Beeps, Buzzers and Alarms
The Hemodialysis machine

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The systems Approach

- The HD machine **cannot be isolated** from the rest
- It is a part of an assembly
  - **The HD machine**
  - The extracorporeal circuit
  - The dialyzer
  - The water treatment system
  - Dialysate concentrate supply
  - The data network

Polaschegg HD, Contrib Nephrol 2002.137;227-235

Is there an Ideal Hemodialysis Machine?

- The ‘ideal’ machine does not exist and will never exist
- The utilitarian philosopher’s ‘ideal’:
  - Achieve minimum dialysis dose
  - Achieve accuracy in controlled values
  - Achieve quality while controlling costs
- Machines are smarter in sensing/measuring/balancing
- User errors are common.

Polaschegg HD, Contrib Nephrol 2002.137;227-235

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Introducing MEDWatch

A New Approach to Reporting Medication and Device Adverse Effects and Product Problems

David A. Kessler, MD; Sharon Natanblut, MPA; Dianne Kennedy, MPH, RPh; Eliot Lazar, MD; Peter Rheinstein, MD, JD, MS; Chuck Anello, ScD; Dave Barash, RPh; Ilisa Bernstein, PharmD; Ross Bolger, RPh; Kay Cook, JD; Mary Pat Couig, RN, MPH; Jerry Donlon, MD, PhD; Joyce Johnson, DO, MA; Catherine Lorraine, JD; Tom McGinnis, RPh; John Nazario, RPh; Stuart Nightingale, MD; Carl Peck, MD; Mary Pendergast, JD; Suresh Rastogi, PhD; Chet Reynolds, MBA; Renie Schapiro, MPH; Linda Tollefson, DVM; Ann Wion, JD

JAMA. 1993;269(21):2765-2768. doi:10.1001/jama.1993.03500210065033.

Text Size: A A A

Machine malfunction is rare

Hemodialysis is prone to user errors

- Poor fixation of cannulas
- Incorrect setting of alarm limits and control values

Failure to follow Protocol is common

Event type	Number	% of total events, N=526
Medication error	150	28.5
Failure to follow protocol	68	12.9
Lab/Blood bank related	52	9.9
Procedure complication	45	8.6
Needle disconnection	32	6.1
Needle infiltration	32	6.1
Equipment failure	25	4.8
System Clotting	23	4.4

Pennsylvania Patient Safety Authority. 2010. 7(3);87-96

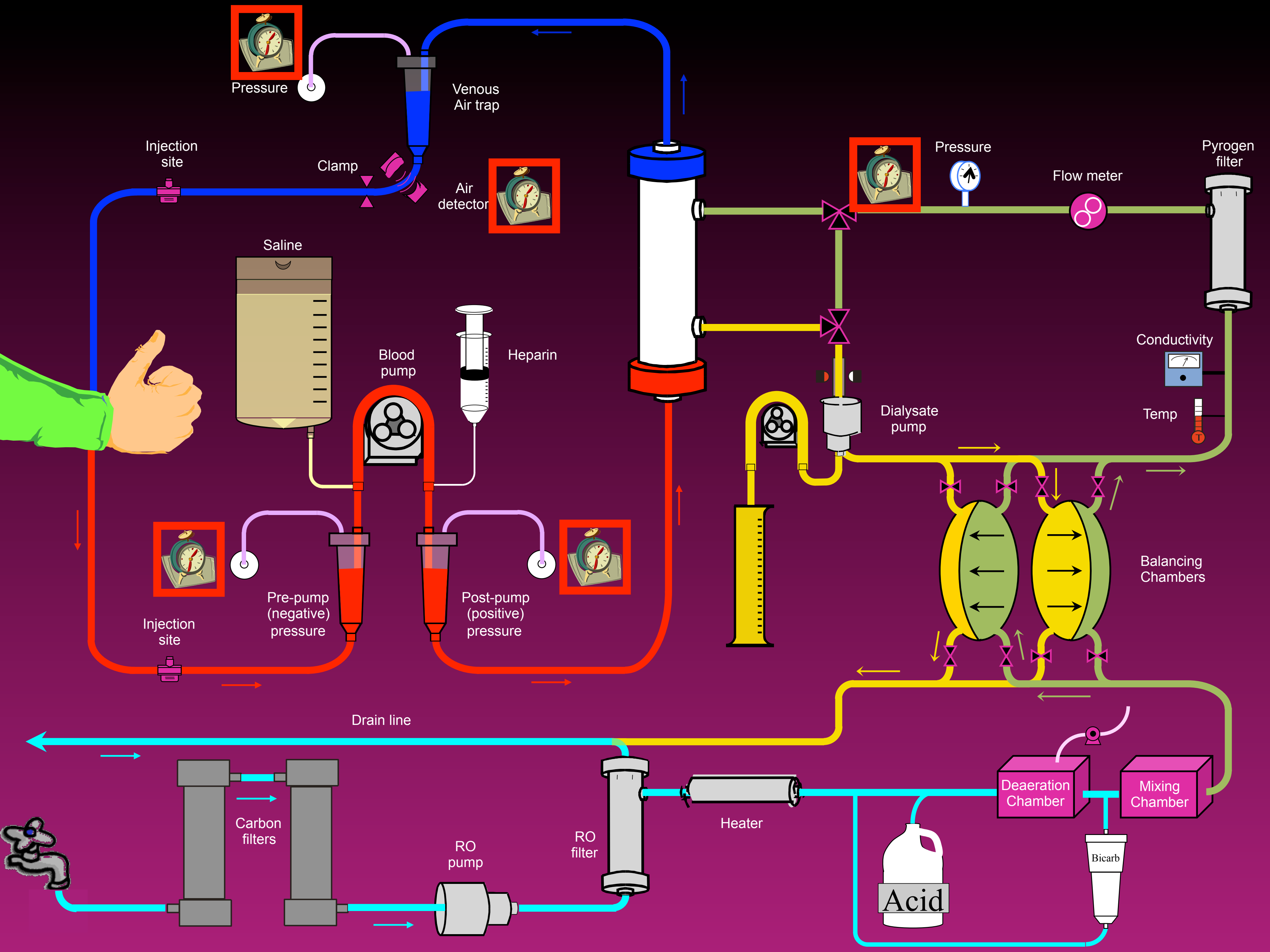
Fundamental Requirements of Hemodialysis Instruments

<u>Practical Aspects</u>

- Propel blood & dialysate
- Provide life sustaining “dose”
- Anticoagulation
- Maintain body temperature
- Prime, rinseback, and rapid hydration
- Add meds/draw blood

<u>Hazard Prevention</u>

- Blood loss to environment
- Hemolysis
- Air embolism
- Excessive or inadequate fluid removal
- Infection
- Acute or chronic toxicity
- Anaphylaxis

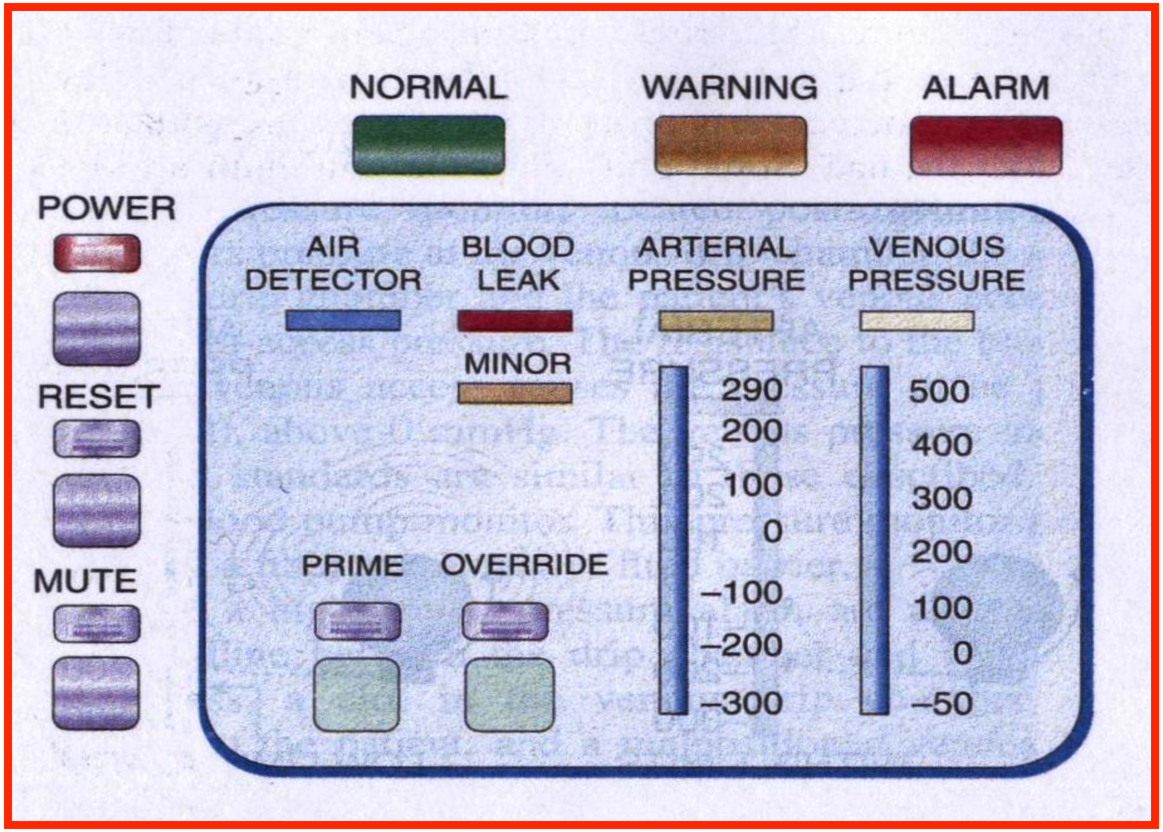

Pressure
Venous
Air trap
Injection
site
Clamp
Air
detector
Saline
Blood
pump
Heparin
Pressure
Flow meter
Pyrogen
filter
Conductivity
Dialysate
pump
Temp
Balancing
Chambers
Injection
site
Pre-pump
(negative)
pressure
Post-pump
(positive)
pressure
Drain line
Carbon
filters
RO
pump
RO
filter
Heater
Deaeration
Chamber
Mixing
Chamber
Bicarb
Acid

Beeps, Buzzers and Alarms

Blood Circuit ⇩	**Dialysate Circuit** ⇩
Inflow pressure	Conductivity
Outflow pressure	Temperature
Air Detector	Hemoglobin

Safety monitors

- Can not ‘prevent’ adverse events
- Can only ‘detect and mitigate’ the potential harm



Adapted from Handbook of Dialysis Therapy. Nissenson and Fine. 4th edition, Saunders Elsevier Pubs.

