XENIOS

NOVALUNG KITS

XLUNG KIT | XLUNG KIT 230 | MINILUNG KIT ⅜"
MINILUNG KIT ¼" | MINILUNG PETITE KIT

INSTRUCTIONS FOR USE

ENGLISH

CE
0123

novalung

	Consult instructions for use
	Do not re-use
	Do not resterilize
	Sterilized using ethylene oxide
	Use-by date
	Manufacturer
	Date of manufacture
	Batch code
	Catalog number
	Non-pyrogenic
	Temperature limit
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	MR unsafe
	Contains or presence of phthalate: bis(2-ethylhexyl)phthalate (DEHP)

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The instructions for use are intended for all medical staff working with the Novalung kit and must be read thoroughly prior to use. The Novalung kit may be used only by specially qualified and explicit trained medical staff.

Although the Novalung kit has been subjected to a risk analysis and the design is in accordance with the current state of technology, residual risks during clinical use remain. These, and all identified risks are addressed in the following instructions for use as contraindications, complications, cautions and warnings.

The Novalung kit is designated as Class III product in accordance with the EU Medical Device Directive 93/42/EEC. The Novalung kit (MiniLung petit, MiniLung and Xlung) must not recomended to be used in combination with the i-cor (synchroniced cardiac assist) therapy mode. Please note that Xenios offers qualitative training courses regarding the exact handling and application of the Novalung kits. For schedules and more information go to www.xenios-campus.com.

1 DESCRIPTION

The Novalung kit is a pump-driven medical device which enables the extracorporeal blood gas exchange of carbon dioxide and oxygen by diffusion across a gas-permeable and plasma-tight polymethylpentene (PMP) membrane, as well as temperature control of blood by a heat exchanger compartment. The extracorporeal circuit: The patient's blood is withdrawn from the patient via vascular access (by central vessels), passed through a non-occlusive centrifugal pump and a tubing system through a membrane lung, and then returned to the patient through the vascular access. The content and clinical use of the Novalung kit is described in chapter 8 of this IFU.

1.1 Novalung kits configuration

	MiniLung petite kit	MiniLung kit ¼"	MiniLung kit ⅜"	XLung kit	XLung kit 230
Oxygenator	MiniLung petite	MiniLung	MiniLung	XLung	XLung
Blood pump	deltastream DP3 ¼"			deltastream DP3 ⅜"	
Tubing size for connection	¼"		¼"(art.)/⅜"(ven.)	⅜"	
Tubing length (proximal tubing line/ distal tubing line)	200 cm/200 cm			182 cm/187 cm	230 cm/230 cm

A non-occlusive blood pump (deltastream DP3) is connected by tubing lines. These tubing lines can be connected to vascular access cannulas. Monitoring of blood pressure is carried out by Integrated Pressure Sensors (IPS). The IPS must be calibrated in un-primed status of the Novalung kit. Recalibration of the IPS during therapy is not required and not allowed.

- The Novalung kit is certified for 29 days application.
- The Novalung kit is sterile according to DIN EN ISO 11135, pyrogen free and for single use only.

1.2 Blood and gas transport

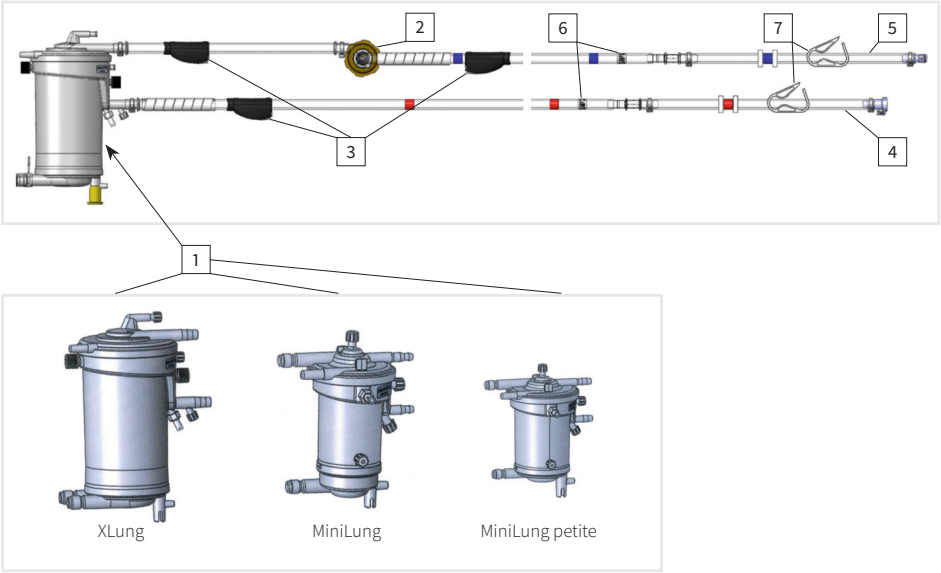


Fig.1 XLung Kit / MiniLung Kit ⅜" and ¼" / MiniLung petite Kit Components

1. XLung/MiniLung/MiniLung petite membrane lung
2. DP3 ⅜" or ¼" pump head
3. Integrated pressure sensor (IPS)
4. Blood outlet tubing
5. Blood inlet tubing
6. Blood flow direction indicators
7. Tube clamps

