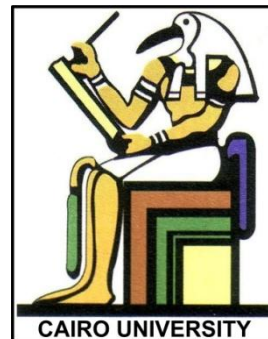


# Medical Equipment I - 2009

## Part II: Hemodialysis

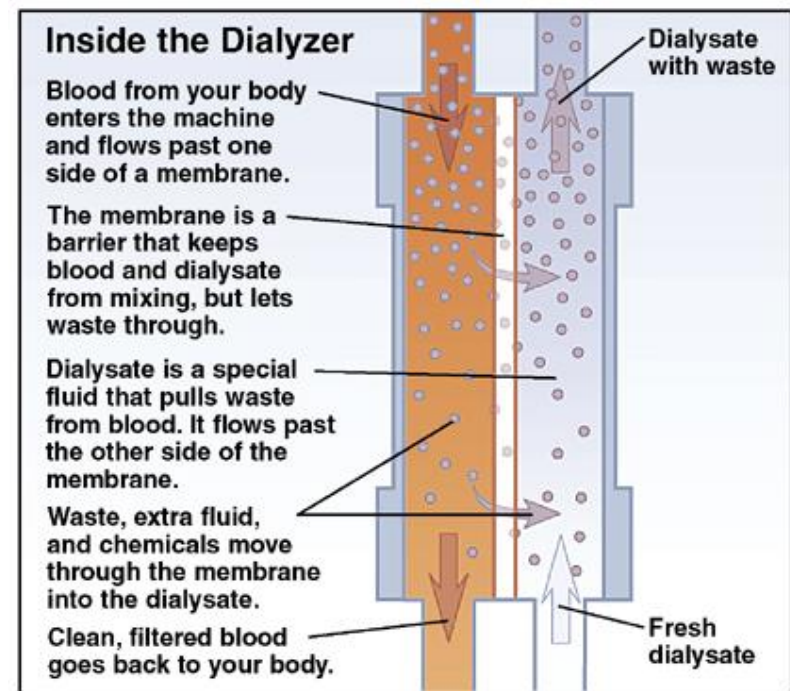
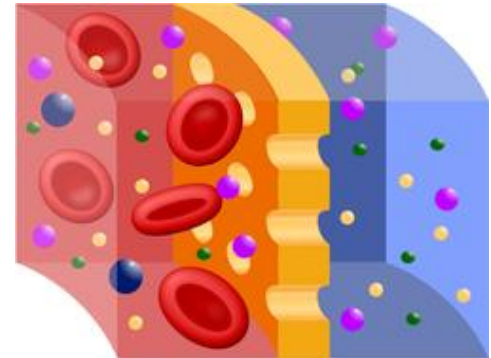
**Professor Yasser M. Kadah**