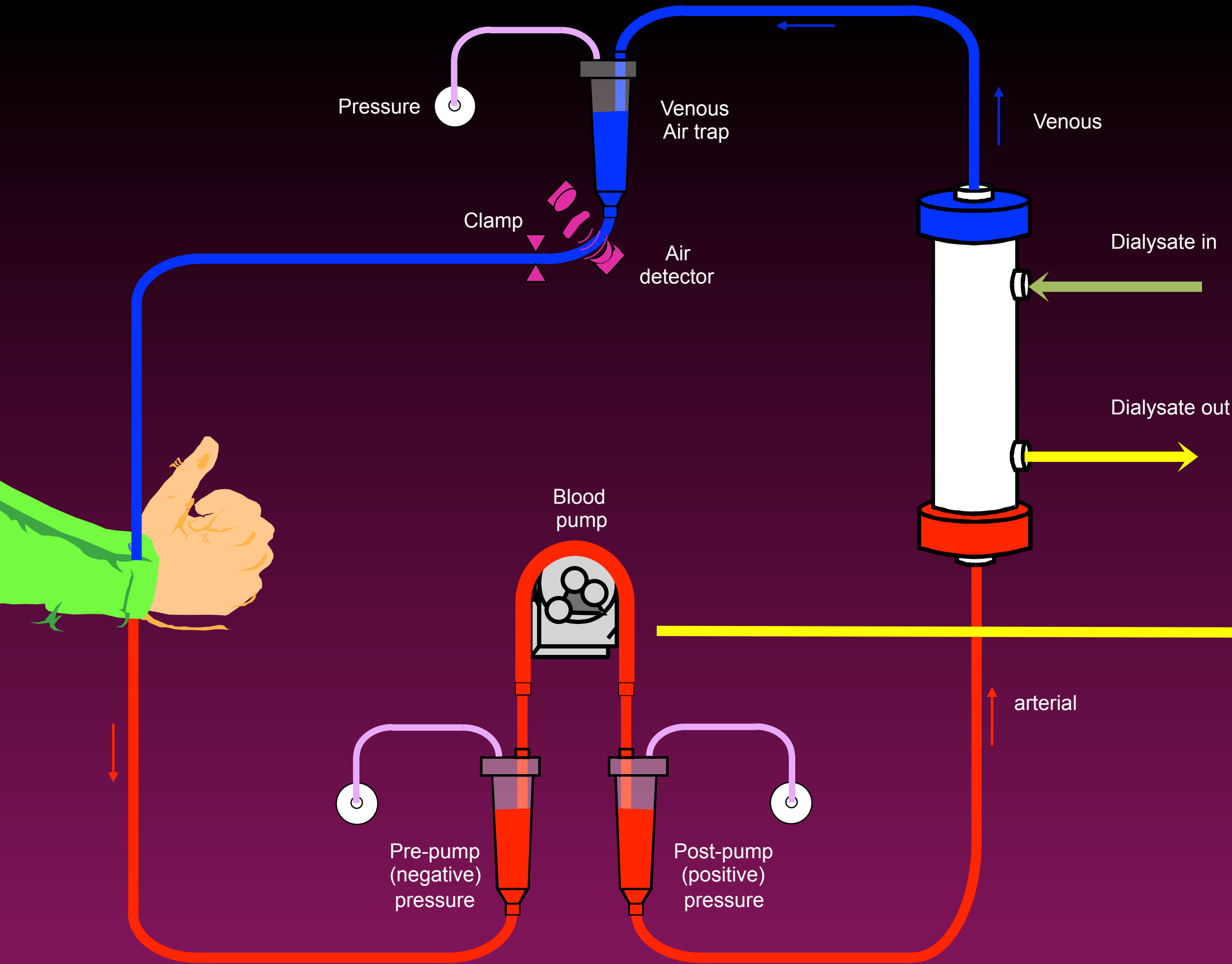
Know your machine!

No Alarm is Fail-Safe

- Alarms represent potential malfunction in the system
- NEVER alter alarm sensitivity and range
- Discourage Alarm disarming
- Alarms should be visible at minimum of 2 m and easily audible (70 dB)
- All blood alarms should isolate the patient
    - Shut off the blood pump
    - Clamp the venous return
    - Stop UF

Misra M. The basics of HD equipment. Hemodialysis International 2005; 9: 30–36

The blood side



Blood is pumped in the circuit @ 200-600 ml/min

The blood pump has 2 rollers compressing the tubing, forcing the blood along the tube

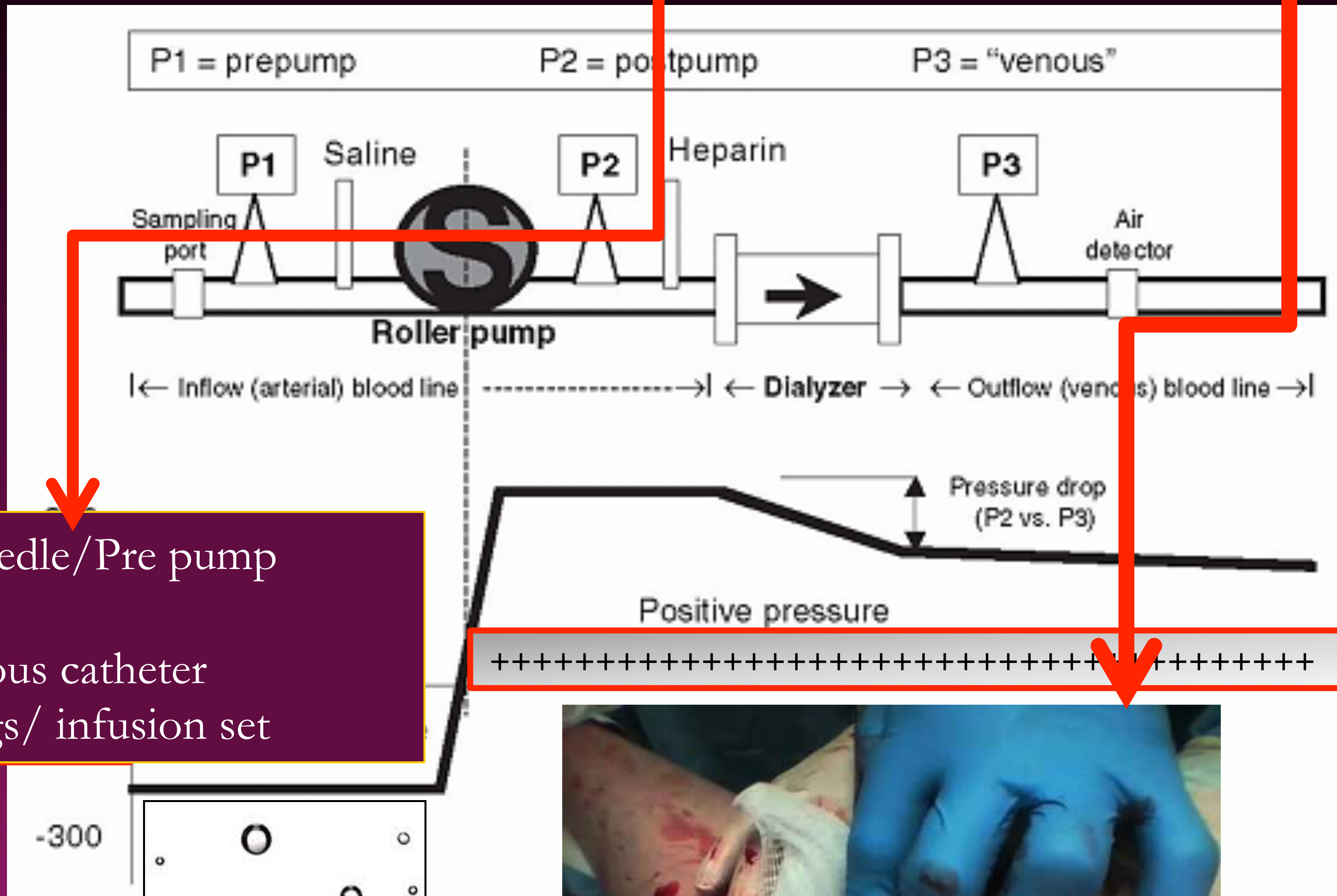
-adaptable to different sized tubing if required clinically

