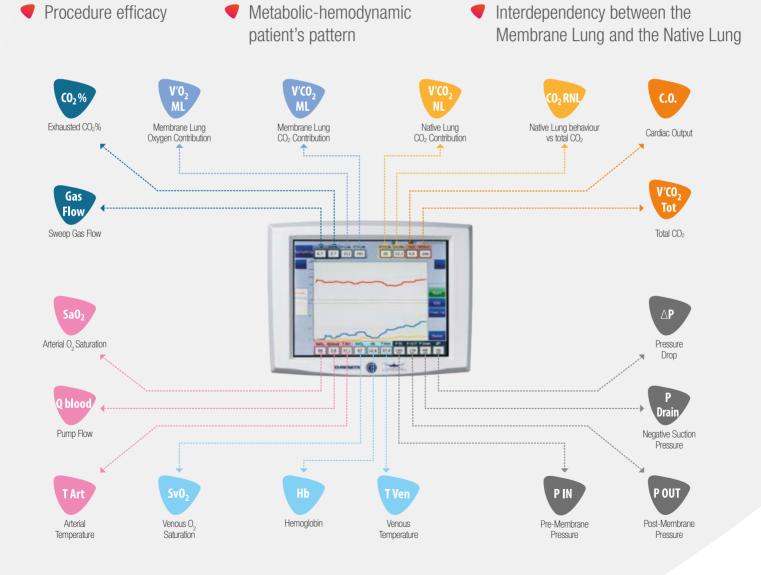






ECMOLIFE can be connected in the ICU to the LANDING ECMO adding an additional cuvette along the arterial line.

LANDING ECMO displays 18 parameters in real time for optimal patient monitoring. Thanks to these 18 parameters, HCPs can easily evaluate:





INTEGRATED BACK UP SYSTEM FOR EXTRA SAFETY IN CASE OF FAILURE

The ECMOLIFE Pump is the only device available on the market with an integrated back-up system that acts as a perfectly functioning replacement in case of failure, ensuring increased patient safety.

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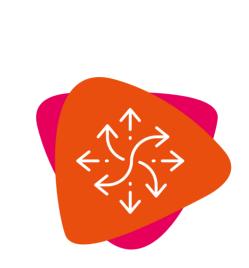
 Compared to standard manual hand cranks, the integrated back-up system ensures superior comfort for HCPs.

AUXILIARY EXTERNAL BATTERY FOR EXTRA PROCEDURAL TIME IN CASE OF EMERGENCY





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VERSATILE

Portable and flexible to address a variety of different practices



COMPACT DESIGN FOR EASY TRANSPORT







ECMOLife is approved for both intra and inter hospital transport. The device not only meets the existing mandatory regulations, but also underwent testing according to UNECE Regulation No.10 to further confirm its electromagnetic compatibility. Test conducted ensure ECMOLife safety during transport.



OPTIMIZED CIRCUITS FOR ECMO AND ECLS

The circuits for ECMO and ECLS come completely pre-connected and assembled in a kit.

Oxygenator and pump are located on a dedicated bracket assuring:

- Easy and quick disposable set up
- Clear view of circuits integrity



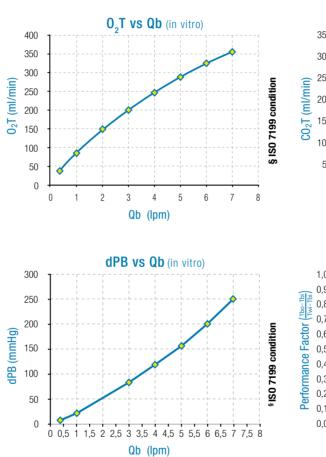


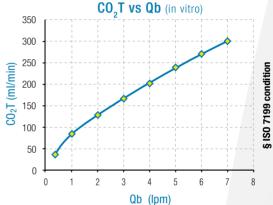


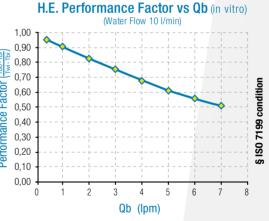
14 Days ECMO oxygenator module

The ECMO adult oxygenator is clinically proven to be an efficient solution for prolonged cardio-respiratory support ^{1,2,4} and **is highly biocompatible**³.









