Instruction for Use

(Advanced Smart Flux-Hollow Fiber Dialyzer)

Medica Middle East for Advanced Medical Industries

Manufactured / Sterilized by:

Medica Middle East for Advanced Medical Industries

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1-Intended Purpose :

Advanced Smart Flux Hollow Fiber Haemodialysers (Polyether Sulfone, Poly Sulfone) are used for patients with acute or chronic renal failure. Advanced Smart Flux Hemodialyzer series are intended to be used during Hemodiafiltration and hemodialysis sessions.

2-Warning :

- Do not use if package is damaged or if blood caps are not in place.
- Do not use for any other purposes than dialysis.
- If foaming, blood leakage, blood coagulation and haemolysis occur during the use of this product, take appropriate measures according to a physician's instructions.
- Do not reuse this device. It is a single use
- The use of blood and dialysate port connectors (female) attached to blood and dialysate lines that are designed in compliance with ISO 8637-1 and ISO 8637-2 is recommended.

3-Caution:

- Medica Middle East for Advanced Medical Industries recommends use dialysis machine equipped with a volumetric ultrafiltration unit, an accurate UF control system and a precise weigh system for Hemodiafiltration.

Caution before use:

- follow machine manufacturer's instructions for the orientation of the device in the support
- Do not use if the package or if product is damaged..
- Use the device immediately after opening the device package
- Avoid air intake and contamination during rinsing and priming operations.
- Blood-side: Rinse with physiological saline (recommended 1,000 ml and 500ml of heparinized physiological saline, 2,000U/500ml) at a flow rate of 100ml/min.
- Perform a leak test to check the integrity of the bloodline and dialyzer.
- Start dialysis mode immediately after priming operation.

Caution in use:

- Continuously monitor the arterial and venous pressures in the bloodline and check for blood leakage during dialysis.
- Set TMP alarm (max. 500mmHg).

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- Monitor the patient's chemistry values using quantitative measurements and analysis to ensure that the expected therapy is delivered. The clinical parameters monitored should, at least, include: Urea, Hematocrit, and Serum albumin .

Caution after use:

- Dispose of the dialyzer immediately after use.
- Dispose of used bloodlines and dialyzer by suitable means as contaminated medical waste and according to any prevailing environmental regulations.

Caution for storage:

- Store at 5°C~35°C avoiding exposure to direct sunlight, severe vibration and keep dry.

4 -Heparinization :

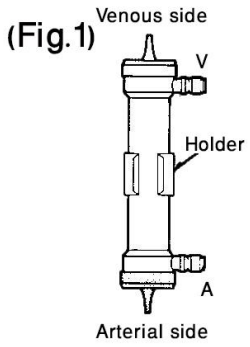
- It is recommended to systemically heparinize the patient by allowing the prescribed loading dose of heparin to circulate for 3 to 5 minutes before beginning extracorporeal circulation. During dialysis, the dosage of heparin and the mode of administration are the responsibility of the attending physician. The coagulation time should be checked regularly.

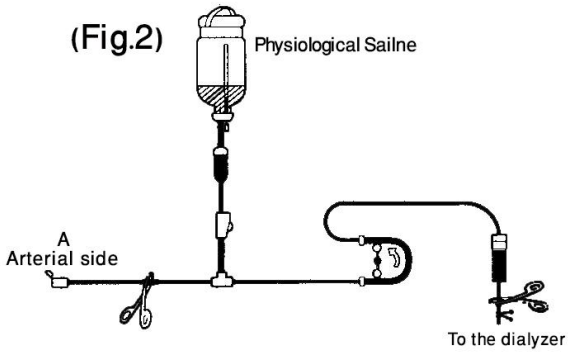
5 -Sterile / Non-pyrogenic:

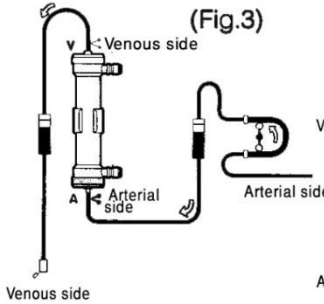
- The dialyzer blood pathway is sterile and non-pyrogenic if the blood port caps are in place and undamaged.
- Gamma sterilized.
- Do not use if the dialyzer is damaged in any way.
- Use aseptic technique for all blood side connections.
- Structural integrity of the hemodialyzer is warranted for the first use only when prepared as directed.

