

Acute Therapy Systems

## Heart and Lung Assist for Pediatric Patients



novalung | medos



**FRESENIUS  
MEDICAL CARE**

Xenios, a Fresenius Medical Care Company, is a pioneer in the field of extracorporeal heart and lung support – for new dimensions in patient well-being. In contrast to standard therapies in this field, patients can remain awake, mobile, and self-determined<sup>1)</sup> with our extracorporeal therapies. They may then spend less time in the intensive care unit<sup>2)</sup>, which helps to improve their prognosis of treatment<sup>3)</sup>.

Our therapies for pediatric patients are focused exclusively on the pediatric and neonatal fields, and answer the specific need with a broad product portfolio for the full spectrum of extracorporeal pulmonary and cardiac support. Products can be tailored to each child-patient's individual needs<sup>4)</sup>.

This specific novalung and medos product portfolio directly addresses the particular challenges associated with the treatment of this young and diverse group of patients.

▶ **Challenge 1:**

Different types of patients – from neonates up to young adults

▶ **Challenge 2:**

Opportunity to use extracorporeal support as long as needed

▶ **Challenge 3:**

Special demands for neonatal patients

▶ **Challenge 4:**

Special patient group – reacting more sensitive to any change in setting, therapy or parameter

## Challenge 1: Different Types of Patients – From Neonates up to Young Adults



### Requirement

- Membrane lungs for a broad range of blood flow
- Huge variety of patient kits with different connector size, pump disposables and lengths for pediatric patients
- Target blood flow range to be covered for all pediatric patients

### Solution

- Different patient kits: Wide range of preconfigured or customized patient kits, tailored to the needs of the pediatric patient population
- Xenios console as one platform and pump (DP3) offer the full range of support

### Reference

“ The low priming volume (16 mL), wide range of flow rate (0–8 L/min), rotation speed (0–10,000 rpm), and production of pressures up to 600 mm Hg allow it to be used in both pediatric and adult patients”<sup>5)</sup>

“ increased flow range offers a higher level of flexibility and safety for a wide range of applications”<sup>5)</sup>

“ In conclusion, the DP3 can be used for individual patient demands and adapted to their most suitable method of support. Meticulous flow adjustments render this pump highly effective for extracorporeal support particularly in pediatric patients.”<sup>4)</sup>

## Challenge 2: Opportunity to Use Extracorporeal Support as Long as Needed



### Requirement

- Long-term approved patient kits

### Solution

- Novalung patient kits certified for 29 days application period

### Reference

“ We used the same ECLS system for up to two weeks without changing it”<sup>6)</sup>

“ [...] enabled intensive care specialists to use VV-ECMO not only as a short-term rescue procedure, but also as a long-term application and bridge to transplantation in adult as well as pediatric patients.”<sup>7)</sup>

“ Within the development and introduction of long-running ECMO devices (including heparin coated tubing, special microfiber polymethylpentene membranes, rotating blood pumps, and percutaneous catheters) with week-long stability [...]”<sup>8)</sup>

## Challenge 3: Special Demands for Neonatal Patients



### Requirement

- Sensitive flow adjustments at low flow ranges with less turbulences and reduced hemodilution

### Solution

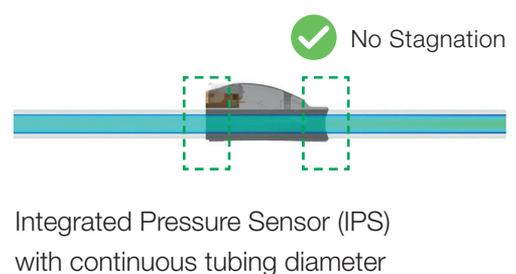
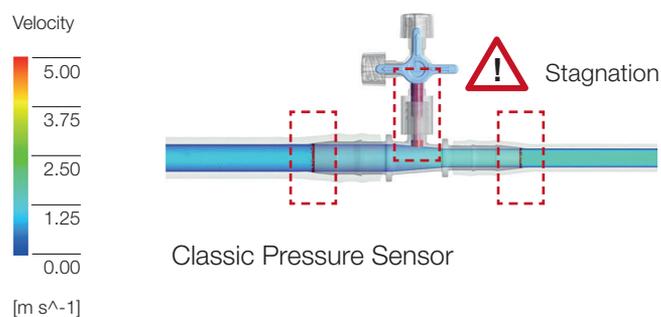
- DP3 pump allows flow adjustment in steps of 10 ml/min (requires ¼" patient kit and ¼" flow sensor)
- Reduced turbulence because of continuous tubing diameter
- Integrated Pressure Sensor (IPS) attributed for less hemodilution, reduced risk of air aspiration and clotting in pediatric patient