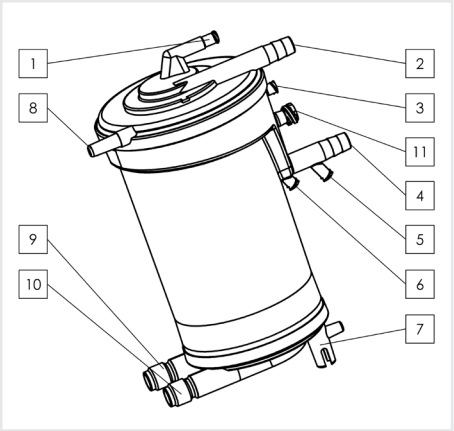


Fig.2 XLung configuration

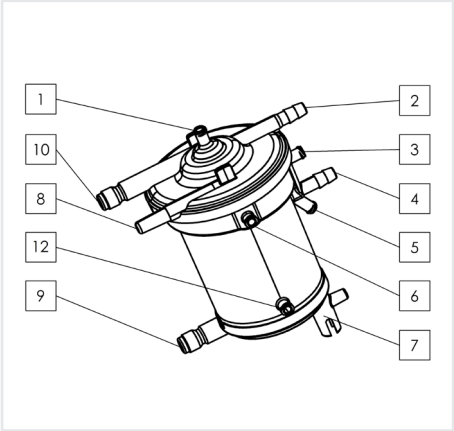


Fig.3 MiniLung and MiniLung petite configuration

1 Vent port, venous
2 Blood inlet
3 Recirculation, Luer-Lock
4 Blood outlet
5 Blood sample, arterial
6 Temperature, arterial
7 Gas outlet
8 Gas inlet
9 Water inlet, Hansen-type coupler
10 Water outlet, Hansen-type coupler
11 Cardioplegia port
12 Rest blood removal port

The blood enters the membrane lung through the blood inlet **2**. The decarboxylated and oxygenated blood flows through the blood outlet **4** back to the patient.

Unhumidified oxygen and/or medical compressed air is used as sweep gas. The sweep gas line is connected to the gas inlet **8**; the gas outlet **7** is located at the bottom of the membrane lung. A heater/cooler device can be connected to the membrane lung via the water inlet **9** and water outlet **10** connectors *(➲ NovaTherm/deltastream HC instruction for use)*.

The blood is transported by a non occlusive centrifugal pump head (diagonal pump). The blood flows from the inlet to the outlet of the pump head *(➲ Fig. 4)*. The direction of flow is indicated by arrows on the pump housing. To operate the Novalung kit, the Xenios DP3* pump drive in combination with the Xenios console* is required.

* Xenios DP3 pump drive and Xenios console are exemplary for iLA activve or deltastream DP3 pump head, respectively for Novalung iLA activve console, deltastream MDC console or i-cor console.

All blood-contacting surfaces of the Novalung kit, except the pump head, are coated with the x.ellence coating. The coating is a stable and a biocompatible surface. The coating components are high-molecular-weight heparin, bound covalently and ionically to immobilized polypeptide.

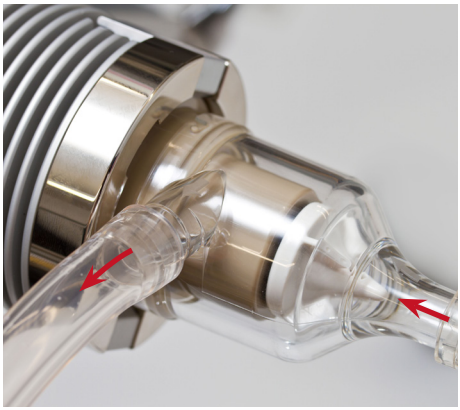


Fig.4 deltastream DP3 pump

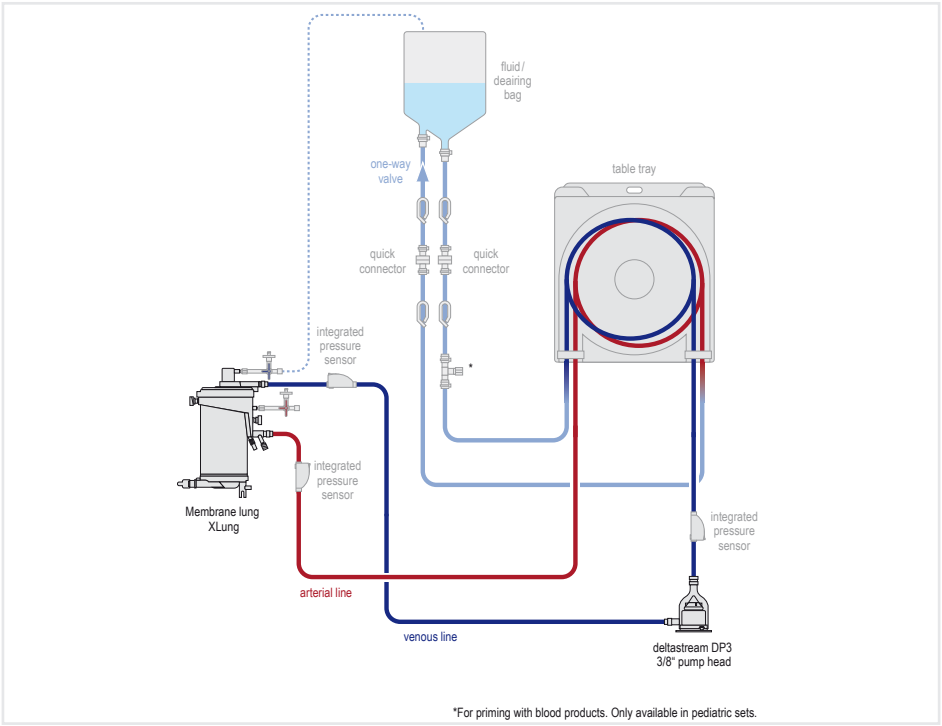


Fig.5 Novalung kit configuration

2 INTENDED USE AND INDICATIONS

2.1 Intended use

The intended use of the Novalung kit is extracorporeal gas exchange, pumping of blood and thermoregulation of blood.