-can be operated manually in case of power loss

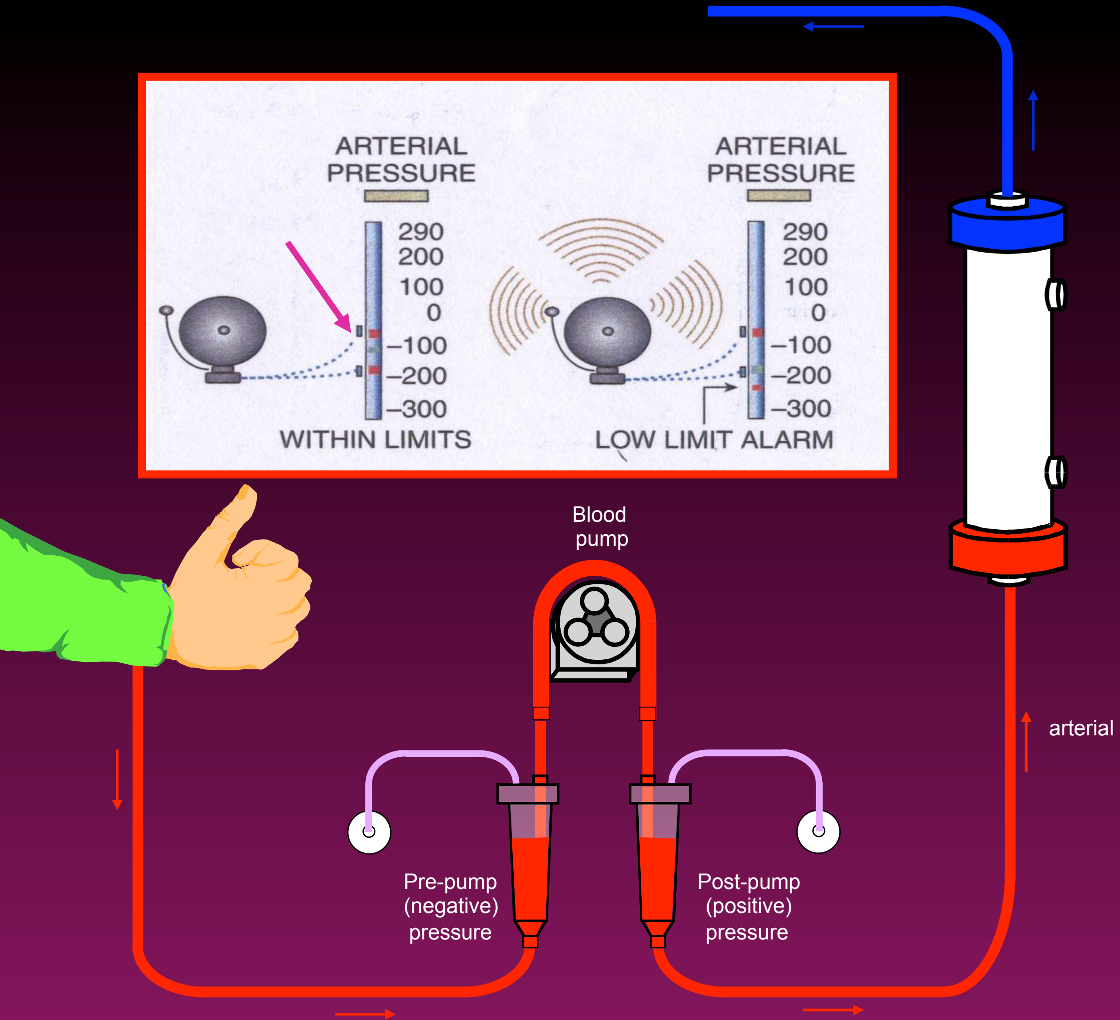
- calibrated to measure blood flow based on the internal diameter of the tubing

BFR= RPM x tubing volume (π.r(squared) x length)

Possible sites for Air entry and blood loss

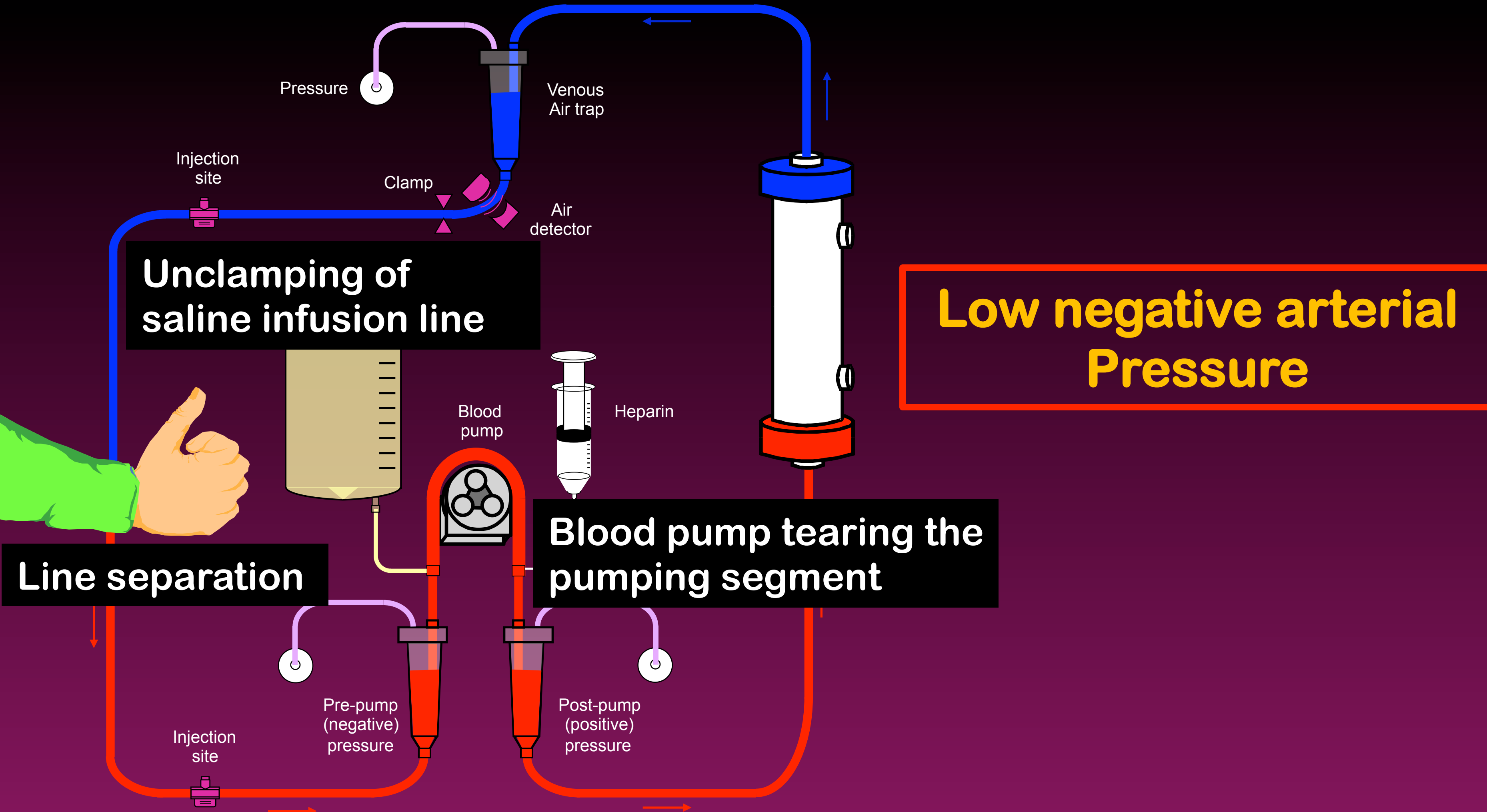


- Arterial needle/Pre pump tubing
- Open venous catheter
- Empty bags/ infusion set

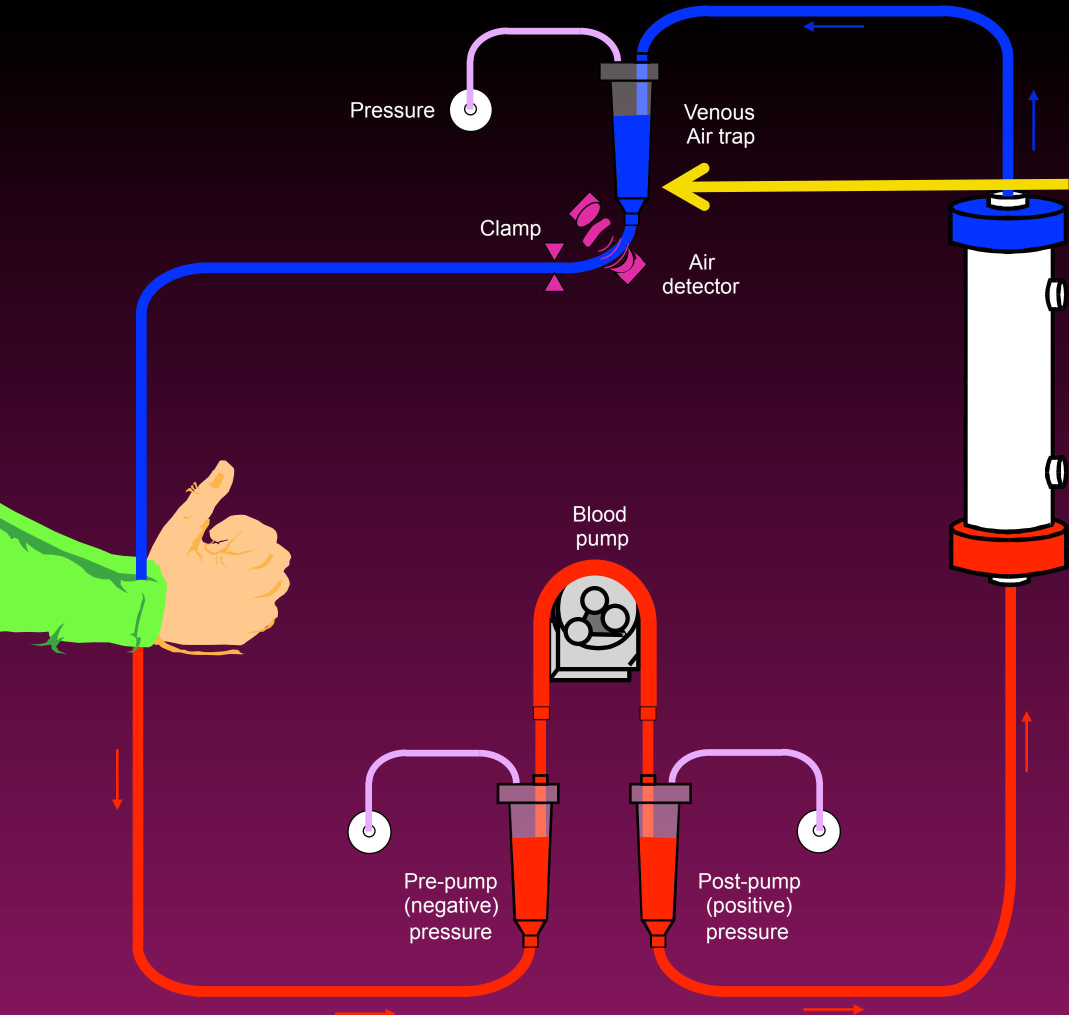


Excessively Negative Arterial pressure

- Low BP
- Catheter /needle malposition
- Kink/Clot
- Suction/spasm of vessel wall
- Stenosis in AVF
- Long small bore needles



