【English】

ABLE®

Disposable Haemodialyser

(POLYETHERSULFONE)

Instruction for use

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Disposable Haemodialyser
Instruction for use

Please read the Instruction for use very carefully before using the product.

Product Name: Disposable Haemodialyser

Model: A-40; A-60; A-80; A-200

Intended use

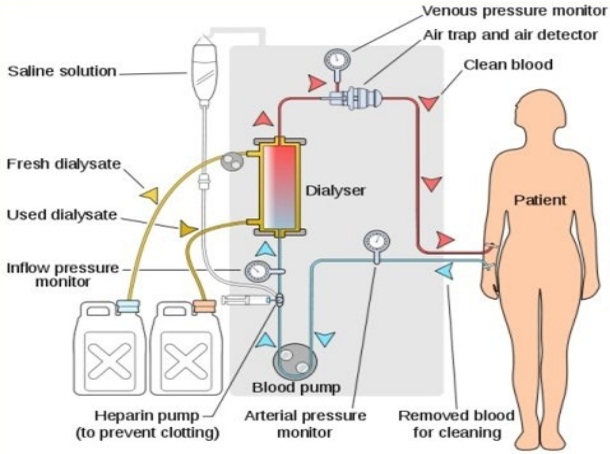
ABLER Dialyzer is designed for the hemodialysis treatment of acute and chronic renal failure and for single use. According to the semi-permeable membrane principle, it can introduce patient's blood and dialysate at the same time, both flows in the opposite direction in the both sides of dialysis membrane. With the aid of gradient of the solute, osmotic pressure and hydraulic pressure, The Disposable Haemodialyser can remove toxin and additional water in the body and at the same time, supply with the necessary material from the dialyzed and maintain electrolyte and acid-base balanced in the blood.

Contraindications

No absolute contraindication for hemodialysis treatment. Strict monitoring must be achieved for the patients who have tendencies of blood bleeding or cruor during the treatment. The dialyzer should only be used as directed by a physician.

Dialysis treatment

1. A typical connection diagram



2. Prepration for dialysis treatment

- If the dialyzate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test the dialysis machine for the absence of germioide residuals with a test for this application, according to the manufacturers' instructions.
- Place the dialyzer in a vertical position, arterial end (red) down.
- Install the arterial and venous bloodlines on the hemodialysis machine.
- Remove any dialyzer blood protective caps and aseptically connect the arterial and venous blood lines to the dialyzer.
- Aseptically spike a 1 liter bag of 0.9% sterile normal saline with a clamped IV administration set. Attach the IV administration set to the patient end of the arterial bloodline.
- Open the clamp on the IV set .Prime the arterial bloodline, dialyzer, and venous bloodline using a blood pump speed of approximately 150ml/min. Discard the first 500ml of solution. The drip chambers should be maintained about 3/4 full.
- Stop the blood pump. Clamp the arterial and venous bloodlines. Turn the dialyzer so that the venous end is downward. Aseptically connect the patient ends of arterial and venous blood lines together in preparation for recirculation. Open the clamps on the bloodlines.
- Verify that the dialyzate is within the prescribed conductivity limits with a calibrated external conductivity meter. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use PH paper or a meter to verify that the approximate pH is in the physiologic range.
- Attach the dialyzate line to the dialyzer. Fill the dialyzate compartment. In order to maximize the efficiency of the dialyzer. The dialyzate flow must be countercurrent to the blood flow.
- Recirculate the blood side at a flow rate of 300-400ml/min and a dialyzate flow of 500ml/min for a minimum of 10-15 minutes Recirculate until all the air has been purged from the system before connecting to patient. Continue recirculation and dialyzate flow until patient connection.
- Ultrafilter or flush an additional 500ml of 0.9% sterile normal saline so that the extracorporeal circuit has been flushed with a minimum 1 liter of saline to minimize

sterilization residues.