2.2 Indications

The Novalung kit can be deployed in various clinical procedures depending on the clinical needs of the individual patient. General indication is extrapulmonary gas exchange (oxygenation and decarboxylation) and/or extracorporeal circulation and/or thermoregulation of the blood.

The application of the Novalung kit is left to the discretion of users based on their knowledge and experience. The indications and handling specifications set out by Xenios should be regarded as recommendations.

The benefit of treatment with the Novalung kit must be weighed against the risks of extracorporeal therapies

3 PERIOD OF APPLICATION

The period of application is certified for 29 days. The period of application of the Novalung kit is dependent on the individual patient situation and its influence on the functionality of the product.

4 CONTRAINDICATIONS, INTERACTIONS AND COMPLICATIONS

4.1 Contraindications

With use as directed and observing all indications and precautionary measures the following contraindications are known:

- Heparin-induced thrombocytopenia (HIT)
- Known paradoxical reactions to heparin
- Aortic dissection (in veno-arterial cannulation setting)
- Severe aortic valve insufficiency (in veno-arterial cannulation setting)

4.2 Interactions

Xenios is not aware of any data indicating an interaction of the x.ellence coating in combination with medical devices of a different surface coating. There are likewise no indications of incompatibility or increased risk in combination with medical products which have a different surface coating. Combinations of medical products with different surface coatings is in the responsibility of the user.

No further interactions with other agents are currently known.

4.3 Complications

The following complications may occur when using the product. In this context please refer also to section 5 Cautions and Warnings.

- Although the product is specified to the highest degree of technical safety, infections, mechanical failure, hemolysis and thromboembolic complications may occur during use.

- As in any contact between human blood or blood cells and foreign surfaces, in this case, too, there is a risk of activating cascade systems.

- Other risks include gas and particle embolism resulting from unintentional back flow of blood in veno-arterial applications.

- To avoid the risk of unintended disconnection, it is necessary to secure the connection between the cannulas and the Novalung kit with a suitable cable tie, to make regular visual checks and to set appropriate alarm limits on the Xenios console.

- Clotting of extracorporeal circuit:
  To minimize this risk, an adequate blood flow and appropriate anticoagulation are necessary. Air accumulations inside the Novalung kit, especially in the membrane lung **1** vent port, Fig. 2) should be avoided and should be removed immediately if they do occur.

- Thrombosis in the vascular system:
  To reduce this risk, an adequate blood flow and appropriate anticoagulation are recommended. In veno-arterial application, blood circulation to the extremities should be monitored by suitable measures: visual checks, pulse oxymetry, doppler sonography.

- Hypocapnia:
  This risk is mitigated by adapting the mechanical ventilation and/or the sweep gas flow to the CO_2 removal capacity of the product. In the case of spontaneously breathing patients, note the reduction in respiratory drive. Please use adequate analysis techniques (e.g blood gas analysis). Especially at the start of therapy it is necessary to increase the sweep gas flow gradually while monitoring the blood gas values and adapting the mechanical ventilation settings.

- Hypoxemia:
  This risk can be mitigated by monitoring blood gas analysis.

- Loss of functionality (decrease of CO_2 removal and/or oxygenation) of the membrane lung.
  The functionality of the membrane lung should be monitored using blood gas analyses. For this purpose use the threeway stop cock of the recirculation port **3**. Possible causes are inadequate blood flow, thrombosis and pseudo-membrane formation (e.g. fat, fibrinogen or clotting products) inside the membrane lung. The problem can be solved by adjusting sweep gas and/or blood flow rates or by replacing the product.

5 CAUTIONS AND WARNINGS

5.1 General cautions and warnings

- Do not use the product if the packaging is opened or damaged.
- Only accessories and/or accompanying material approved by Xenios may be used to operated the medical device.
- The Novalung kit may only be used with the Xenios console*, DP3 pump drive, with specified mounting systems (please refer to the relevant instruction for use of the specific medical device), standing upright, with the gas inlet at the top.
- Always observe strict asepsis when handling the Novalung kit.
- Unhumidified oxygen and/or medical compressed air is used as sweep gas to the membrane lung.
- Monitor the blood flow and speed of the blood pump.
- The systemic antagonization of heparin by administering protamine during an extracorporeal procedure is potentially linked to the risk of clotting/coagulation and performance loss of the extracorporeal system.
- It is essential to check the coagulation status of the patient regularly. The protocol for coagulation management is the responsibility of the user in charge.
- Even small amounts of visible air in the membrane lung must be removed via the vent port of the membrane lung. To remove air out of the membrane lung completely, please tap and agitate the membrane lung slightly. The maximum pressure on the blood side of 600 mmHg (80 kPa) must not be exceeded during this process.
- When applying high blood flow rates in particular, convection may lead to patient hypothermia. Active warming of the patient is recommended; suitable temperature control must be implemented to counter this risk.
- Before priming to check the tightness of the membrane lung: leave the water to recirculate inside the heat exchanger for a minimum of 5 minutes that way it can be checked if the structure of the heat exchanger is leakless and no fluid leaks from the water side to the gas exchange compartment. Should a leakage be present of the heat exchanger unit of the membrane lung, the fiber bed of the gas exchange compartment of the membrane lung slowly fills with water. Check the lower part of the membrane lung for this reason. This test is necessary although the membrane lung left facility in a faultless state, because the modus which the device will be handled after dispatch can not be known. Leaky membrane lung must not be used. These products will have to be replaced.