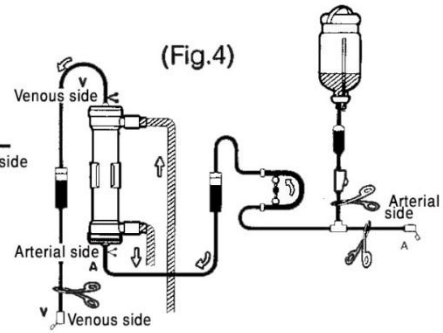
6-preparation for dialysis:

- Place the dialyzer in a vertical position, arterial end downward fig (1), follow the machine manufacturer's instructions for the orientation of the device
- Install the arterial and venous bloodlines on the hemodialysis machine
- Remove any dialyzer blood port 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 fig (2).









- Open the clamp on the IV set. Prime the arterial bloodline, dialyzer, and venous bloodline using a blood pump speed of approximately 150 mL/min. Discard the first 500 mL of solution. The drip chambers should be maintained about 3/4 full **fig (3)**.
- 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 the arterial and venous lines together in preparation for recirculation. Open the clamps on the bloodlines.
- Verify that the dialysate 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 dialysate lines to the dialyzer. Fill the dialysate compartment. In order to maximize the efficiency of the dialyzer, the dialysate flow must be countercurrent to the blood flow **fig (4)**.
- Rotate the dialyzer so that the arterial end is downward. Recirculate the blood side at a flow rate of 300- 400 mL/min and a dialysate flow of 500 mL/min for a

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minimum of ten to fifteen minutes and until all the air has been purged from the system before connecting to the patient. Continue recirculation and dialysate flow until patient connection.

- Ultra filter or flush an additional 500 cc of 0.9% sterile normal saline so that the extracorporeal circuit has been flushed with a minimum of 1 L of saline to minimize sterilization residues.
- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test for the absence of germicide residuals with a test intended for this application, according to the test manufacturer's instructions.
- Do not infuse the recirculated saline prime into the patient. Discard the recirculated saline and fill the entire extracorporeal circuit with fresh saline prior to connecting to the patient. The volume of fresh saline used to fill the extracorporeal circuit should be equal to the volume of the dialyzer and blood tubing set in use

7- Initiation of dialysis:

- To initiate dialysis; stop the blood pump, clamp the dialysis priming set and the arterial and venous bloodlines.
- Aseptically attach the patient ends of the bloodlines to the patient's arterial and venous access. Open the arterial and venous bloodline clamps and the clamps on the patient access.
- Increase the blood pump speed slowly to the prescribed blood flow rate. Be sure to monitor the arterial and venous blood pressures carefully during this process to note any possible flow restrictions or inappropriate pressure readings.
- Once the prescribed blood flow rate has been achieved, set the prescribed ultrafiltration rate.

8- During 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 the extracorporeal circuit during dialysis is 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 the venous return line with an air detector is essential. Should air get into the venous line during treatment, the dialysis must be discontinued without returning any of the patient's blood that is mixed with air.

9-Termination of dialysis:

- Stop the blood pump, clamp the arterial line and remove the line from the arterial blood access site; then connect the line to the physiological saline vial for blood recovery.
- Unclamp the arterial line and run 100~200ml of physiological saline at a flow rate of about 100ml/min to expel blood from the arterial and venous lines and the dialyzer.
- After blood recovery, discard the arterial and venous lines and the dialyzer.

