

Hollow Fiber Dialyzer (L Series) Instruction for Use

Please read the Instruction for Use carefully before using the product.

Indications: VITAL Dialyzer can be used for the hemodialysis treatment of acute and chronic renal failure.

Contraindications: No absolute contraindication for hemodialysis treatment. Strict monitoring shall be achieved for the patients who have tendencies of blood bleeding or clotting during the treatment. In case of any complication that would affect the stable condition, the treatment shall be terminated.

Warning:

- The dialysate and the blood should flow in counter-current.
- The maximum flow rate of dialysate is 800 mL/min.
- Do not use on non-degas dialysis fluid delivery systems.
- During the treatment, the transmembrane pressure shall not exceed 500 mmHg.
- The blood flow rate shall not be less than 150 mL/min, but not more than 500 mL/min.
- The preparation for hemodialysis and treatment should be carried out under aseptic operation to avoid infection.
- VITAL Dialyzer shall be used under certain medical supervision. To avoid bacterial and pyrogenic contamination, it is suggested to use together with hemodialysis machine and dialysate which are in accordance with the international standards, and most importantly, with the water, concentrated solution and dialysate which are in accordance with the international standards.
- This dialyzer is sterile and nonpyrogenic, sterilized by Gamma ray, which shall be checked before use. To avoid infection, do not use the expired product. Do not use the product if the package is damaged.

- This dialyzer is for single use and reuse is strictly prohibited. Reprocessing of this product may lead to adverse patient reactions and/or device failure. It should be discarded according to laws and regulations relevant to disposal of infectious medical waste so as to prevent infection.
- If abnormal conditions arise during the dialysis, such as bubbles, foreign body, blood leak, clotting, or hemolysis, proper measures shall be taken according to doctor's advice.

- Color identification:

Arterial: Red

Venous: Blue

Instructions for Installation

- Take out the dialyzer from the pouch, and check whether the dialyzer and its components are in good condition.
- Set up the dialyzer vertically to the holder, the red (arterial) port is located downwards.
- Make sure the dialyzer stays firmly in the holder.

Instructions for Use

1. Priming

- Prepare no less than 500ml normal saline and add appropriate amount of heparin if needed under the doctor's advice.

- Place the arterial line and the venous line onto the dialysis machine according to the instructions for use of the blood line tubing set.
- Connect the arterial line, the venous line and the dialyzer.
- Control the flow rate of blood pump within 80~100ml/min, use normal saline to totally remove air from blood line and blood side of the dialyzer. The direction of normal saline flow is arterial line → dialyzer → venous line, and counter-current flow is forbidden.
- Turn the flow rate up to 200~300ml/min, connect the dialysate and the dialyzer, and remove air from the dialysate side.

Note: The dialyzer should be replaced if there is bubbles inside.

2. Heparinization

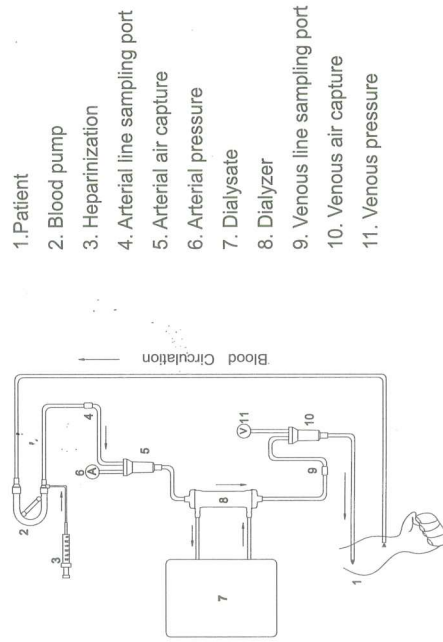
- Carry out the heparinization process under the doctor's advice.

3. Termination of Treatment

- Prepare 500 mL normal saline and turn off the blood pump.
- Withdraw the arterial line from the patient and connect it to the normal saline then set the blood flow rate at 100 mL/min, meanwhile prevent air from the blood line. Intermittently clamp the venous line to return the blood to the patient as much as possible.
- Turn off the blood pump and disconnect the patient's venous line.

Note: Do not turn off the air monitor system before blood returns completely to prevent the air flowing into the patient from the blood line.

A typical connection diagram



	Single use only		Date of manufacture
	Temperature limited		Lot Number
	Sterilized using irradiation		Caution
	Do not use if package is damaged		Use-by date
	Authorised Representative in European Community		Manufacturer

Product Performance: This dialyzer has reliable performance, which can be used for hemodialysis. The basic parameters of product performance and the laboratory data of this series will be provided as follows for reference.

Note: The laboratory data of this dialyzer was measured according to the standard ISO 8637.

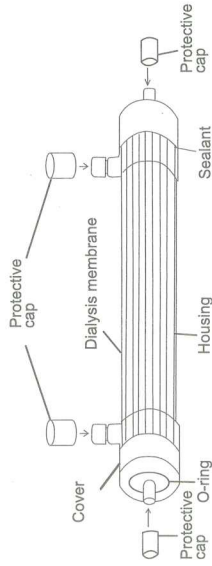
These data represent typical in vitro performance actual in vivo performance will differ due to the patient's blood composition and clinical settings.

Model Product ref.	DIA 13L VHL13		DIA 15L VHL15		DIA 17L VHL17		DIA 19L VHL19		DIA 21L VHL21		
	Clearance / Q _B (mL/min)	200	300	400	200	300	400	200	300	400	200
Urea (mL/min)	188	253	277	191	260	294	197	274	301	199	
Creatinine (mL/min)	179	221	254	183	230	273	191	244	281	194	
Phosphate (mL/min)	151	177	198	158	197	238	169	204	246	173	
Vitamin B ₁₂ (mL/min)	98	109	118	105	113	139	113	134	147	116	
KOA(Urea)	861		961	1083		1239		1382		1382	
Pressure drop of blood compartment (mmHg)	<50	<60	<80	<45	<55	<70	<40	<45	<70	<40	<70
Pressure drop of dialysate compartment (mmHg)	<35		<40	<45		<45		<45		<45	
Ultrafiltration Coefficient (mL/hr/ mmHg)	16		18	19		21		23		23	
Q _B =300mL/min, TMP=50mmHg	78		86	100		108		115		115	
Priming volume (mL)	1.3		1.5	1.7		1.9		2.1		2.1	
Effective membrane area (m ²)	1.3		1.5	1.7		1.9		2.1		2.1	

Special Storage Conditions and Methods: Please avoid crash and exposure to rain, snow, and direct sunlight during transportation. Please store it in a well-ventilated indoor place with storage temperature of 0°C-40°C, with relative humidity no more than 80% and without corrosive gas. DO NOT store it in a warehouse together with chemicals and humid articles.

Shelf life: 3 years after the sterilization date.

After-sale service: if any product inquire is needed, due to manufacturing quality problem, please keep the primary package of the product for product tracing.



Main Structure:

Component	Housing	Dialysis membrane	Cover	O-ring	Sealant	Protective cap
Material	Polycarbonate	PES membrane	Polycarbonate	Silicone Resin	Polyurethane	Polypropylene

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Keep this instruction for use after all of the products in this carton are used up.