**Web: <http://ymk.k-space.org/courses.htm>**

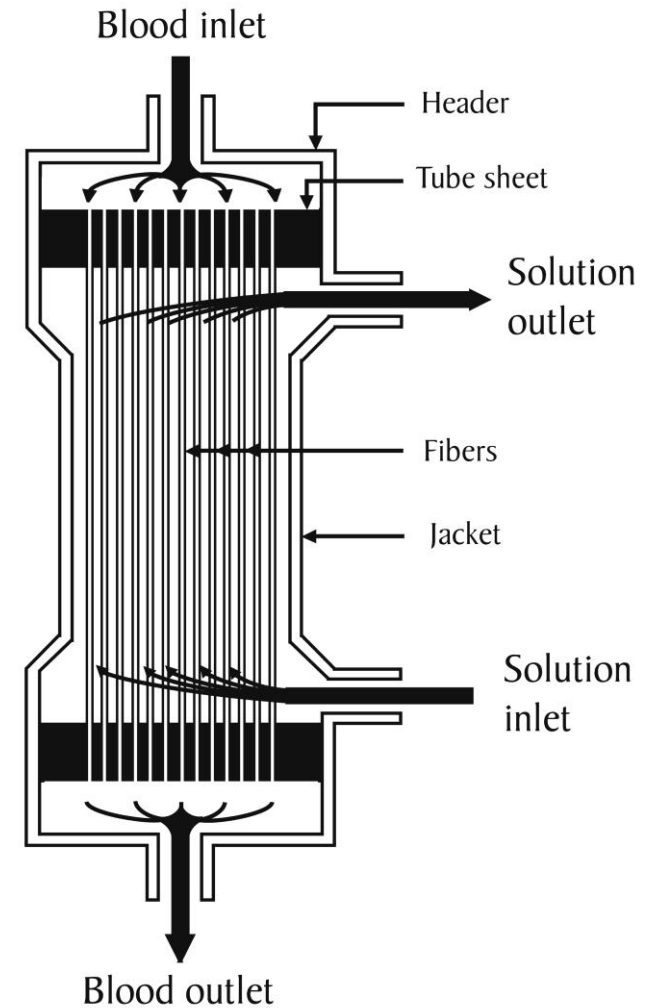


# Hemodialysis Operation

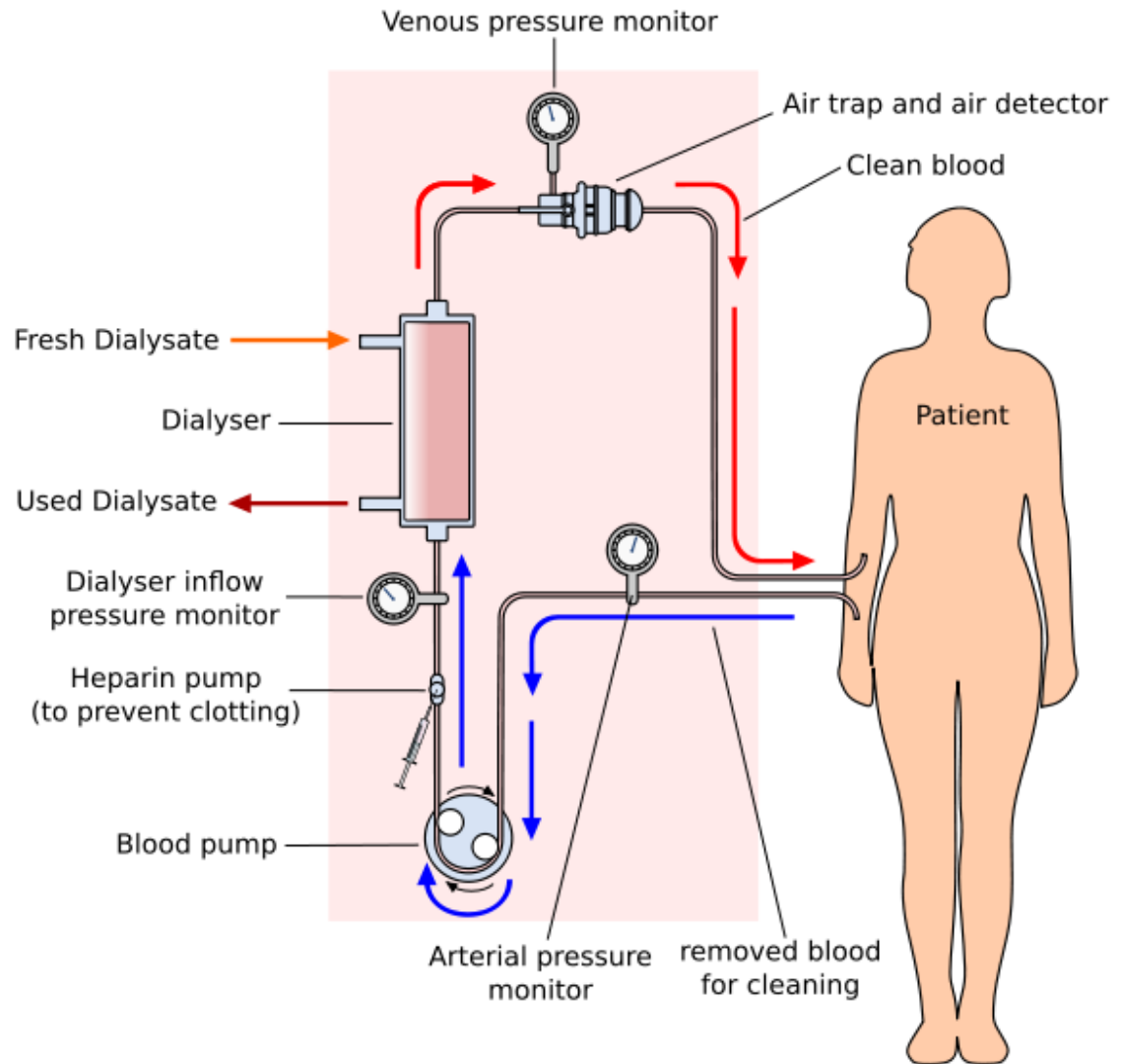
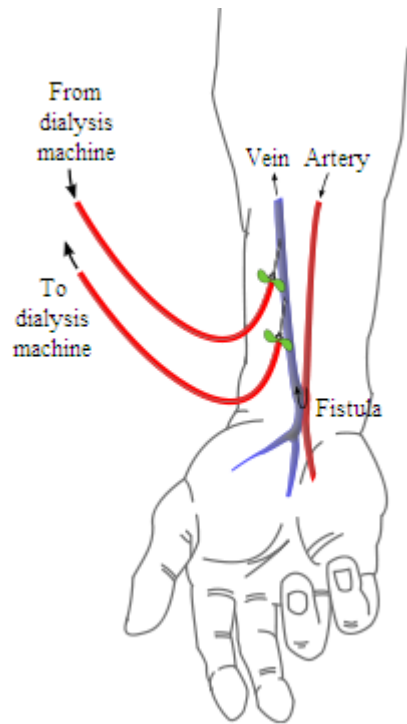
- Semi-permeable membrane
- Diffusion
  - Passive
  - Metabolite removal
- Ultrafiltration
  - Active
  - Water removal