- Discard the prime solution when starting blood flow through the dialyzer. If the prime solution must be given to the patient for volume enhancement, replace the fluid in the circuit with fresh saline just before attachment to the patient.
- It is the responsibility of the Medical Director to assure that the residual levels are acceptable.

3. Initiation of dialysis treatment

- Turn the blood pump off. Clamp the saline line and the arterial and venous bloodlines.
- Do not infuse the recirculated saline prime into patient. If saline is required for volume enhancement, discard the recirculated saline and fill the bloodlines with fresh saline.
- Aseptically connect the arterial blood lines to the patient's arterial access. Open the arterial bloodline clamp.
- Place the venous bloodline in a drain container, making sure not to contaminate the end of bloodline. Open the clamp on the venous bloodline.
- Turn the blood pump speed up to 100-150 ml/min and fill the extracorporeal circuit with the patient's blood.

Warning: This step must be carefully monitored to prevent any possibility of blood loss.

- Turn off the blood pump and clamp the Venous bloodline
- Aseptically connect the patient end of venous bloodline to the patient's venous access. Open the clamp to the venous access.
- Unclamp the venous bloodline and set the blood flow to the prescribed rate. Rotate the dialyzer so that the venous end is downward.
- Set the prescribed ultrafiltration rate.

4. During the dialysis treatment

- If a blood leak should occur during the treatment, the decision to attempt to allow the leak to clot off by reducing the blood flow and ultrafiltration rate to minimum values is a clinical decision. The decision whether or not to return the blood to the patient must be made by a medical professional .

- Air entering to the extracorporeal circuit during dialysis may be very serious and should be avoided. A routine check of all connections prior to initiation of dialysis and periodically throughout the treatment is recommended. Constant monitoring of venous return line with an air detector is essential .If air get into the venous line during the treatment; the dialysis treatment must be discontinued without returning any of the patient's blood that is mixed with air.
- All blood tubing connections must be checked for security or obstruction to prevent damage or loss of blood or entry air. Dialysate circuit leaks allowing air entry or fluid loss may cause significant ultrafiltration errors.
- If hypersensitive reaction occurs to the patient, proper measures shall be immediately taken, stop the treatment as well as provide proper medications. Change the dialyzer and the blood line.

5. Termination of dialysis treatment

- When the dialysis treatment is completed, turn the blood flow rate to zero an UF rate to recommended minimum.
- Clamp arterial bloodline and aseptically disconnect from the patient's arterial access.
- Using the blood pump, rinse the patient's blood back using 0.9% saline solution at a slow rate. Do not allow air to enter the extracorporeal circuit.
- Once the blood has been returned, turn the blood pump flow rate to zero.
- Clamp the venous bloodline.
- Clamp the patient's venous access and aseptically disconnect the venous bloodline from the patient's access.

Warning

- The maximum fixed flow rate of dialysate is 800ml/min.
- During the treatment, the transmembrane pressure shall not exceed 500mmHg.
- The blood flood flow rate shall not be less than 150ml/min, but no more than 500ml/min.
- TABLE@ Disposable Haemodialyser 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 national and

international standards, and most importantly, with the water, concentrated solution and dialysate which are in accordance with the national and international standards.

- 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.
- Color identification:

  The junction between dialyzer and arterial line is blood inlet coded red.

  The junction between dialyzer and venous line is blood outlet coded blue.

Storage Conditions

Please avoid crash and exposure to the rain, snow and direct sunlight during transportation. Please store it in a well-ventilated indoor place with storage temperature of 0℃~40℃,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.