- The pressure at the water inlet of the membrane lung must not exceed 750 mmHg (100 kPa).
- Do not operate the blood pump with the inlet tubing clamped off.
- The Novalung kit should only be operated and monitored by explicit trained and qualified medical staff.
- Read the Instructions for Use of this Novalung kit carefully prior to use.
- The Novalung kit must not undergo further processing, be modified in its technical properties or design, or be subjected to any post-treatment.
- If the Novalung kit is used incorrectly or for purposes other than those set out in these Instructions for Use, the sole responsibility is with the user.
- Do not use the Novalung kit if the “use by” date has expired.
- Do not expose to heat or sun.
- During extracorporeal therapy a Novalung kit should always be available as replacement.
- Due to its priming volume, the XLung kit / XLung kit 230 is not suitable for neonatal applications or for small children (the extracorporeal shunt volume is too high compared to the total patient volume). For the treatment of newborn and premature infants, the extracorporal volume of the respective Novalung kit (MiniLung petite, Minilung) has to be considered due to the hemodilution effect of additional volume.
- If the blood pump has to be switched off during veno-arterial application, the tubing must be clamped.
- Use a flow meter to control sweep gas flow.
- High blood fats or high fibrinogen values, among other factors, can lead to secondary membranes and impairment of gas exchange performance. (Par)enteral nutrition and medication regimes or anticoagulation should be adapted to the given situation.
- The maximum recommended sweep gas flow rate for specific membrane lung should not be exceeded (please refer to chapter 7 Specifications).

* Xenios console is exemplary for Novalung iLA activve console, deltastream MDC console or i-cor console.

- To monitor the functional capability of the membrane lung, continuous measurement of the blood flow is required. Additionally it's recommended to measure the carbon dioxide and oxygen partial pressures.

- Do not use solvents on the product such as alcohol, ether, acetone, liquid inhalation anaesthesia (e.g. halothane, enflurane, isoflurane, etc.). They can damage the Novalung kit from the inside and outside.

- The period of application is limited to 29 days.

- The Novalung kit is designed for single use on one patient; do not re-use, do not resterilize. Re-used, reprocessed and resterilized products could be contaminated, unsuitably packaged, or unsuitably labeled. The material properties, function and sterility of the product may be compromised, resulting in failure, malfunction, incorrect storage or use of the product, non-compliance with the expiration date or infection of the patient or user. Damage to the health of or even death of the patient, user, or third parties may result.

- Note on products containing phthalates: Animal tests have shown that phthalates (e.g. DEHP) are potentially toxic to reproduction. The medical device is composed of materials and parts, which can contain plasticizer such as DEHP. The material used for the medical device has a very low potential of releasing any organic substances, including DEHP, into the patient's blood during clinical application, because DEHP was only detected when isopropanol was used as extraction medium during chemical analysis. Moreover, the medical device has a coating that minimizes the risk of DEHP being released into the patient's blood. The risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP. The benefit of the MD overweighs the possible adverse effects, DEHP can cause in patients. For reasons of precaution, medical products containing phthalates (e.g. DEHP) must not be used for pregnant or breastfeeding women.

5.2 Cautions and warnings before and during use

- Remove Novalung kit from its packaging and ensure that the content is complete.
- Ensure that all connections are securely fitted; tighten if necessary.
- The IPS must be calibrated in un-primed status of the Novalung kit. Recalibration of the IPS during therapy is not required and not allowed.
- To prevent sensor leakage avoid mechanical load (e.g. kinking) in the area before and after IPS.
- Before initiating extracorporeal circulation, ensure that the extracorporeal circuit is fully deaired *(➔ 8.2 Preparation)*.
- Operating the pump head when not completely deaired destroys the bearing of the pump head. The blood volume to be conveyed by the blood pump depends on the individual patient and the selected vascular access.
- Check the extracorporeal circuit, including the pump head, for leaks prior to starting.
- Ensure that all components are connected properly prior to use.
- The membrane lung and blood pump should be positioned as low as possible. The blood pump should be positioned at the same height or slightly below the height of the membrane lung.
- The specified maximum blood flow rate of the membrane lung used (MiniLung petite 0.8 l/ min, MiniLung 2.4 l/min, XLung 7 l/min) must not be exceeded. Please note the minimum blood flows as well (MiniLung petite 0.1 l/min, MiniLung 0,35 l/min, XLung 1,0 l/min). Consider the overall situation of the patient and the type of cannulas used. These have an influence on the maximum blood flow rate, which may not be fully achieved.
- The maximum gas pressure of 20 mmHg must not be exceeded.
- When using a ⅜" or ¼" standard connector between the tubing and the cannula, the connection must be secured using a suitable cable tie.
- The pressures and flow inside the patient kit must be continuously monitored and the alarm setting adjusted accordingly in order to prevent an exceeding of product specifications.

6 PACKAGING AND STORAGE

The Novalung kit is delivered sterile and pyrogen free. Sterility is only assured if the packaging has not been opened or damaged and the “use by” date has not expired. The Novalung kit must be stored in its original packaging, in a dark, dry location at a storage temperature of +10 °C to +30 °C (+50 °F to +86 °F).