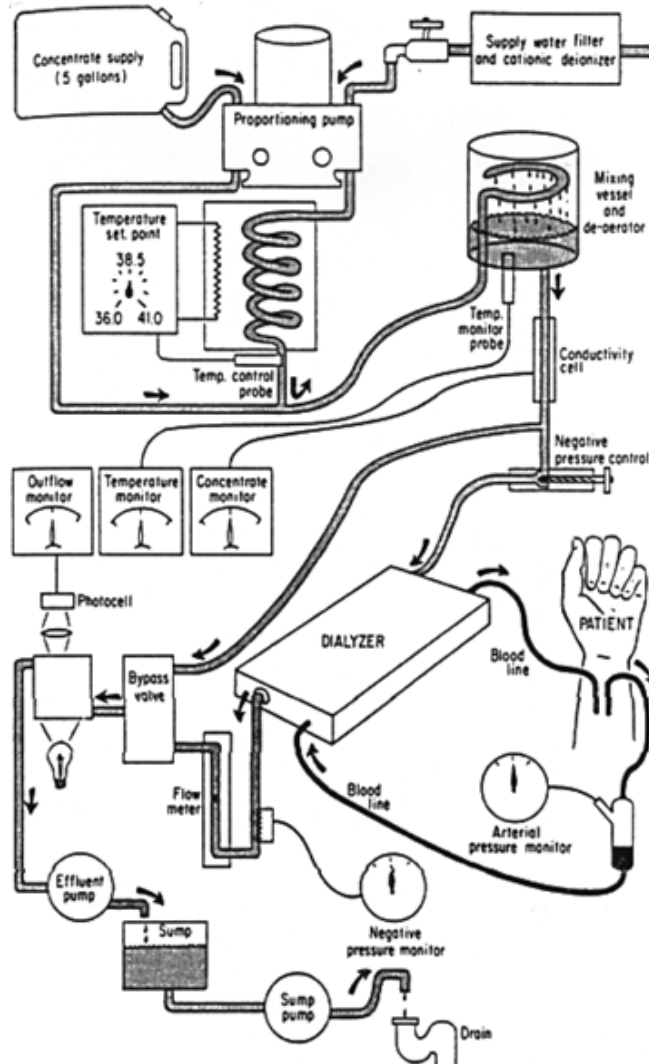
# [ Hollow Fiber Dialyzer ]



# Hemodialysis Block Diagram



# Hemodialysis System



# Standard Definitions

- 3.1 air detector:** Device (sensor) that detects air or foam in the extracorporeal circuit.
- 3.2 blood line, arterial:** Blood line leading from the patient to the hemodialyzer.
- 3.3 blood line, venous:** Blood line leading from the hemodialyzer to the patient.
- 3.4 batch system:** Apparatus in which the dialysate is prepared in bulk before each dialysis session.
- 3.5 dialysate:** Aqueous fluid containing electrolytes and usually dextrose, which is intended to exchange solutes with blood during hemodialysis. The word “dialysate” is used throughout this document to mean the fluid made from water (see normative reference 2.4) and concentrate(s) that is delivered to the dialyzer by the dialysate supply system. It does not include peritoneal dialysate. Such phrases as “dialyzing fluid” or “dialysis solution” may be used in place of dialysate.
- 3.6 dialysate supply system:** Devices that prepare dialysate online from water and dialysis concentrate(s) or store and distribute premixed dialysate; circulate the dialysate through the dialyzer; monitor the dialysate for temperature, conductivity (or equivalent), pressure, flow, and blood leaks; and prevent dialysis during disinfection or cleaning modes. The term includes reservoirs, conduits, proportioning devices for the dialysate, and monitors and associated alarms and controls assembled as a system for the characteristics listed above. The dialysate supply system is often an integral part of single-patient dialysis machines (see normative reference 2.6).
- 3.7 dialysis concentrate:** Fluid containing high concentrations of electrolytes. It is intended to be diluted with purified water to form dialysate. Dialysis concentrate comes in various formulations and concentrations (dilution ratios). It comes in liquid form or can be mixed at the point of use from powder or cartridges containing powder (see normative reference 2.3). It is referred to as “concentrate” throughout this document.