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

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

Table 1 Basic parameters of Product Performance

Model	A-40	A-60	A-80	A-200
Sterilization Way	Gamma ray	Gamma ray	Gamma ray	Gamma ray
Effective membrane area(m^2)	1.4	1.6	1.8	2.0
Maximum TMP(mmHg)	500	500	500	500
Inner diameter of membrane(μm±15)	200	200	200	200
Inner diameter of housing(mm)	38.5	38.5	42.5	42.5
Ultrafiltration Coefficient(ml/h.mmHg) (QB=200ml/min,TMP=50mmHg)	18	20	22	25
Pressure drop of blood compartment(mmHg) Q_B=200ml/min	⩽50	⩽45	⩽40	⩽40
Pressure drop of blood compartment(mmHg) Q_B=300ml/min	⩽65	⩽60	⩽55	⩽50
Pressure drop of blood compartment(mmHg) Q_B=400ml/min	⩽90	⩽85	⩽80	⩽75
Pressure drop of dialyzate compartment(mmHg) Q_D=500ml/min	⩽35	⩽40	⩽45	⩽45
Volume of the blood compartment(ml)	80±5%	90±5%	100±5%	110±5%

Table 2 Clearance

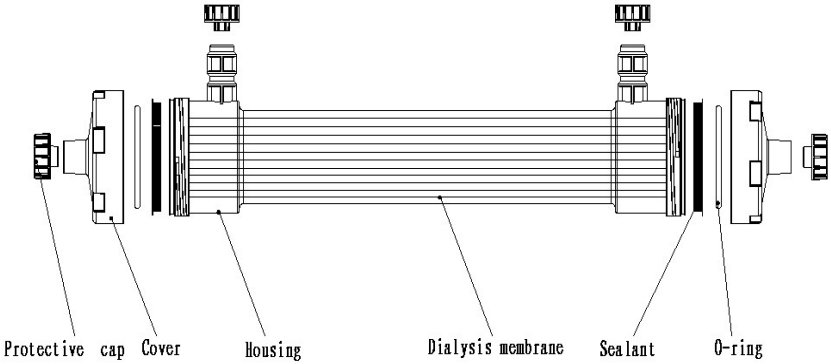
Model		A-40	A-60	A-80	A-200
Test Condition :Q_D=500ml/min,temperature:37℃±1℃, Q_F=10ml/min					
Clearance (ml/min) Q_B=200ml/min	Urea	183	185	187	192
	Creatinine	172	175	180	185
	Phosphate	142	147	160	165
	Vitamin B_{12}	91	95	103	114
Clearance (ml/min) Q_B=300ml/min	Urea	232	240	247	252
	Creatinine	210	219	227	236
	Phosphate	171	189	193	199
	Vitamin B_{12}	105	109	123	130
Clearance (ml/min) Q_B=400ml/min	Urea	266	274	282	295
	Creatinine	232	245	259	268
	Phosphate	200	221	232	245
	Vitamin B_{12}	119	124	137	146

Remark: The tolerance of the clearance date is ±10%

Main Structure:

Component	Housing	Dialysis membrane	Cover	O-ring	Sealant	Protective cap
Materials	Polycarbonate	PES membrane	Polycarbonate	Silicone Rubber	PU	Polypropylene

Declaration: all the main materials are non-toxic, meet the requirement of ISO10993



Symbol clarification:

	Single use	STERILE R	Sterilized using irradiation
LOT	Lot Number		Manufacturer
	Expired date		Do not use if package is damaged
	Caution		Temperature limitation
CE 0197	CE MARK	EC REP	EC Representative

Quality Assurance and Responsibility Limitation

- The manufacturer hereby guarantees that this dialyzer has been manufactured completely according to the standard of manufacturer, it complies with the manufacturing process specified in the standard, it complies with the manufacturing process specified in the standards ISO 8637.
- If the manufacturer receives any notices within 3 years since the date of sterilization, the defective dialyzer can be replaced according to the lot number printed on the package of the product.

- The manufacturer is free of responsibility on condition that: a) The dialyzer is lost in the place where the product is used; b)The dialyzer is directly or indirectly damaged artificially; c) The product failure results from the operation error of the user, carelessly reading and comprehending the correspond instruction and indication for use before using.
- The manufacture is responsible for quality of the product when it is firstly used only if the preparation and operation described in this instruction for use are implemented.

Manufacturer has been granted certificates of ISO13485

EC REP

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