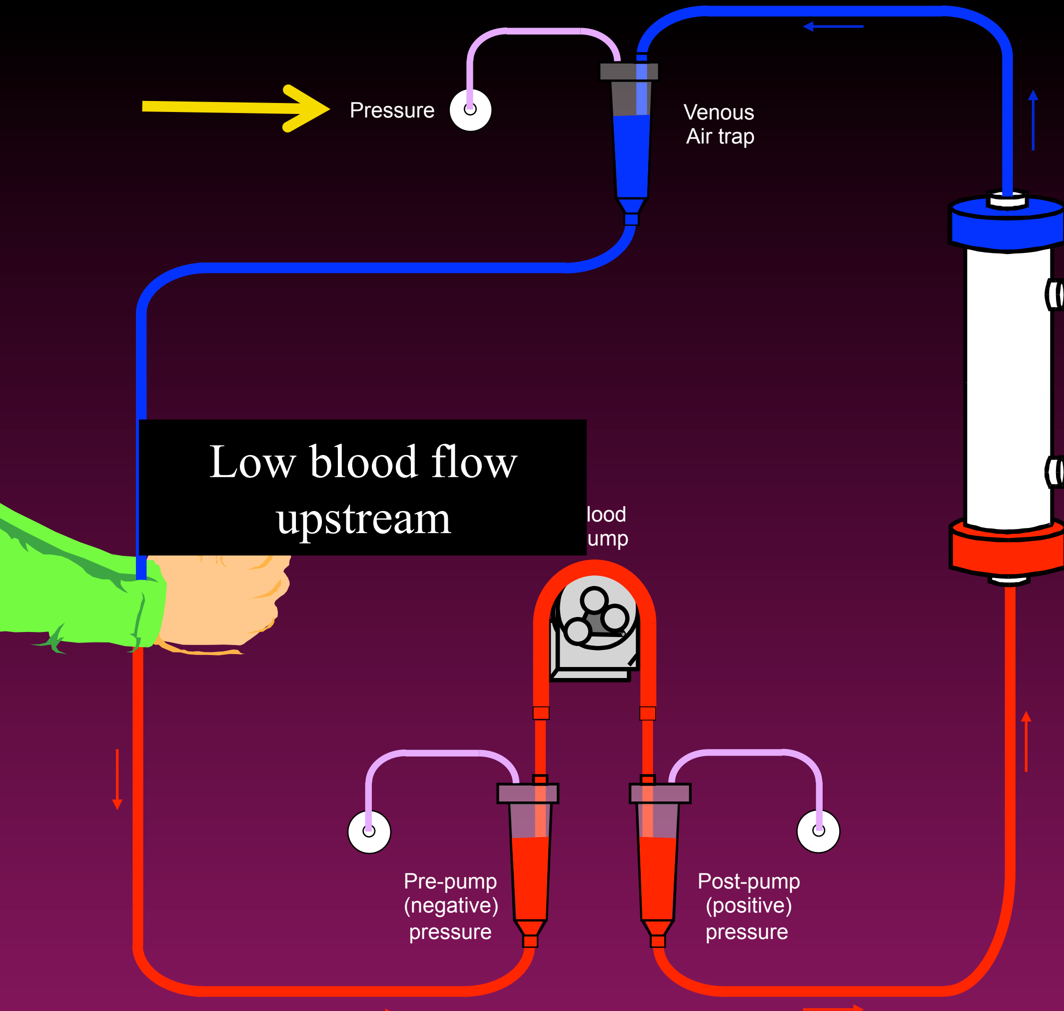
Pressure
Venous
Air trap
Injection
site
Clamp
Air
detector
Unclamping of
saline infusion line
Low negative arterial
Pressure
Blood
pump
Heparin
Blood pump tearing the
pumping segment
Line separation
Injection
site
Pre-pump
(negative)
pressure
Post-pump
(positive)
pressure



The Venous Chamber

1. Allows for determining Positive pressure on the blood access site

2. Allows for separation of air bubbles (*excessive air, when present, may still enter the patient*)



High venous pressure alarm

- High Qb, narrow needle
- Clot in the venous drip chamber, needle, venous limb
- Spasm of venous limb of AV access
- Kink in the venous return line
- Needle malposition

Low blood flow upstream

Disconnection downstream

Low venous pressure alarm

Question

- 2 hours into HD, a patient c/o feeling weak. He has been c/o cramps for last 2 weeks.
- BP is 110/70 mm Hg (initial BP 150/95 mm Hg). HR 75/min, regular. Qb 500 ml/min. Qd 800 ml/min.
- Nurse checks HD machine, turns UF off, reduces blood flow to 200 ml/min
- HD is resumed

What happened?
Venous Needle Dislodgement

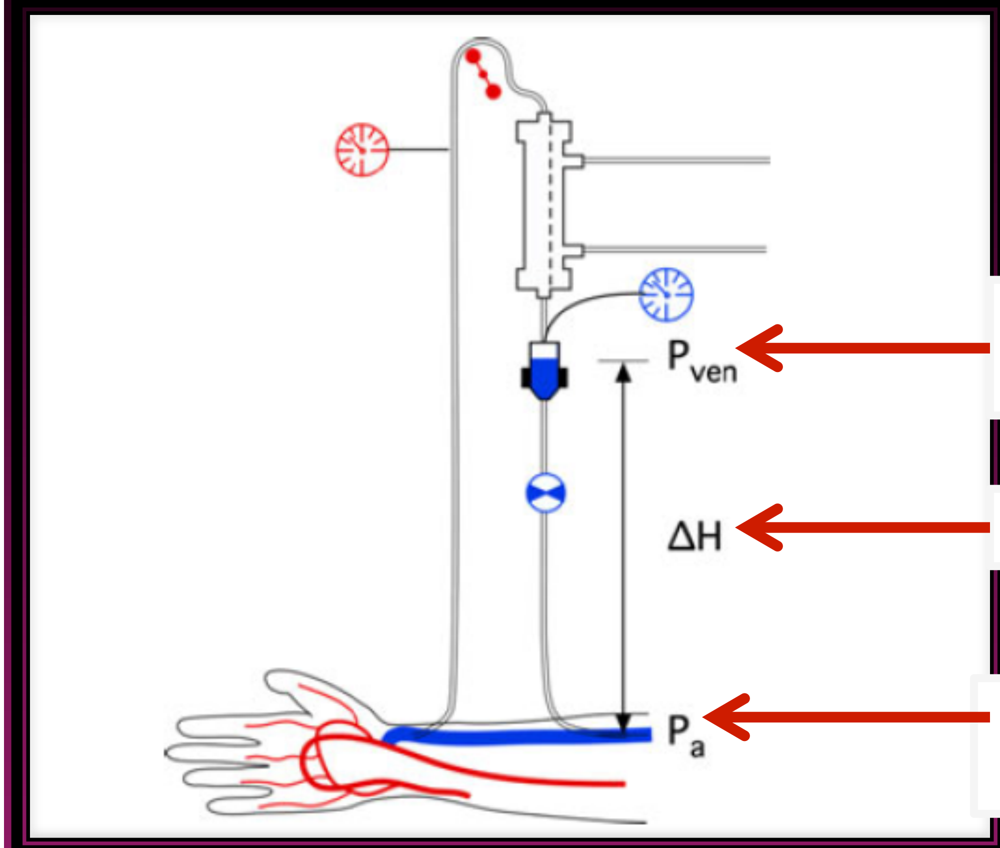
Why did the venous alarm not sound?

The venous pressure reading during HD is determined by

A. Intra access pressure
B. Needle/Cannula geometry
C. Blood flow rate and viscosity
D. All of the above

Venous monitor: Pressures and Heights

- The fistula pressure
- Qb, viscosity
- Flow resistance
- The height difference between AVF and the level in the venous chamber



Venous Pressure Monitor reading

Height difference

Intra-access pressure

Ribitsch W. et al Seminars in Dialysis 2013

In absence of blood flow

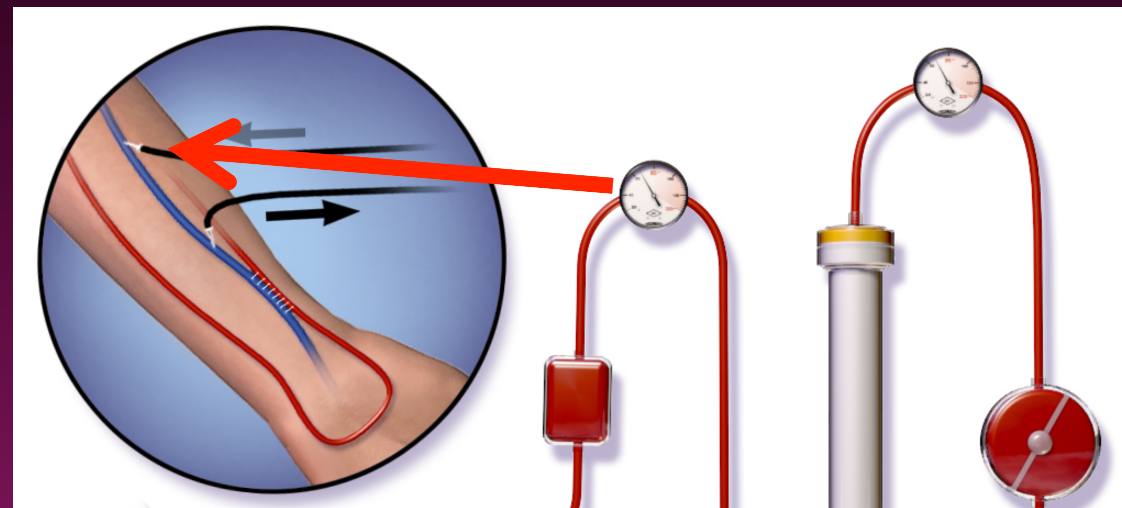
- Venous pressure reading = Intra access pressure
  - (when corrected for height difference between the access and the pressure monitor)

- When needle slips out from access but remains at the same height, the venous pressure will decrease by the amount of the access pressure