7 SPECIFICATIONS

7.1 Novalung kits specifications

	MiniLung petite kit	MiniLung kit ¼"	MiniLung kit ⅜"	XLung kit	XLung kit 230
Blood flow rate (in accordance with ISO 7199)*	0.1 – 0.8 L/min*	0.35 – 2.4 L/min*		1.0 – 7.0 L/min*	
Maximum gas flow rate	10 L/min			14 L/min	
Maximum pressure on gas side	12 mmHg			25mmHg	
Maximum pressure on blood side	600 mmHg (80 kPa)				
Maximum recommended water pressure	750 mmHg (100 kPa)				
Surface of the gas exchange membrane	0.32 m^2	0.65 m^2		1.9 m^2	
Total priming volume of the set	195 mL ± 10%	240 mL ± 10%	300 mL ± 10%	605 mL ± 10%	670 mL ± 10%
Rest blood volume in the oxygenator	20 mL	53 mL	53 mL	65 mL	65 mL
Size of blood inlet and outlet connectors	3/16"; 3/16"	¼"; ¼"	⅜"; ¼"	⅜"; ⅜"	
Tubing length (inlet/outlet line)	200 cm/200 cm			182 cm/ 187 cm	230 cm / 230 cm

*Determined with a water-glycerol solution (viscosity: 4.0cP and a backpressure of 150mmHg

7.2 Specifications of the pump head

	DP3 ⅜"	DP3 ¼"
Speed	0-10,000 rpm	0-10,000 rpm
Pressure difference	0-600 mmHg/0-80 kPa	0-600 mmHg/0-80 kPa
Size L; Ø	approx. 75; 50 mm	approx. 75; 50 mm
Tubing fitting	⅜", approx. 9.5 mm	¼", approx. 6.35 mm

7.3 Integrated pressure sensor (IPS)

Integrated Pressure Sensor (IPS)	
Measuring range	-400 mmHg to +400 mmHg (-53kPa to +53kPa)
Accuracy	± 1% (0 to ± 50 mmHg) / ± 3% (51 to ± 400 mmHg)

7.4 Materials (blood-contacting)

Oxygenator	Housing	Polycarbonate (PC)
	Gas exchange fibers	Polymethylpentene (PMP)
	Potting material	Polyurethane (PU)
	Inlet/outlet tube	Polyvinylchloride (PVC)
	Connectors	Polyvinylchloride (PVC)
	Tubing	Polyvinylchloride (PVC)
	Protective caps	Polyethylene (PE)
	Heat exchanger fibers	Polyethylene terephthalate (PET)
	Temperature sensor	Stainless steel (SS), polypropylene (PP)
	Luer lock adapter	Acrylnitrile butadiene styrene (ABS)
	Closed male DIN cap	Polyvinylchloride (PVC)
Blood pump	Outer housing	Polycarbonate (PC)
	Inner housing	Polyetheretherketone (PEEK)
	Rotor	Polycarbonate (PC)
	Bearing	Aluminum oxide (AL2O3)
Adhesives		Isobornylacrylate, acryl, epoxy resin
Coating		Heparin and albumin
Sterilization method		Ethylene oxide (EO)

7.5 Other documents

The following detailed information is available on request:

- Sterilization method
- List of blood-contacting materials
- Pressure drop on blood side for the blood flow indicated by the manufacturer, when used as directed in a clinical setting
- Pressure drop on gas side for the maximum blood and sweep gas flows indicated by the manufacturer, when used as directed
- Information on blood cell damage
- Information on the release of particles from the oxygenator according to the manufacturer's quality management system
- Relevant tolerances of the information listed

8 APPLICATION

8.1 Content of Novalung kit

Check the Novalung kit and accessories for damage in transit, and check the sterile packing. Open the packaging and the sterile outer packaging and ensure that the content is complete. The Novalung kit contains:

MiniLung petite kit	MiniLung kit ¼"	MiniLung kit ⅜"	XLung kit	XLung kit 230
1 Tubing set 800 LT IPS	1 Tubing set 2400 LT IPS	1 Tubing set 2400 LT IPS ⅜"	1 Tubing set 7000 LT IPS	1 Tubing set XLung kit 230
1 DP3 pump head ¼"			1 DP3 pump head ⅜"	
1 Priming line 1-4			1 Priming line 3-8	
1 Filling line SQ40 1100 mm			–	
1 Purge line 40 mm blue				
1 Purge line 40 mm red				
1 Gas line short				
1 Gas line long				
1 Syringe 50 mL				
3 Luer caps				
1 Christmas tree connector				
4 Clamps				

1. Aseptic technique is to be used at all times.

2. Remove the supplied accessories.

3. Open the tapes.

4. Remove the protection caps and the short tubing parts from the colder couplings.

5. Connect the filling bag with the table set via the colder couplings.

6. Hang the priming solution on the infusion hook.

7. Position the membrane lung onto its corresponding holder, remove the white and yellow cap.

8. Hang the table set on the system trolley (max. at the height of membrane lung).

9. Hang the filling bag on the infusion hook.

10. Remove the transportation lock from the pump head. Do not insert the pump head yet.

11. Close the two tube clamps (Roberts clamps) of the filling bag.

12. Connect the sweep gas line at the gas inlet of the membrane lung.

13. Prepare the Xenios HC unit* (please consider corresponding IFU).

14. Deaire the Xenios HC unit*.

15. Connect the water hoses of the Xenios HC unit* to the water inlet and water outlet connector of the membrane lung.

16. Switch on the Xenios HC unit*, set target temperature and allow water to circulate (please consider corresponding IFU.

17. Check membrane lung for leakage (tightness). If water occurs in the gas exchange compartment, replace the Novalung kit.

* Xenios HC Unit stands for: deltastream HC or NovaTherm heater/cooler unit

1. Switch on the Xenios console: Push and hold the [ON/OFF] button for at least 2 seconds.

2. Attach the flow sensor to the tubing set, after P3 (please note direction of arrow).

3. Connect the IPS cable to the corresponding IPS (please note the correct order – P1, P2, P3, please refer to the instruction of use of Xenios console)

4. Select the therapy mode.

5. A visual imaging of the sensor box with connected cables appears on the display after completing the start-up procedure.