# [ Standard Definitions ]

**3.8 transmembrane pressure:** As related to the dialysis machine, transmembrane pressure is the pressure difference between the blood compartment and dialysate compartment of the dialyzer. In some dialysis machines, the transmembrane pressure (TMP) is approximated as the difference between the pressure measured at the outlet of the blood compartment ( $P_{bo}$ ) and outlet of the dialysate compartment ( $P_{do}$ ), or  $TMP = P_{bo} - P_{do}$ .

**3.9 labeling:** Any written material accompanying the hemodialysis machine or instructions or control feature markings attached to the machine.

**3.10 manufacturer:** Entity that designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and foreign distributors performing these functions.

**3.11 proportioning system:** Apparatus that proportions water and dialysate concentrate(s) to prepare dialysate.

**3.12 user:** Physician (medical director) or his or her representative (i.e., the clinical team responsible for installing, using, or repairing the equipment).

# [ Standard Monitors ]

## ■ Temperature

- System shall maintain the temperature of the dialysate between 33 °C and 40 °C and within  $\pm 1$  °C of its set point value.
- No single fault of the temperature control and monitor system shall allow dialysis when the dialysate temperature is above 42 °C.



# [ Standard Monitors ]

- Transmembrane pressure monitor
  - function with an accuracy of  $\pm 20$  mmHg or 10 %, whichever is greater.
- Ultrafiltration control system
  - function with an overall accuracy of  $\pm 5$  % of the selected ultrafiltration rate or  $\pm 100$  mL/h, whichever is greater.

# Standard Monitors

- Blood circuit pressure monitor
  - accuracy of  $\pm 20$  mmHg (2.66 kPa) or  $\pm 10$  % of reading, whichever is greater.
- Conductivity monitor
  - No single fault shall allow dialysis when dialysate conductivity varies more than  $\pm 5$  % from its nominal value without activating an alarm.

# [ Standard Monitors ]

- Blood leak detector
  - High alarm limit for the blood leak rate shall be not more than 0.35 mL/minute of blood loss for a fixed alarm limit and not more than 0.45 mL/minute of blood loss for a variable alarm limit at a hematocrit of 25 % (.25) and over the range of specified dialysate flow rates.

# [ Standard Monitors ]

- Blood Circuit Air bubble detection
  - The system should detect an individual bolus of air larger than 1 mL, at operating pressure, or the presence of a series of microbubbles that occur within a short period of time and total more than 1.5 mL/30 s.
  - The system shall include a clamp that is capable of occluding the venous return line.

# Standard Alarms

Condition	Equipment response	Document reference
1) Dialysate temperature (above 42 °C)	Audible and visual alarms; interrupt delivery of dialysate to hemodialyzer; stop blood flow in the extracorporeal circuit	4.2.4.2
2) Transmembrane pressure	Audible and visual alarms; minimize ultrafiltration	4.2.4.3
3) Blood circuit pressure (high or low)	Audible and visual alarms; shut off blood pump; clamp venous return line or otherwise prevent air from reaching the patient; minimize ultrafiltration	4.2.4.5
4) High or low dialysate conductivity	Audible and visual alarms; interrupt delivery of dialysate to hemodialyzer and/or stop blood flow in the extracorporeal circuit	4.2.4.6 (Not applicable to batch systems)
5) Blood leak	Audible and visual alarms; shut off blood pump; minimize ultrafiltration	4.2.4.7

# [ Standard Alarms ]

Condition	Equipment response	Document reference
6) Blood circuit air protection	Audible and visual alarms (for alarm conditions or when monitor has not been activated and patient is connected to the dialysis machine); turn off blood pump to prevent air in venous bloodline from reaching patient (alarm condition only, to prevent pressure in the blood circuit from forcing air toward the patient); minimize ultrafiltration	4.2.4.8
7) Disinfection protection	Visual alarm; prevent dialysis of patient	4.2.4.9
8) Ultrafiltration control/monitor	If monitored, audible and visual alarms should be included indicating nature of malfunction	4.2.4.4
9) Power failure	Audible alarm	4.4.2(5)