Needles may contribute significantly to venous pressure readings

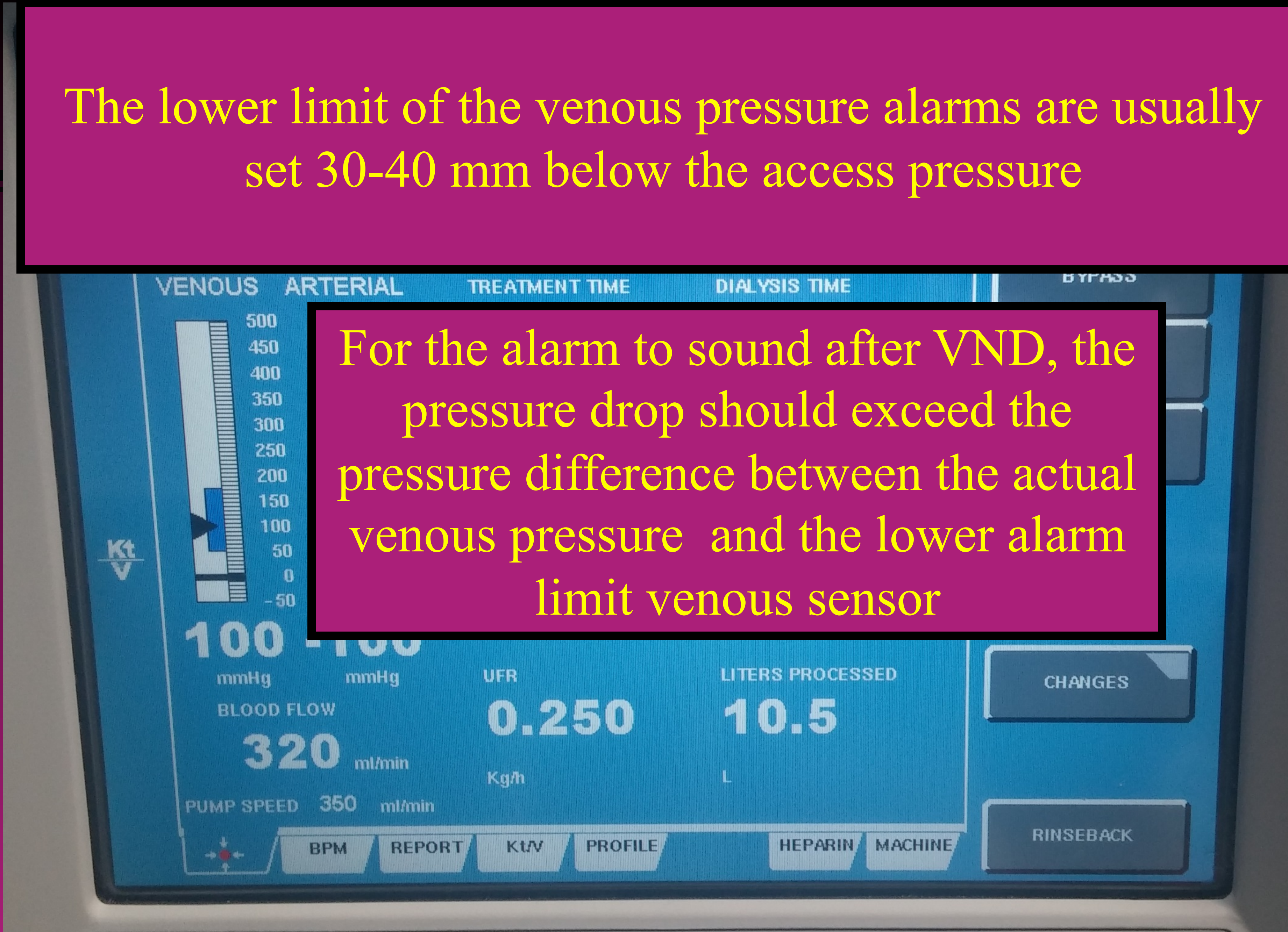
- ❑ Venous pressure

- Intra-access pressure
- Qb
- Needle length/gauge/ thickness
- Blood viscosity



With narrow gauge needles and high Qb, the relatively higher flow resistance within needle may prevent the venous pressure to fall low enough to set off the alarm

The lower limit of the venous pressure alarms are usually set 30-40 mm below the access pressure



For the alarm to sound after VND, the pressure drop should exceed the pressure difference between the actual venous pressure and the lower alarm limit venous sensor

Fistulae have much lower pressure than grafts

AVG 60 mm Hg ; AVF 32 mm Hg

Over 90% AVG have access pressures >40
Only 30% AVF have access pressures >40

It may be difficult to detect VND in AVFs

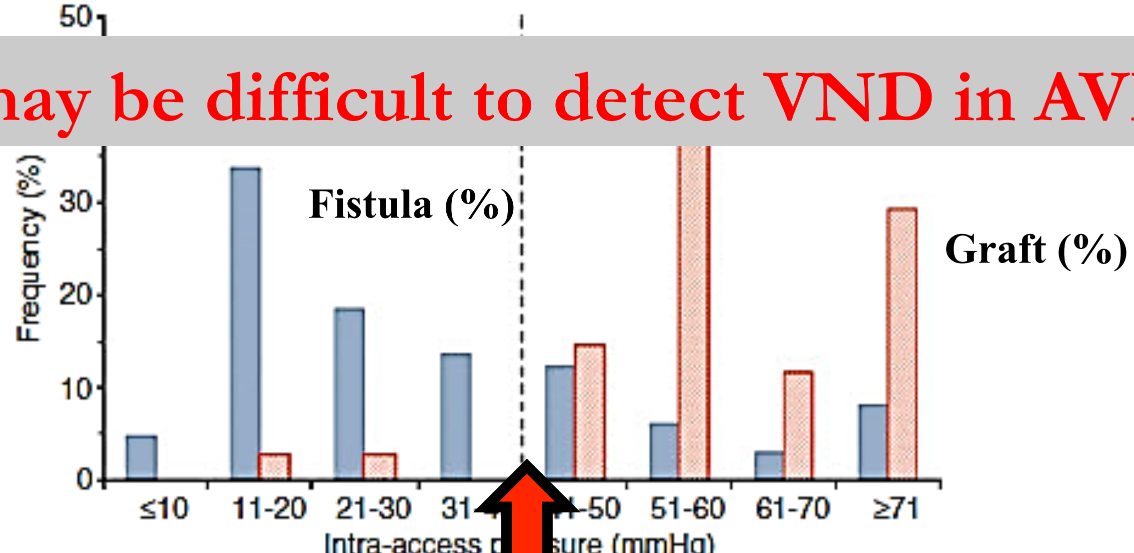


FIG. 2. Intra-access pressure (mmHg) in fistula … ates the lower detection limit of the venous sensor. VND: venous needle dislodgemen…

Ribitsch W. et al Seminars in Dialysis 2013

Risk factors associated with venous needle dislodgement

- ❑ Never set wide alarm windows for VP monitors
- ❑ Check access and tubing when alarms are reset
- ❑ Secure tubing connections and cannula position
- ❑ Avoid covering access sites

Loss of 15-20% of blood volume over half an hour will cause death of a person with impaired sympathetic reflexes. **Guyton AC. 1991**

In just 5-7 minutes a patient on HD can lose **40%** of blood Volume from a **Venous Needle dislodgement**

UK Renal unit Survey [Clinical Directors and Lead renal nurses]

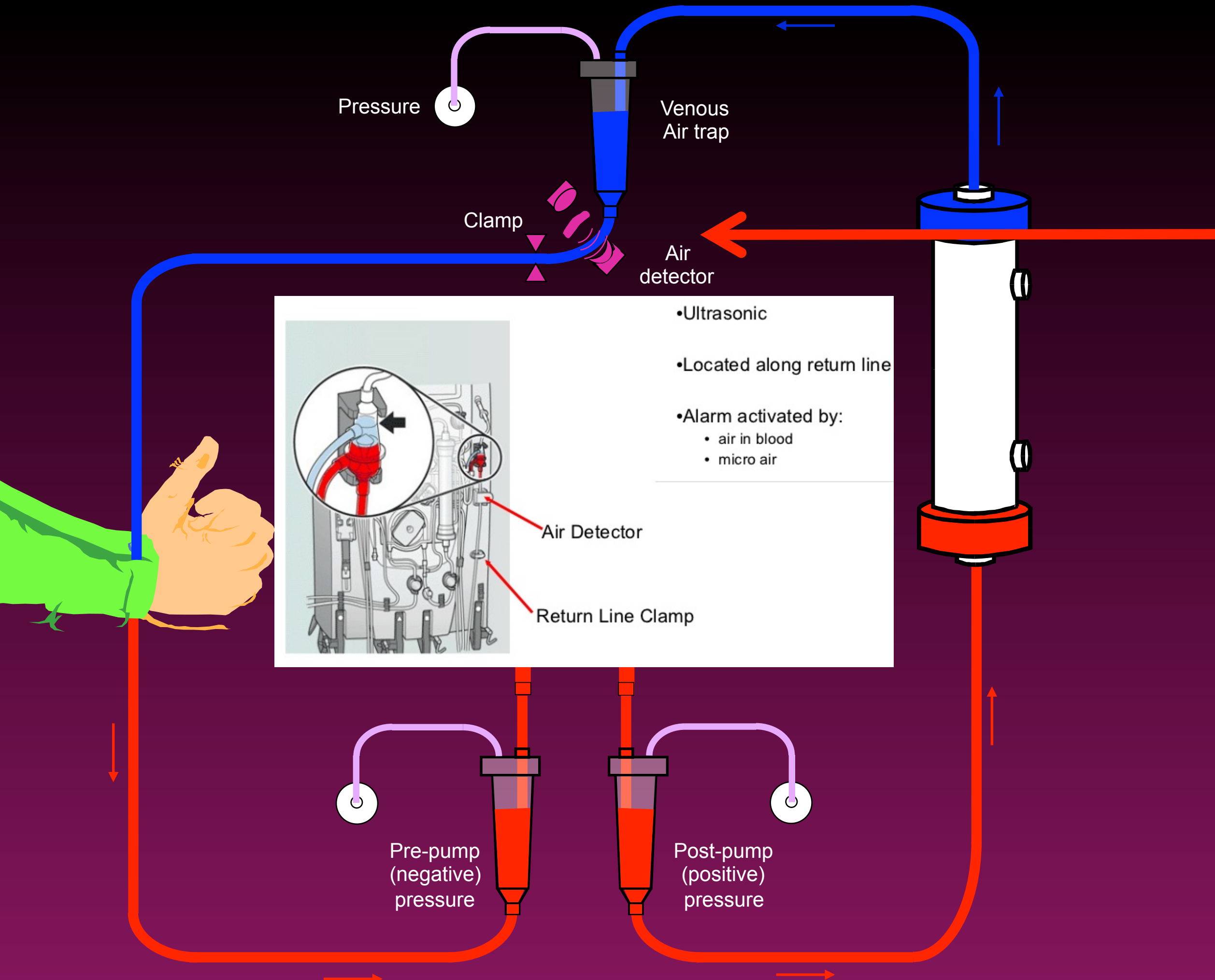
- Estimated prevalence/incidence of dislodgement
  - UK ~ 100/year (0-4 episodes/unit/year)
  - ~ **1/100,000 haemodialysis sessions**
- Severity
  - 1 death (0.6%)
  - 6.4% Moderate/Severe harm (e.g. hospitalization)
  - 93.0% No/Mild Harm