6. Select the pressure measurement mode. Use integrated pressure sensor (IPS).

7. Calibrate the pressure sensors. Ensure that the tubing kit does not contain priming solution.

8. Stick the spike of the filling bag into the priming solution, hang the filling bag downwards and allow priming solution to fill the bag.

9. Hang the filling bag on the infusion hook with a minimal height of 50 cm e.g. above the table set, pump head or membrane lung level.

10. Open the clamps and wait for passive filling of the set (approx. 30 seconds).

11. Tap pump head lightly to remove any remaining air inside.

12. Connect pump head to pump drive.

13. Connect the recirculation line to the vent port **1** of the membrane lung. Open the clamp of the recirculation line and the three-way stopcock of the vent port.

14. Actively vent the tubing set in the “de-airing mode” with 3000 rpm.

15. Remove the membrane lung from the holder to allow for complete de-airing, turn it upside down and tap it lightly to remove any remaining air bubbles.

16. Place the membrane lung back onto the holder.

17. Remove the de-airing filter from the membrane lung (vent port **1** and recirculation port **3**). Close the Luer-Lock with sterile luer caps (included in the accessory).

18. Deactivate the de-airing mode once there is no more air inside the tubing system.

19. Calibrate the flow sensor. For calibration please close clamps of the filling bag.

20. Optional: Activate “Zero flow (air bubbles)”.

21. After closing all four tube clamps, disconnect the filling bag from the tubing system.

22. Connect both ends of the tubing set with one another air-free and open the tube clamps. If residual air should get into the circuit, remove it via the recirculation line at the membrane lung.

Proceed as follows for this:

- Put a syringe filled with rinsing solution on the 3-way stopcock of the recirculation port on the oxygenator.
- Open the 3-way stopcock to the syringe. Inject the rinsing solution until the remaining air is removed completely.
- Close the 3-way stopcock of the recirculation port on the oxygenator.
- Seal the 3-way stopcock with a sterile cap.

23. Start the blood pump on the Xenios console and allow the priming fluid to circulate at a low flow rate (max. 2000 rpm).

24. Check the pump head again if there is any remaining air and eliminate it.

25. Disconnect the recirculation line from the membrane lung. Close the Luer-Lock with a sterile luer cap (included in the accessory).

8.4 Priming with allogeneic blood

1. Ensure that the pump speed is 0 rpm.

2. Close the blue 3-way stopcock on the oxygenator's recirculation line.

3. Close the clamp on the recirculation line.

4. De-air the blue 3-way stopcock close to the table set by opening it to allow saline to displace any remaining air.

5. Close the blue 3-way stopcock close to the table set.

6. Close the clamp located next to the blue 3-way stopcock close to the table set.

7. Unpack the blood priming line, slide the clamp next to the Luer cap, and close the clamp.

8. Remove the secure cap of the blood priming line's spike and then spike the transfusion bag's spike port.

9. Open the clamp on the blood priming line, slowly lower the blood priming line to fill it and then close the clamp when no visible air bubbles remain.

10. Hang the transfusion bag on the infusion hook.

11. Connect the blood priming line to this blue 3-way stopcock.

12. Open the clamp on the blood priming line.

13. Immediately open the blue 3-way stopcock to allow the blood to enter the table set.

14. Increase the pump speed to 2000 rpm to allow the blood to circulate at a low flow rate.

15. When blood is visible in the filling bag, close the clamp on the blood priming line and decrease the pump drive's speed on the console to zero (0).

16. Close all four (4) clamps on the filling bag and table set.

17. Close the blue 3-way stopcock near the table set, disconnect the blood priming line from the 3-way stopcock and close it using a sterile Luer cap.

NOTE: Start treatment immediately after priming with allogeneic blood.

8.5 Starting to use the Novalung kit

According to the patient's specific situation, after creating the vascular access start with systemic anticoagulation. Please consider the basic information of the ELSO society (Extracorporeal Life Support Organisation) for anticoagulation. The ACT (activated clotting time) has to be adjusted to the patient's individual medical need (e.g., ACT in range of 180-220 seconds).

To connect patient to the tubing system, turn down the speed of the blood pump to zero. After connecting to the vascular access while avoiding air bubbles, start the pump drive while turning the wheel of the Xenios console* to increase the speed. Secure the vascular access and increase the blood flow gently up to the prescribed value.

After the start of extracorporeal circuit start the gas exchange with a sweep gas flow of 1 l/min. To avoid negative effects of the extracorporeal decarboxylation which now begins (decrease in $PaCO_2$ and increase in pH), in mechanical ventilation mode simultaneously adapt the respiratory minute volume incrementally.

In case of spontaneously breathing patients, note the reduction in respiratory drive. The clinical monitoring of these changes must be carried out regularly and always when a parameter has been changed. Regular monitoring of clinical parameters (e.g. blood gas analysis) is recommended.

* Xenios console is exemplary for Novalung iLA activve console, deltastream MDC console or i-cor console.

- The system should be positioned as low as possible using the height-adjustment mechanism of the system trolley. This will ensure optimum blood supply to the blood pump (passive drainage) and adequate pressure in the membrane lung.

- Pay attention to the harmful effects on blood cells of negative pressures upstream of the blood pump. Activate preload monitoring (P1 limiter). Please consider the circulatory effect of the P1 limiter functionality in veno-arterial application.

- Flow control can be activated additionally in order to safeguard the blood flow and thus the gas exchange performance.

- In order to detect changes in the system, the blood flow and pump speed must be monitored with appropriate alarm limits.

- Inspect the complete extracorporeal system regularly. In the event of visible clotting, air and deposits of fat and fibrin, the causes should be eliminated as far as possible and/or the anticoagulation therapy should be adapted as far as is reasonable.