10-Indications:

- Dialysis of patients with Acute or chronic renal failure.
- Target group: patients suffer from acute or chronic renal failure.

11- Side Effects:

- Adverse reactions such as hypertension, hypotension, headache, and nausea may be associated with hypervolemia or hypervolemia and can usually be avoided with careful management of patient fluid, electrolyte balance, blood flow rate, and ultra-filtration rate.
- In rare cases, thrombocytopenia or hypersensitivity reactions including anaphylactic or anaphylactoid reactions to the dialyzer, or other elements in the extracorporeal circuit, may occur during hemodialysis. Hypersensitivity reactions may cause mild to severe signs and symptoms, including: itching, flushing, hives, swelling, fever, leukopenia, hypotension, shortness, of breath with wheezing, arrhythmias, and/or respiratory arrest.
- Patients with a history of hypersensitivity reactions or patient who have a history of being highly sensitive and allergic to a variety of substances should be carefully monitored during treatment. With severe hypersensitivity reactions, dialysis must be discontinued and aggressive first line therapy for hypersensitivity reactions must be initiated. The decision to return the patient's blood in the event of a hypersensitivity reaction is determined by the physician.

12-Contraindications:

- Specific contraindication for the dialyzer are unknown, generally, the contraindications for hemodialysis are applicable. The dialyzer should only be used as directed by a physician.
- Avoid use of Hemodialyzer made of Polyethersulfone or polysulfone membrane in patients with known hypersensitivity.
- Not recommended for paediatric use
- Do not use on non-de-aerated dialysis fluid delivery systems

13-Guarantee:

- Medica Middle East for Advanced Medical Industries strict quality control and the quality is assured. If the Hemodialyzer is defective (broken package, damaged Hemodialyzer), however, it shall be replaced with a new one at our cost upon return of the broken package or damaged dialyzer. We will not be responsible, however, for the injury on a patient or any person or the damage to any object that is attributed to transport, storage and operation in your institution.
- Information about performance data and test methods used to obtain performance characteristics is available upon request, and you can find performance data on website

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- We do not guarantee the device performance if the device used at the below certain flow rates, below a certain pressure or in particular orientation
- In-vitro results of performance data are likely to differ from in-vivo results and the device performance might change with the duration of observation
- any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

14-General:

Generic name of the raw materials

PC	Polycarbonate	PE	Polyethylene
PES	Polyether Sulfone	O-ring	Poly-dimethyl silicane
PUR	Polyurethane system	PS	Poly Sulfone

EC REP	**Qualitech Internatonl B.V.**	
	Add.	**SIRIUSDREEF 17, 2132WT HOOFDDORP, The Netherlands**,
	Web	**http://www.qt-int.uk/**

List of Medical device covered by the EC Certificate:

Description		**Code**
Advanced Smart	POLY SULFONE Hollow Fiber Dialyzer (High Flux)	M10HPS TO M22HPS
	POLY SULFONE Hollow Fiber Dialyzer (Low Flux)	M10LPS TO M22LPS
	PUREMA Hollow Fiber Dialyzer (High Flux)	MPH01 TO MPH 22
	PUREMA Hollow Fiber Dialyzer (Low Flux)	MPL01 TO MPL 22

CE

2265

Symbols

MD	**Medical device**
	Caution
	Do not re-use
35°C 5°C	**Temperature limit**
LOT	**Batch code**
EG	**Date of manufacture / Country of Manufacture**
	Use-by date
STERILE R	**Sterile fluid pathway sterilized by gamma sterilization**
2 STERILIZE	**Do not re-sterilize**
	Non-pyrogenic
	Consult instructions for use
#	**Model Number**
	Do not use if package is damaged and consult instructions for use
	Manufacturer
EC REP	**Authorized representative in the European European Union/ Community**
	Single sterile barrier system
UDI	**Unique Device Identifier**
	Fragile, handle with care
	Keep away from sunlight
	Keep dry

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