Many nurses and doctors are unaware of the limitations of venous alarms

Vascular Access Monitoring To Prevent Blood Leakage

Vascular access monitoring with blood sensor connected via Bluetooth to HD monitor

Gutter of drainage with blood sensor stopping blood pump



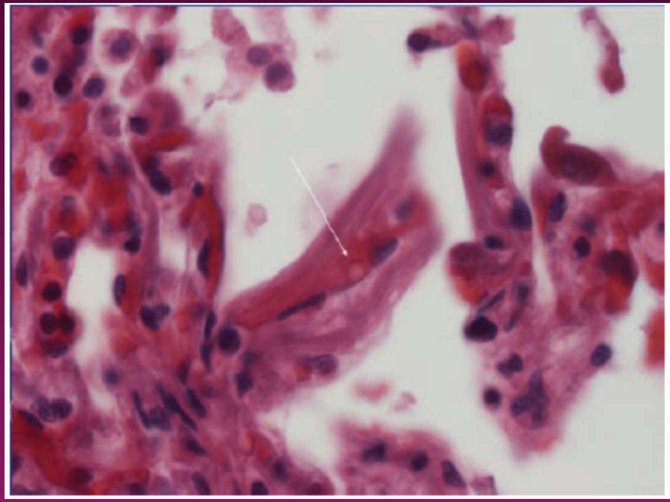
- Ultrasonic
- Located on return line
- Alarm activated by air in blood/saline or both

UABD lies below the bubble trap to prevent air passage

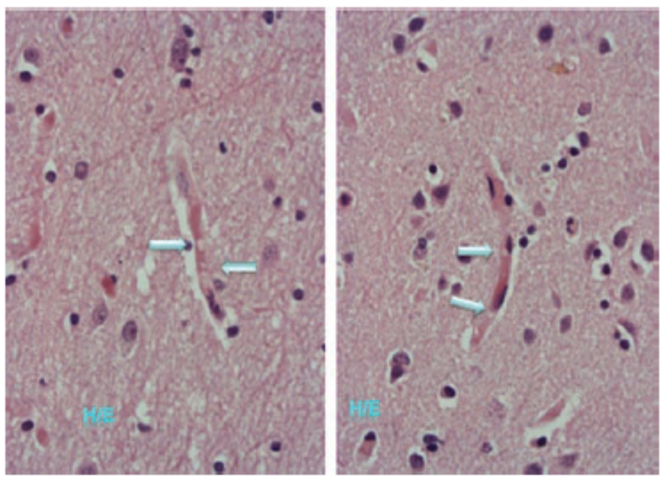
- Incidence of major air embolus 1:2000 treatments
- Usual volume required= 60-125 ml, esp. if injected rapidly

Lodi CA et al CJASN 5: 2004 –2017, 2010

Air Microbubbles are found in Hemodialysis Patients



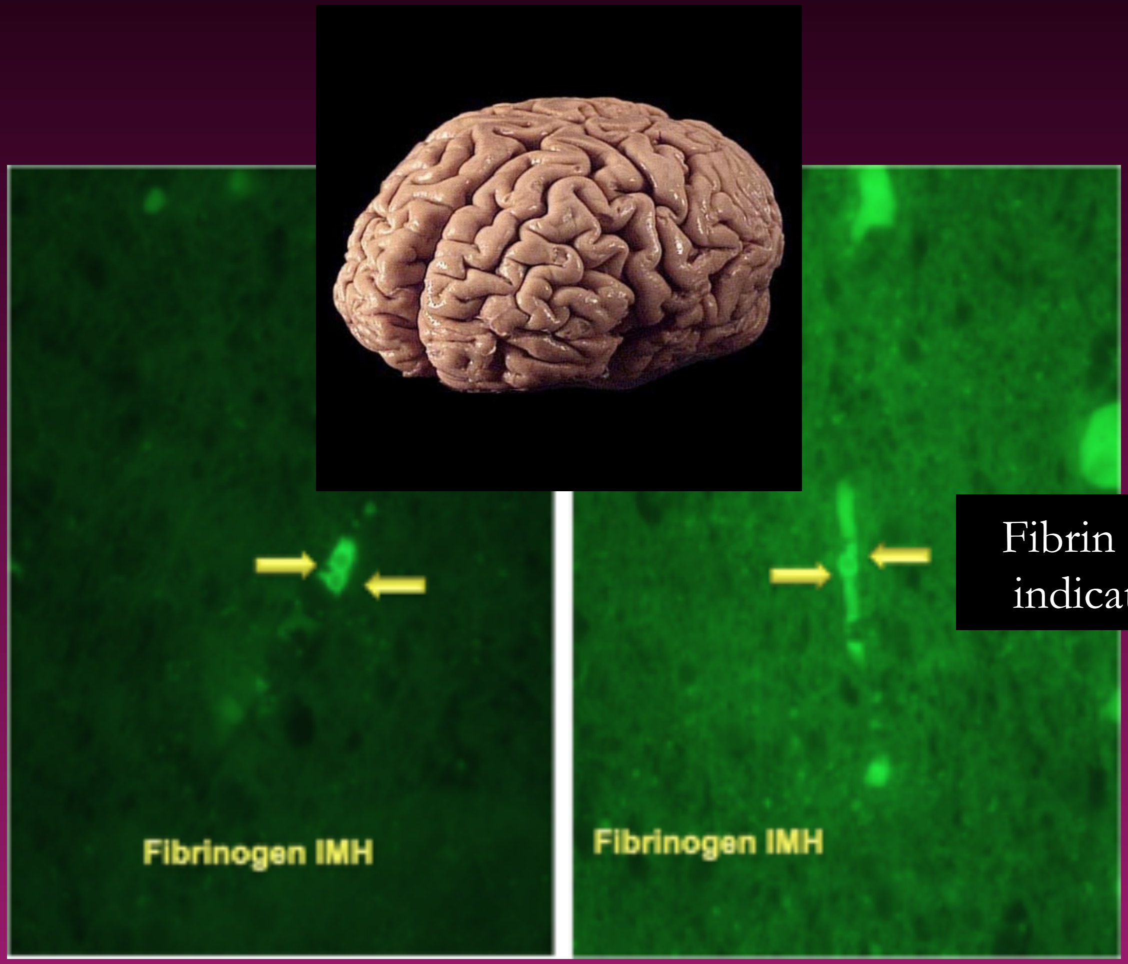
Microscopic finding of microbubbles of air (arrow) in pulmonary capillary; also, increased fibrosis of tissue (red areas).



Microscopic finding of microbubbles of air in the brain (arrow).

Stegmayr B et al ASAIO Journal 2012; 58:177–179

Microemboli in brain in HD

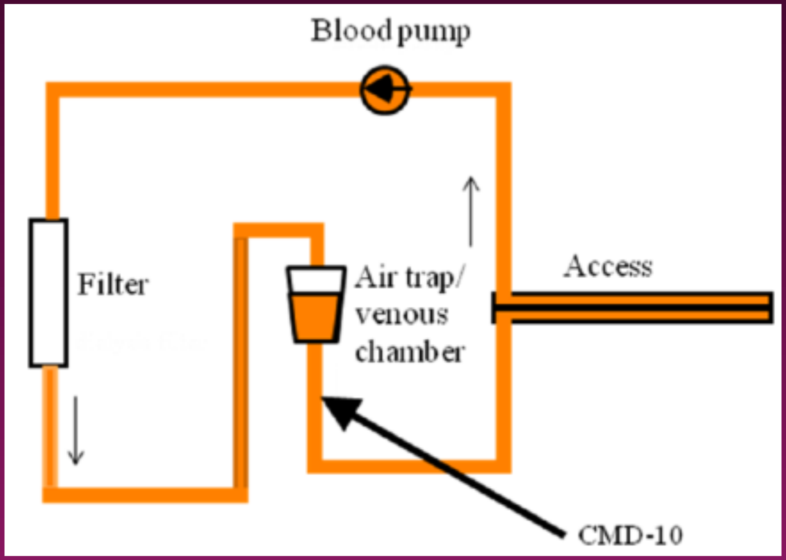


Fibrin around air bubbles indicating clot formation

(antifibrinogen antibody staining)

Stegmayr et al. Hemodialysis International. 2(2);168-172:2016

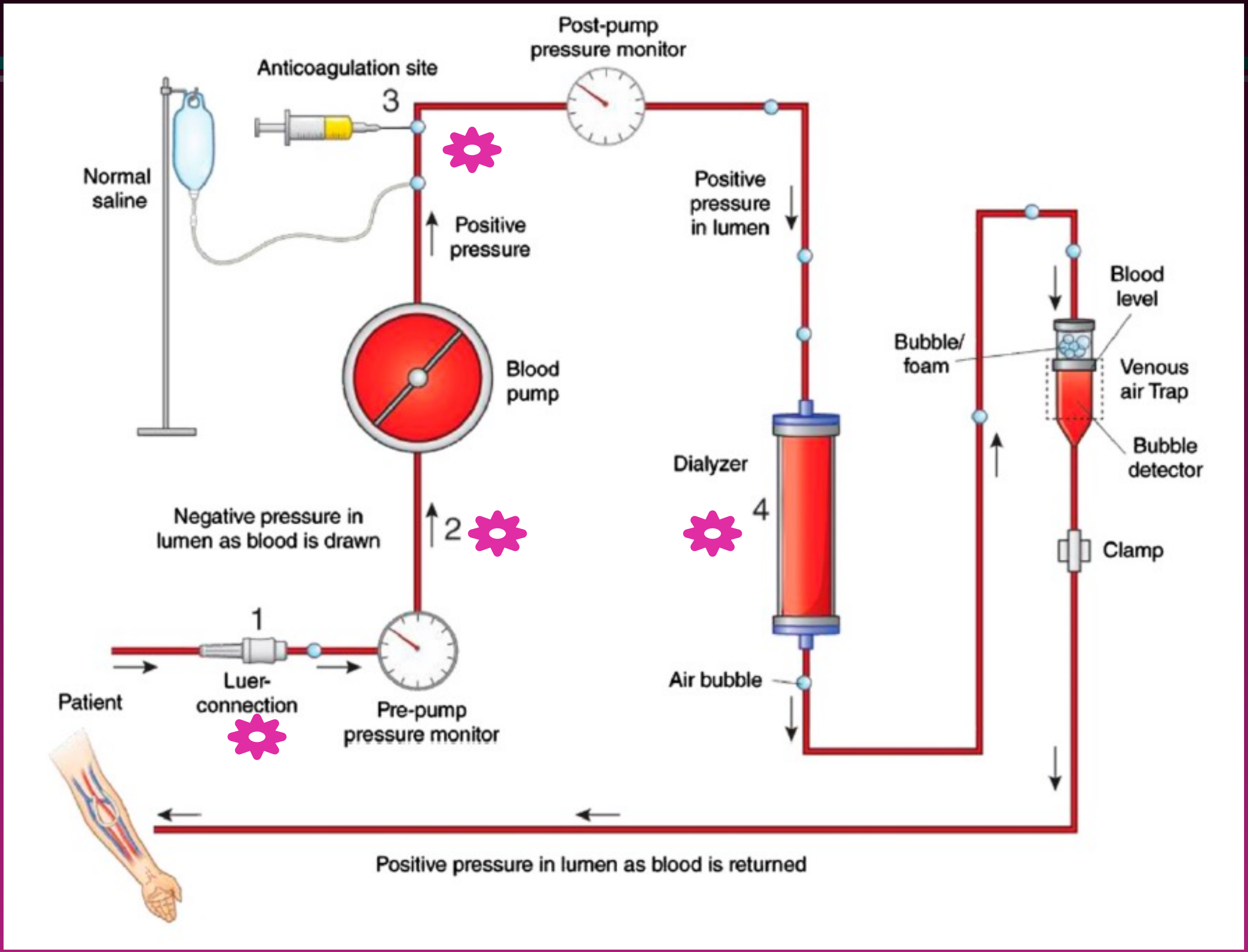
Microemboli can enter into HD patients without triggering alarms