### Reference

“ It was shown that calculated low flow rates needed for support particularly in neonates can be maintained over a long period of time.”<sup>9)</sup>

“ Critical elements of construction related to the whole system are the connecting tubes, which conically increase from the venous ¼ inch to 3/8 inch at the pump entrance. This may predispose to turbulent flow and thrombus formation.”<sup>9)</sup>

### Connector Fluency Chart



## Challenge 4: Special Patient Group – Reacting More Sensitive to Any Change in Setting, Therapy or Parameter



### Requirement

- Safety features for more secure extracorporeal treatment of pediatric patients

### Solution

- Xenios console provides several safety features for example bubble detection
- One platform and pump (DP3) offer the full range of support
- Possibility to connect a heater cooler unit to the circuit for temperature management

### Reference

“ Safety functions are ensured by several control systems: cannula aspiration is prevented by preload control; a brief interruption of the flow can be managed with the zero-flow mode without risking back-flow.”<sup>10)</sup>

“ [...] it is the prevention of backflow and features for pressure, bubble and flow control offering fine adjustments down to zero, which make the DP3 safe.”<sup>9)</sup>

“ The system was complemented with an MDC console, which included valuable safety mechanisms such as a flow sensor with an integrated bubble detector, backflow detection, and temperature sensors.”<sup>5)</sup>

# By Your Side



## Clinical Support

We accompany excellent use of our technology and implementation of our therapies with far-reaching individual support and application-oriented services. This includes an international support hotline.

Our console is always accompanied by comprehensive support from our Clinical Support Team. Each of our application specialists has many years of real-world experience from specialists working in clinics. These highly qualified experts provide with on-site support – comprising instructions/training and help in implementing our technology in the day-to-day business of your clinic.



## Technical Service

Our Technical Service Team is available to answer any and all technical questions you may have in and around the Xenios platform. In addition to this, the Academy offers you professional events for both basic and advanced training. The Xenios campus-our e-learning platform - offers divers study modules and videos tailored to your specific areas of interest.

## References

- 1 Langer et al., (2016) "Awake" extracorporeal membraneoxygenation (ECMO) : pathophiology, technical considerations, and clinical pioneering. *Critical Care* 20:150.
- 2 BrauneS. et al. (2015) The use of extracorporeal carbon dioxide removal to avoid intubation in patients failing non-invasive ventilation--a cost analysis. *BMC Anesthesiol* 15:160.
- 3 Teno JM et al., (2000) Decision - Making and outcomes of Prolonged ICU Stays in Seriously Ill Patients. *J Geriatr Soc.*; 48 (5 Suppl): p.70-4.
- 4 Speth, Marlene et al. (2016) Pediatric extracorporeal life support using a third generation diagonal pump. *ASAIO J.* 62(4):482-490: p.482.
- 5 Okan, Yildiz et al. (2017) Initial Clinical Experiences With Novel Diagonal ECLS System in Pediatric Cardiac Patients. *Artificial Organs* 41(8):717-726: p.718.
- 6 Okan, Yildiz et al. (2017) Initial Clinical Experiences With Novel Diagonal ECLS System in Pediatric Cardiac Patients. *Artificial Organs* 41(8):717-726: p.722.
- 7 Schmidt, Florian et al. (2012) Concept of "awake veno-venous extracorporeal membrane oxygenation" in pediatric patients awaiting lung transplantation. *Pediatric Transplantation.* p.1.
- 8 Schmidt, Florian et al. (2012) Concept of "awake veno-venous extracorporeal membrane oxygenation" in pediatric patients awaiting lung transplantation. *Pediatric Transplantation.* p.5.
- 9 Speth, Marlene et al. (2016) Pediatric extracorporeal life support using a third generation diagonal pump. *ASAIO J.* 62(4):482-490: p.489.
- 10 Stiller, Brigitte et al (2017) Multicenter Experience With Mechanical Circulatory Support Using a New Diagonal Pump in 233 Children. *Artificial Organs.* p.3.



**FRESENIUS  
MEDICAL CARE**

End of 2016, Xenios with its brands Novalung and Medos has become part of the FME family, the worldwide market leader in renal support.

Head office: Fresenius Medical Care Deutschland GmbH · 61346 Bad Homburg · Germany  
Phone: +49 (0) 6172-609-0 · Fax: +49 (0) 6172-609-2191  
[www.freseniusmedicalcare.com](http://www.freseniusmedicalcare.com)