

Instruction for Use

(Blood Line)



Medica Middle East for Advanced Medical Industries

Manufactured / Sterilized by:



Medica Middle East for Advanced Medical Industries

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	<h2>Blood Line</h2>	<h2>English</h2>
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A-Intended Purpose :

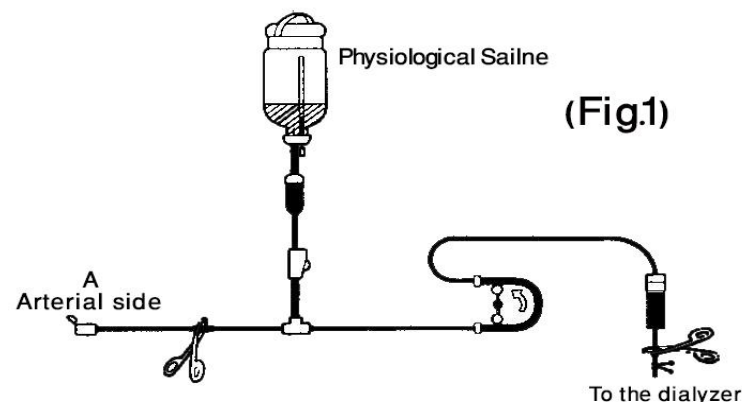
Blood lines intended to channel blood through external circuit for patients suffering from acute or chronic renal failure and in ultra-filtration.

B. Procedure

- (1) Insert pump segment inside its cavity in the hemodialysis machine.
- (2) Connect dialyzer connector of venous blood tubing to the blood outlet access port of Hemodialyzer.
- (3) Connect dialyzer connector of arterial blood tubing to the blood inlet access port of Hemodialyzer.
- (4) Ensure venous and arterial clamps remain open during dialysis session.
- (5) Put venous chamber in the proper place of hemodialysis machine.
- (6) Put heparin infusion set at proper place in hemodialysis machine and adjust the rate according to patient requirements.
- (7) Ensure air detector monitor alarm in hemodialysis machine is well functioned.
- (8) Ensure venous chamber is 2/3 of its volume to inhibit bubbles formation.
- (9) Close clamps, if needed.

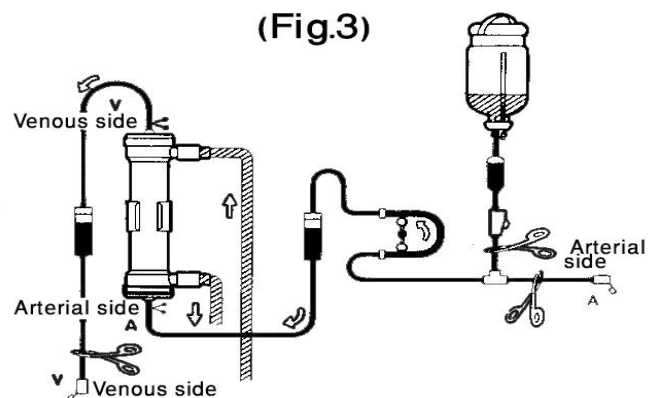
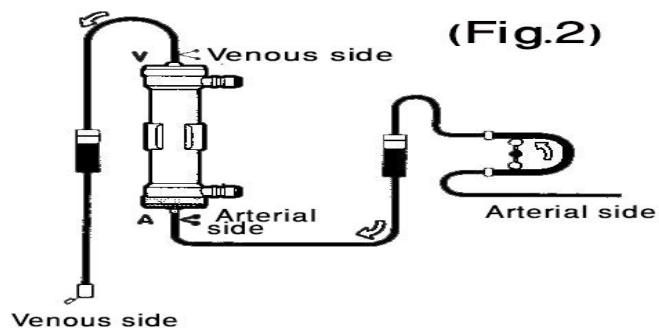
C. Rinsing and air removal

- (1) Unpack Blood Tubing Set.
- (2) Connect the arterial line to the physiological saline vial (Fig.1).
- (3) Connect the arterial and venous line to the dialyzer and remove air completely by running physiological saline (recommended volume 1000 ml) at a flow rate of about 100 ml/min(fig.2).



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D. Priming

Following rinsing and air removal, run about 500ml of physiological saline (eventually heparinized, 2000U/500ml) through the arterial line at a flow rate of about 100ml/min; then clamp the necessary sites on the arterial and venous lines. Complete all connections for dialysis (Fig.3).

E. Leakage test

- (1) Prime the arterial and venous line completely with physiological saline by operating the blood pump; then stop the pump operation.
- (2) Clamp the arterial line near the dialyzer and the distal end of the venous line with forceps.
- (3) Place the clamped distal end about 1mm below the dialyzer and remove the forceps. This results in application of a negative pressure of about 70mmHg to the blood compartment of the dialyzer.
- (4) Examine for any or no continuous stream of bubbles in the venous header to check for leakage from the Blood Tubing Set. If observed, replace the Blood Tubing Set with a new one.