- 54 HD patients (16 CVC, 38 AVF)
- Microemboli measured at AVF and Common Carotid artery before and during HD
- Significant increase in microembolic signals detected at both sites during HD

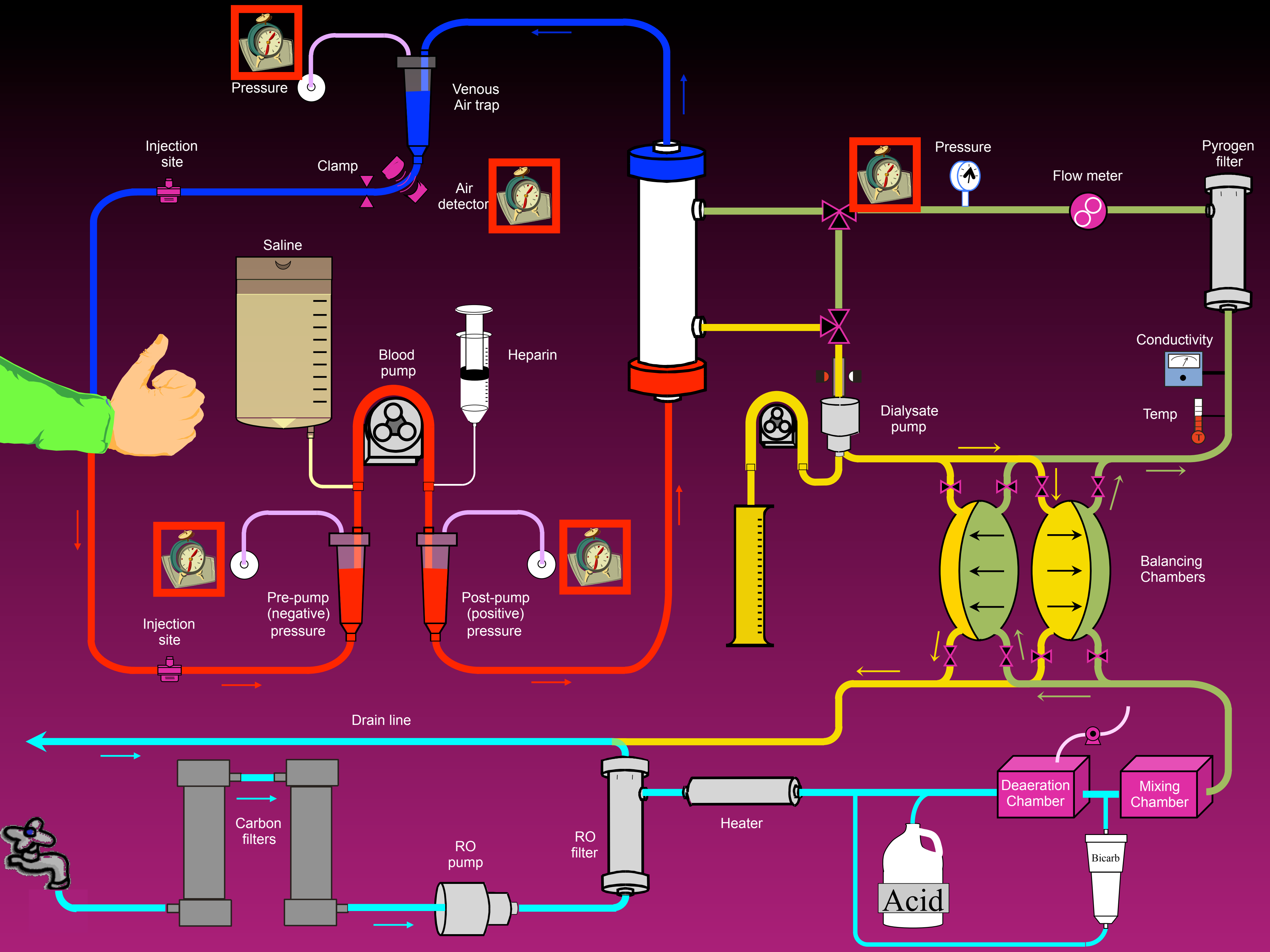
Forsberg U et al, Nephrol Dial Transplant 2010; 25: 2691–2695

Preventing air embolism



Handling	Measure
Negative Pressure Connections	Connection between needle/CVC and arterial tube closed Heparin tube connector closed Arterial Pressure tube tightly applied
Priming of EC circuit	More volume is better (1.5l) Turn and knock on steam sterilized dialyzers
Blood Pump	Qb <200 ml/min
Venous air trap	Avoid low fluid level
Syringes	Take care to empty air
Dialyzer	Wet stored dialyzer preferred; careful connection to avoid air contamination
Air trap and dialysis device	Each brand has different conditions. Check with provider
EC components (tubing sets, dialyzers)	Each brand has different conditions. Check with provider

The Dialysate pathway



Pressure
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Pyrogen
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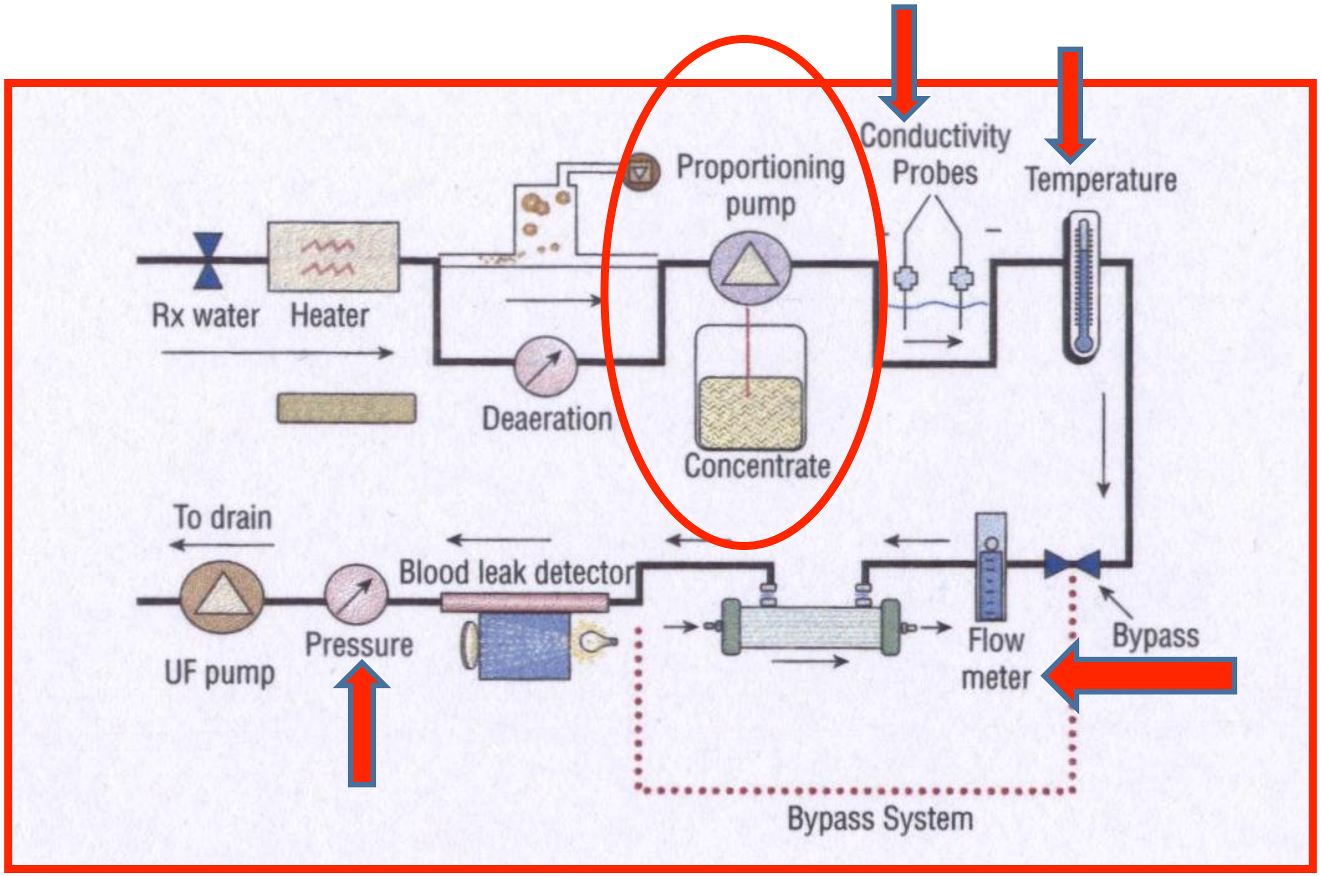
Heparin
Conductivity
Dialysate
pump
Temp
Balancing
Chambers
Injection
site
Pre-pump
(negative)
pressure
Post-pump
(positive)
pressure
Drain line
Carbon
filters
RO
pump
RO
filter
Heater
Deaeration
Chamber
Mixing
Chamber
Bicarb
Acid