- Remove accumulated condensation inside the membrane lung by flushing the membrane lung with the maximum specified sweep gas flow, then immediately reset the sweep gas flow to the prior setting.

- Do not take any blood samples from fittings of the membrane lung, except from those provided (three-way stopcock of vent port and recirculation port). Do not administer any fluids or medication through them.

- Dispose the Novalung kit after use according to clinical and legal regulations.

- If you have any questions, or if problems or malfunctions occur, please consult your Xenios sales representative or contact Xenios AG directly. Please make a note of the product lot and serial numbers.

The Novalung kit should only be replaced during operation if a malfunction or defect occurs. It is important to assure strictly aseptic handling when replacing the product. Maintain the blood and sweep gas flows of the Novalung kit that is connected to the patient until the replacement Novalung kit has been deaired and is ready for use.

1. Prepare additional accessories:

- **a.** 4 tube clamps
- **b.** 1500 ml crystalloid solution
- **c.** 2 syringes 50 ml or 20 ml filled with heparinized saline solution (10 I.U. Heparin/ml) (size of the syringes according to the cannulas used)

2. Put the currently running extracorporeal system on emergency drive (connect the pump drive directly to a battery pack). Monitor the patient closely! Restart Xenios console to setup a new Novalung kit. For preparation and priming of a new Novalung kit follow the instructions according to ➔ *8.2 Preparation* and ➔ *8.3 Priming/De-airing*.

Blood return:

Xenios can't recommend any method of blood return. If blood should be retransferred to the patient, this is only in responsibility of the physician in charge. Possible risks of retransferred blood must be considered.

3. Stop the sweep gas flow and disconnect the sweep gas line.

4. Stop the blood flow.

5. Clamp the extracorporeal circuit at access and return line prior to the cannula and behind the Luer-Lock connector (e.g. Novaport cannula).

6. Clamp the drainage cannula and close the safety clamps of the Novalung kit and remove the cable ties.

7. Disconnect the two tubing ends and remove the Novalung kit.
Attention: Please detach the water connections prior to disposal of the Novalung kit in case the membrane lung is connected to a Xenios HC unit* *(➔ NovaTherm / deltastream HC instruction for use)*.

8. Connect the unfilled syringe to one cannula, open the clamp and aspirate blood; afterwards connect one of the filled syringes and flush the cannulas. Follow the same procedure for the second cannula.

9. Connect the new Novalung kit to the cannulas, remove the clamps, connect the sweep gas line.

* Xenios HC Unit stands for: deltastream HC or NovaTherm heater/cooler unit.

10. The use of a cable tie is recommended to avoid unintended disconnection of the Novalung kit from the cannula.

11. After releasing the blood flow, adapt the sweep gas flow to the residual capacity of the exchanged membrane lung. Monitor the blood and sweep gas flow rates carefully when doing so. Check the functionality of the Novalung kit by means of blood gas analyses as soon as possible.

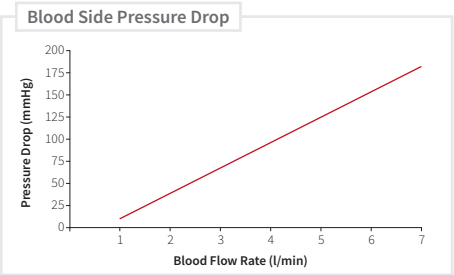
Attention: There is the possibility of an unwanted decrease in CO_2 partial pressure due to the now improved functioning of the new membrane!

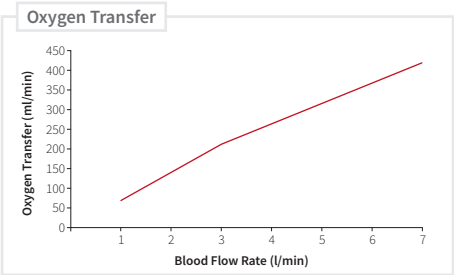
8.8 Connection to heater/cooler device

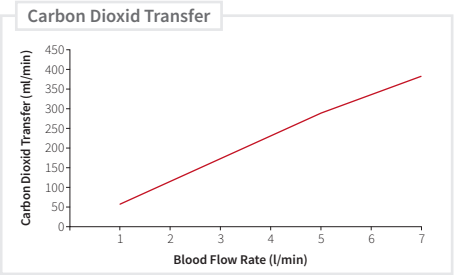
Please refer to *NovaTherm/deltastream HC instruction for use.*

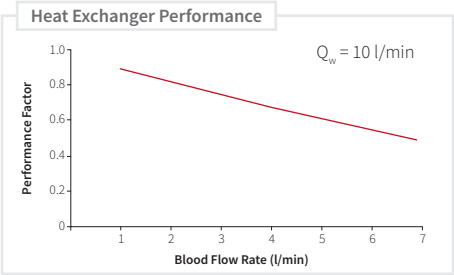
9 PERFORMANCE DATA ACCORDING TO DIN EN ISO 7199