# Selection of Components

- Challenging material problem because of corrosive dialysate
- Valves
- Dialysate Pumps
  - Proportioning pump
  - Flow pump
- Blood line



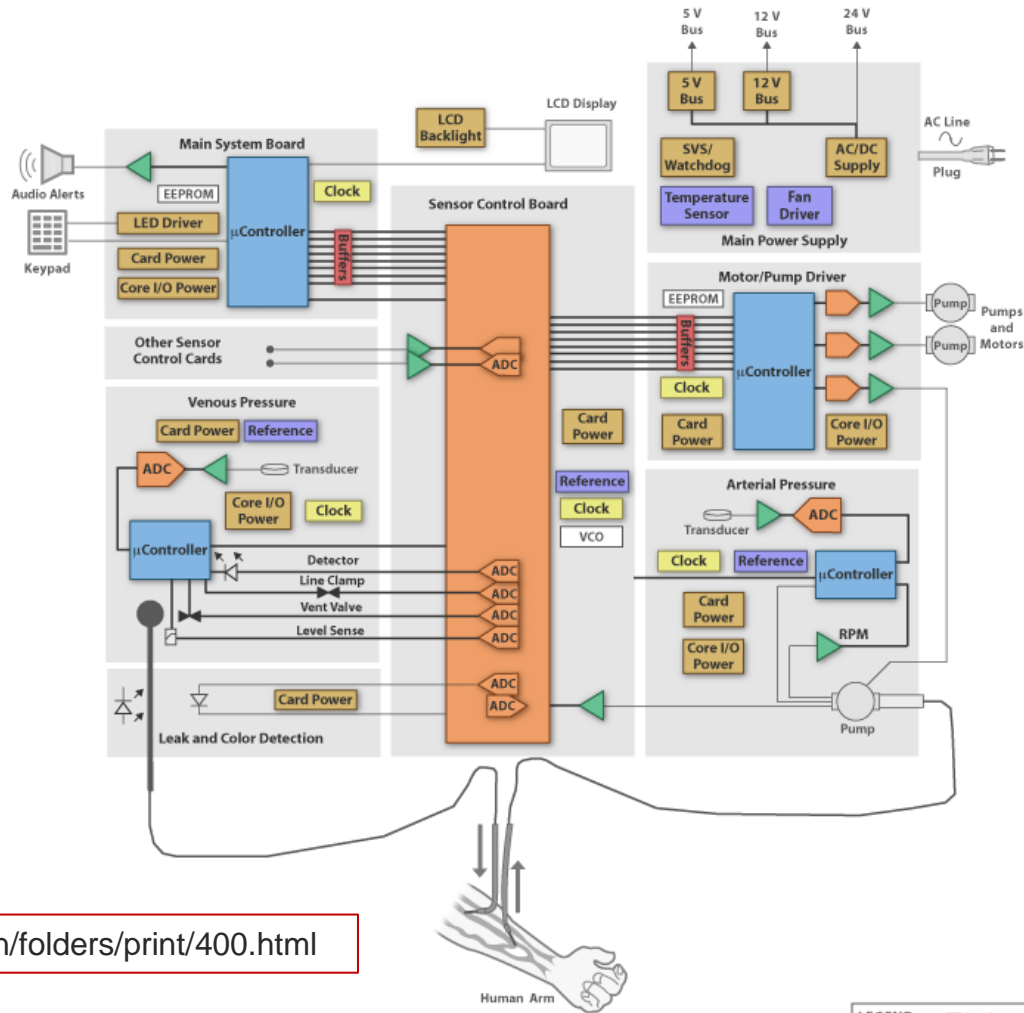


# [ Blood pump ]

- Peristaltic pump type
  - Minimize cross-contamination
  - Minimize destruction of cells



# Design Resources: TI



<http://focus.ti.com/docs/solution/folders/print/400.html>

Product Availability and Design Disclaimer - The system block diagram depicted above and the devices recommended are designed in this manner as a reference. Please contact your local TI sales office or distributor for system design specifics and product availability.

LEGEND	
	Processor
	Power
	Interface
	RF/IF
	Amplifier
	Logic
	ADC/DAC
	Clocks
	Other

# [ Presentation Download ]

- Posted on class web site
- References also posted there
- You are required to study only what was given in the lecture

Web: <http://ymk.k-space.org/courses.htm>