REFERENCES

- S.Calvi et al. 55 days ECMO support for post-cardiotomy, by-ventricular failure: a case report. Abstract presented at 14th FECECT congress, 2011.
- Nagi el Shouki, M.Stiller. Case report of 19 days extra corporeal life support with a new ECMO oxygenator. Abstract presented at 14th FECECT congress, 2011.
- M.Pieri et al. A new phosphorylcholine-coated polymethylpentene oxygenator for extracorporeal membrane oxygenation: a preliminary experience. Perfusion 2012; Volume: 28 issue: 2, page(s): 132-137.
- M.Belliato et al. A brief clinical case report of real-time monitoring of oxygenator performances and patient-machine interdependency during a prolonged VvECMO support. J Clin Monit Comput. 2017 Oct;31(5):1027-1033



THE PROPRIETARY LEONARDO TROLLEY FOR CONVENIENT TRANSPORTABILITY ACROSS DIFFERENT HOSPITAL FACILITIES

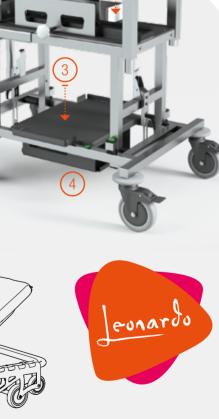
The Leonardo trolley has been designed to facilitate easy transportation accross hospital facilities.

Leonardo consists of 2 IV Poles and 4 level floors to hold:

00700 00700

- 1 ECMOLIFE console
- 2 Oxygen bottle (2-5L)
- 3 Heater cooler
- 4 Isolation transformers

Part of the trolley can be used as accessory shelf adaptable to any stretchers.





REUSABLE N°/PACK CODE DESCRIPTION EU5086 **ECMOLIFE SYSTEM** 1 includes: Console 1 (A) 2 **B** Motor driver 2 (C) Clamp on transducer sct 3/8" x 3/32" 1 **D** Air sensor 3/8" x 3/32" ecls 1 (E Bracket 1 (**F** Venous probe 3 **G** Ecmolife pressure sensor cable 3 **H** Logical pressure transducer 3 Holder for reusable pressure transducer 2 Ecmolife power cord EU 1 EU5093 **LEONARDO Trolley** 1 (L - ECMOLIFE Cables Holder includes: -REOMED 1000 isolating trans-formers 1000VA 1 -REOMED Plug C13-C14 2 EU10775 **ECMOLIFE Power Cord GB** 1 1 (M) 2M85274 Holder with BAR 25x10 mm 1 (N) ECMOLIFE Auxiliary batteries Kit with transport bag EU3899 1 (0) EU2511 **ECMOLIFE Holder Motor Driver**

Product not manufactured by EUROSETS S.r.I. - The CE mark, if applicable, is applied by the manufacturer.













REUSABLE			
CODE	DESCRIPTION		N°/PACK
R229P01-010	MAX BLEND 0-15 LPM		1 💌
R100P26	Bracket, Pole mount, gas blender	2093	1 💌
R129P91	Air Tube	0000	1 \star
R129P94	Oxygen Tube		1 💌
R219P31	3 in 1 single pack (connector gas outlet)	1	1 \star
R219P31	ECOMLIFE HEATER COOLER	8-6	1
includes:	HC Unit	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	1
	UK and EU Power Supply Cables		1
	Hoses 1,5m (x2)	00	1
	Hanses connection tube		1
	Water discharge hose (female)		1
EU3943	Hoses 3m		2
EU3898	ECMOLIFE Ambulance Plate holder		1
EU3953	ECMOLIFE Ambulance 24V Pov	ver	1

SINGLE USE		
CODE	DESCRIPTION	N°/PACK
14AG70232	ECMOLIFE ECMO tubing set Includes: Oxy, pump, circuit, press. transducers Metallux 3to1	1
14AG70232/SM	ECMOLIFE ECMO tubing set Includes: Oxy, pump, circuit, press. transducers Smith Medical	1
14AG70231/SM	ECMOLIFE VAS tubing set Includes pump, circuit, press. transducers Smith Medical	1
EU5083	ECMO ADULT console Sterile (Stand alone ECMO 0xy)	2
AG5078	ECMOLIFE centrifugal pump (without luer port)	1
AG5079	ECMOLIFE centrifugal pump W/Pdrain (with luer port)	1
EU1589	Smith Medical sigle use pressure transducer (CE0473 - Smith Medical code: MX960XXP1)	1 *



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