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F. Start of dialysis

- (1) Prepare the blood access site and connect to the arterial line. Remove the forceps from the arterial and venous lines. While running dialysate at a flow of about 500ml/min, operate the blood pump at a flow rate of about 50ml/min.
- (2) Confirm that no air bubbles remain in venous header or venous blood line.
- (3) Fully prime the arterial and venous lines including the dialyzer with blood by operating the blood pump, and then stop the pump operation. Clamp the distal end of the venous line with forceps.
- (4) Prepare the blood return site and connect to the venous line. After confirming that there are no bubbles in the line, remove the forceps from the line. After checking that there are no forceps on the lines and no line folding, operate the blood pump at a low flow rate. Take care not to apply excessive pressure to the lines and the dialyzer to avoid leakage from the dialyzer and separation of each of the connections.
- (5) After confirming that there are no bubbles in the arterial and venous headers, turn the dialyzer 180° to allow removal of bubbles from dialysate. If bubbles are detected in the venous header before the turning, run blood at a prescribed flow rate for 5~10minutes with the venous side kept upward.
- (6) Adjust the arterial drip chamber to about 1/3.
- (7) Adjust the venous drip chamber to about 2/3.

G. Dialysis treatment-end and blood recovery

- (1) 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.
- (2) Unclamp the arterial line and run 100~200ml of physiological saline at a flow rate of about 100ml/min to flush blood from the arterial and venous lines and the dialyzer.
- (3) After blood recovery, discard the arterial and venous lines and the dialyzer. Do not reuse them.

H. Indications

Blood Tubing Set is intended to facilitate channeling blood through external circuit outside the body when correctly installed to a Hollow Fiber Hemodialyzer, dialysate reservoir, and dialysis machine in patients suffering from acute or chronic renal failure hemodiafiltration.

I. Contraindication

Patients with sensitivity to ETO should not be exposed to Medica Middle East for Advanced medical industries blood tubing.

J. Warning

- (1) Do not use for any other purposes than dialysis and ultra-filtration procedures.

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- (2) If foaming, blood leakage, blood coagulation and haemolysis occur during the use of this product, take appropriate measures according to a physician's instructions.
- (3) Do not reuse the device.
- (4) If the patient exhibits any abnormal symptoms such as discomfort, pruritus, urticaria, asthmatic reaction, hypertension and/or arrhythmia during the use of this product, take appropriate measures according to a physician's instructions.
- (5) Medica Middle East for Advanced medical industries assumes no responsibility, for the use of the Blood Tubing Set with any device incompatible with this circuit.
- (6) The expiry date refers to undamaged and properly stored product.
- (7) Kinked tubing can lead to haemolysis
- (8) Pump segments can collapse partially at great prepump negative pressures or at reduced blood flow rates.
- (9) Safety has not been approved for treatment of children or treatment of pregnant or nursing women to use this device.
- (10) Don't start session without using heparin connection.

K. Caution

Medica Middle East for Advanced medical industries recommends use of a dialysis machine that is equipped with a volumetric ultrafiltration unit, an accurate UF control system and a precise weight system for hemodiafiltration.

• Caution before use

- a. Do not use if the package or if product is damaged.
- b. Avoid air intake and contamination during rinsing and priming operations.
- c. Check the seal of the connection made and the seal of the protection caps of the unused inlets.
- d. Check proper mounting of the pump tube and perform filling and rinsing of the Blood Tubing Set with a sterile pyrogen-free physiological solution.
- e. Adhere to these instructions for rinsing.

• Caution for storage

Store between (5°C–35°C) avoiding exposure to direct sunlight, severe vibration and keep dry.

L. Guarantee

Blood Tubing Set is manufactured under strict quality control and the quality is assured. If the Blood Tubing Set is defective (broken package, damaged product), however, it shall be replaced with a new one at our cost upon return of the broken package or damaged Blood Tubing Set. 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.

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M. Performance characteristics

• Generic name of the raw material:

PVC	Polyvinyl chloride
PE	Polyethylene
PP	Polypropylene

Qualitech Internatonl B.V.

EC	REP	Address
		SIRIUSDREEF 17, 2132WT HOOFDORP, The Netherlands,
		Web http://www.qt-int.uk/

List of Medical device covered by the EC Certificate:
















Description	Code
Blood Line Fresenius	MAVF01 to MAVF14 , MAVFU2 to MAVFU3
Blood Line Gambro	MAVG01 to MAVG14 , MAVG21 to MAVG30 , MAVGU5 to MAVGU6
Blood Line Bellco	MAVL01 to MAVL10 , MAVL21 to MAVL30
Blood Line B.Braun	MAVB05 to MAVB20



Symbols

	Medical device
	Caution
	Do not re-use
	Temperature limit
	Batch code

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	Date of manufacture / Country of Manufacture
	Use-by date
	ETO sterilization
	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
	Authorized representative in the European European Union/ Community
	Single sterile barrier system
	Unique Device Identifier
	Fragile, handle with care
	Keep away from sunlight
	Keep dry

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