9.1 XLung



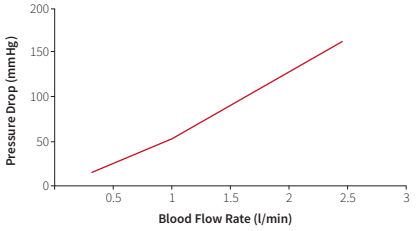




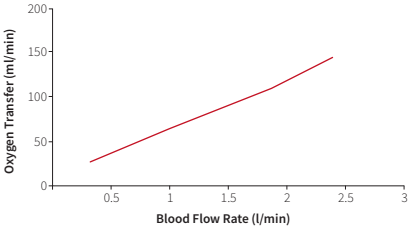


9.2 MiniLung

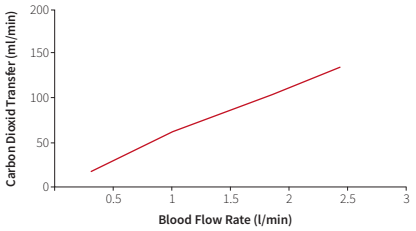
Blood Side Pressure Drop



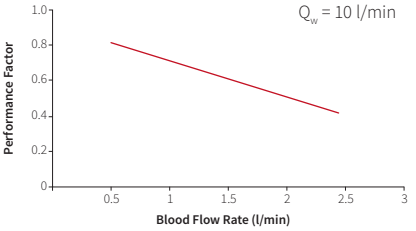
Oxygen Transfer



Carbon Dioxid Transfer

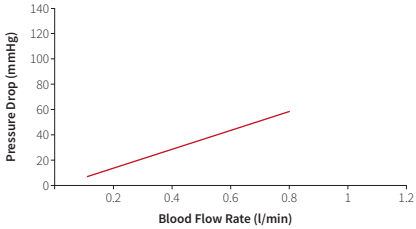


Heat Exchanger Performance

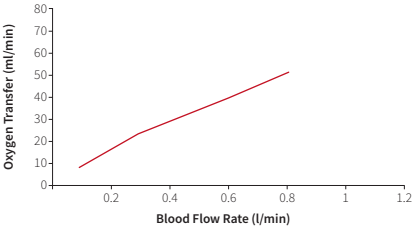


9.3 MiniLung petite

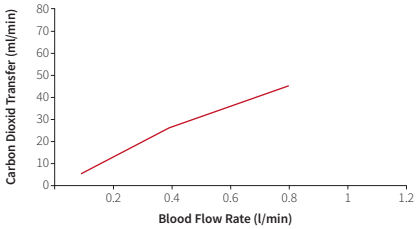
Blood Side Pressure Drop



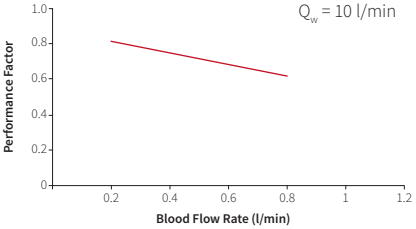
Oxygen Transfer



Carbon Dioxid Transfer



Heat Exchanger Performance



10 ORDER INFORMATION

Type	Name	Xenios Item No.
Treatment unit	**XLung kit**	**32000000**
Main circuit	Tubing set 7000 LT IPS	32020000
Accessories	–	–
Treatment unit	**XLung kit 230**	**32000014**
Main circuit	Tubing set XLung kit 230	32190008
Accessories	–	–
Treatment unit	**MiniLung kit ⅜"**	**32000002**
Main circuit	Tubing set 2400 LT IPS 3-8	32020001
Accessories	–	–
Treatment unit	**MiniLung kit ¼"**	**32000001**
Main circuit	Tubing set 2400 LT IPS	32020002
Accessories	–	–
Treatment unit	**MiniLung petite kit**	**32000003**
Main circuit	Tubing set 800 LT IPS	32020003
Accessories	–	–

The detailed contact Informations for the legal Manufacturer which are listed in #10 Order Information are:

Xenios:

Xenios AG
Im Zukunftspark 1
74076 Heilbronn
Germany

info@xenios-ag.com
www.xenios-ag.com
Phone +49 7131 2706-0
Fax +49 7131 2706-299

11 GUARANTEE AND WARRANTY

Xenios AG guarantees that this medical product conforms to the legal requirements, in particular those laid down in EU Directive 93/42/EEC relating to medical products. Pursuant to the said guarantee, in the event of the product exhibiting verifiable material faults or faults in workmanship prior to reaching its use-by date (UBD) which originated during production or packing, ("defects"), Xenios AG shall, at its own discretion:

- Replace the Novalung kit with an identical model of patient kit or with a Novalung kit which provides equivalent functionality.

All the following preconditions must be met for guarantee claims to be asserted:

- Do not use the Novalung kit if the expiry date has been exceeded.
- The defect occured first time the product was used befor the expiry date.
- In case of a product approved only for one-time use, or intended by Xenios AG only for one-time use, the defect must have occurred during first use.
- The defect must be reported immediately to Xenios AG or one of its representatives.
- Once a defect has been reported, the defective product must be immediately returned to Xenios AG or one of its representatives.

The above guarantee does not restrict, and applies in conjunction with the vendor's statutory warranty obligations and applicable product liability law.

In respect of other matters the guarantee applies only to the extent specified above. Further claims arising from the guarantee are excluded. The guarantee and the statutory claims cited apply in place of, and to the exclusion of, any other verbal or written, explicit or implicit, assurances, or any other assurances in any other form, given by Xenios AG. None of our representatives or employees is authorized to give any other assurances or to enter into agreements containing different provisions.

In view of the many factors which are beyond the control of Xenios AG, such as in relation to shipping, storage, handling by the user, misuse or failure to comply with the Instructions for Use or with warning notices, Xenios AG shall not be held liable in particular for loss of any kind resulting directly or indirectly from the product or its use, if the said loss was not verifiably caused by defects in the product. Xenios AG shall also not be held liable in particular for loss resulting from the resterilization or re-use of products which are approved only for one-time use, or intended by Xenios AG only for one-time use.

24/7 Xenios Clinical Support +49 7131 2706 345 **www.xenios-ag.com**

Item no: 8200672, Version: EN_007_2021_05

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