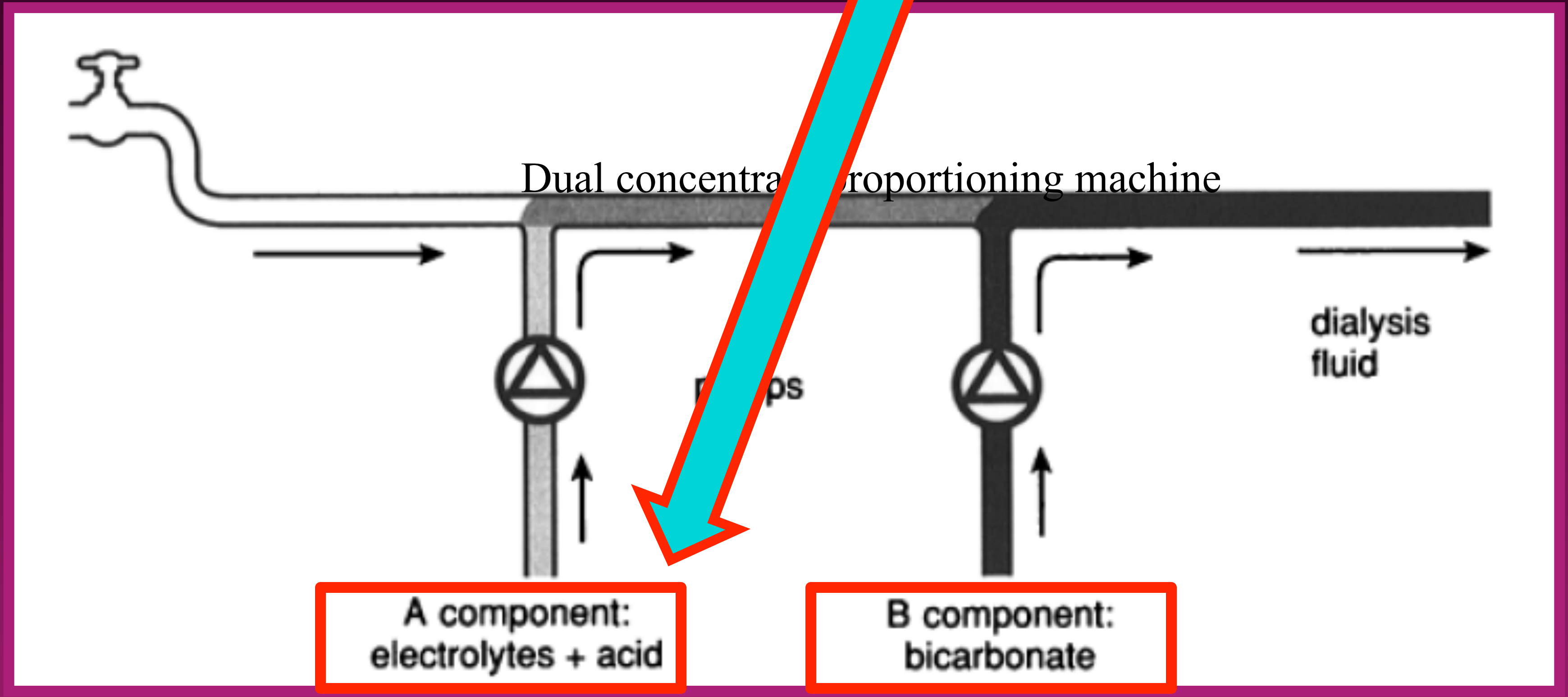
Simplified Fluid Pathway



Adapted from Handbook of Dialysis Therapy. Nissenson and Fine. 4th edition, Saunders Elsevier Pubs.

The three stream method of preparing a bicarbonate based dialysate

Organic acid
Glacial acetic acid/sodium diacetate/ citric acid



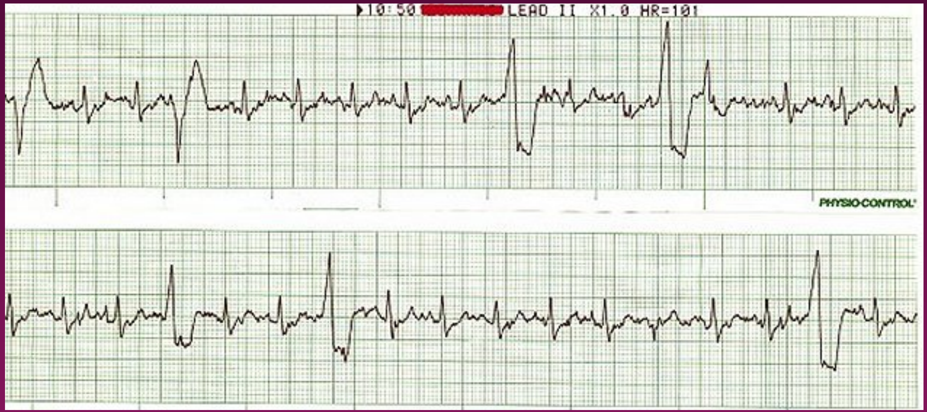
Adapted from Bosch JP and Stein JH, eds. Hemodialysis: High Efficiency Treatments, Churchill Livingstone, New York NY. 1993;9-26

45 y/ white male on HD X 4 y.
Cause of ESRD: Chronic GN
Pre Labs (midweek): K 5, Na 138, CO2 30, Cl 112, Ca 9.3, Phosphorus 6

Dialysis Prescription

Pre 86.5 kg
Target 84 kg
Temp 37.2 c
Dialysate Temp 36 c
Qb 350
Qd 800
Time 240 min
Dialysate 3K/2.5 Ca/ 39 Bicarb
Pre K 5, Na 138, CO2 30, Cl 112, Ca 9.3, Phosphorus 6
Dialyzer F80

2 hours into dialysis, patient c/o palpitations. HR 150, irr.irr, BP 90 mm systolic, RR 24/min, SaO2 85% on room air



Rx

- ❖ Patient is disconnected and HD is stopped.
- ❖ Oxygen, IV Saline
- ❖ Stat blood draw: K 2.0 meq/L, HCO3 36 meq/L
- ❖ IV Potassium, Cardiology consult, CICU
- ❖ Dialysate and Patient Chemistry match analysis

The final dialysate solution

Na Bicarbonate (37 mEq/L) + Acetic acid (4 Mm)

Carbonic Acid + Na acetate

Carbon dioxide + water + Na acetate (4 mEq/L)

The loss of bicarbonate is balanced by a gain in acetate (bicarbonate precursor)

Total buffer base = Na Bicarbonate (33 mEq/L) + Na acetate (4 mEq/L) **= 37 mEq/L**

It is vital to know the total buffer base available for administration to the patient via the final dialysate at a specific machine setting and concentrate pairing

The dialysate acid concentrate can contain acetic acid, acetate or citrate, in amounts ranging from 1.5 to 8 mEq/L This generates bicarbonate in the body!

- **Possible in all currently marketed dialysate concentrate products containing acetate, acetic acid, or citrate.**
- 50 HD patients hospitalized in October 2010
- Their outpatient dialysate prescription included **a 39 mEq/L bicarbonate solution and an acid concentrate which contained** 8 mEq/L of acetate (total bicarbonate of 43 mEq/L).
- At presentation, the patients' mean serum bicarbonate level was 31.3 mEq/L and **54 percent had a** serum bicarbonate >30 mEq/L.

Pande S, Raja R, Bloom E et al. Effect of dialysate baths on serum bicarbonate levels in hemodialysis patients. AJKD 2011; 57(4): A75 (Abstract #234))

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Sodium Diacetate, has equal parts of acetic acid and sodium acetate.

The product dialysate has a total of 8 mEq/L of acetate, 4 from each component.

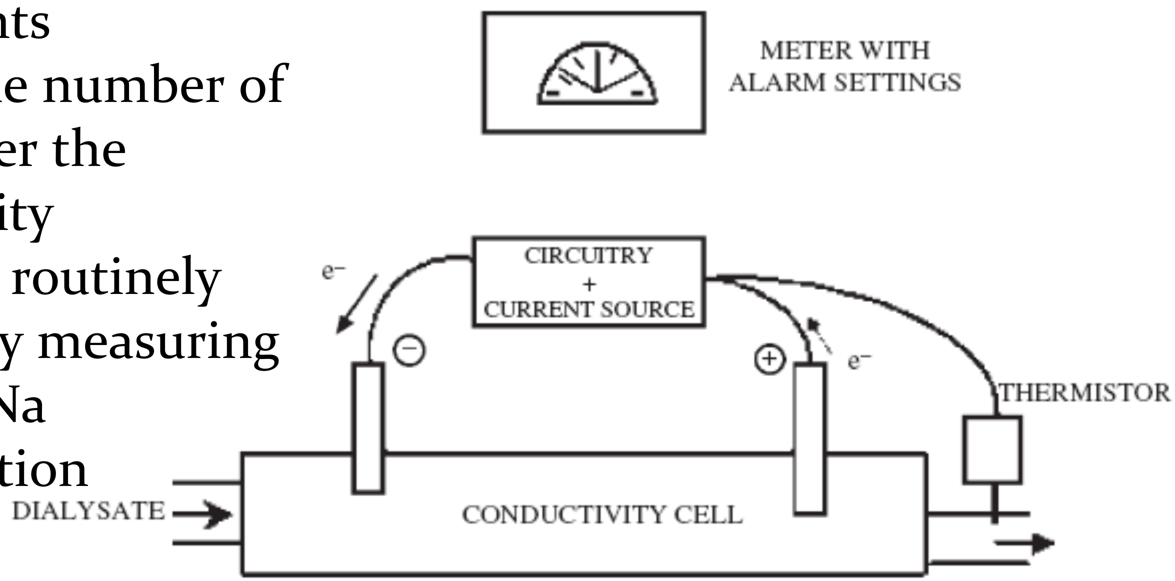
With a starting Bicarbonate concentration of 37 mEq/L, the total buffer base in the final dialysate will be 41 mEq/L
(37- 4 = 33 + 4 +4 = 41)

(acetic acid plus acetate) contained in Fresenius' Naturalyte Liquid and Granuflo Dry Acid Concentrate. Inappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest. This product may cause serious adverse health consequences, including death.

FDA has issued a general safety communication related to inappropriate prescription and resultant alkali dosing errors in the dialysate concentrates used in hemodialysis.

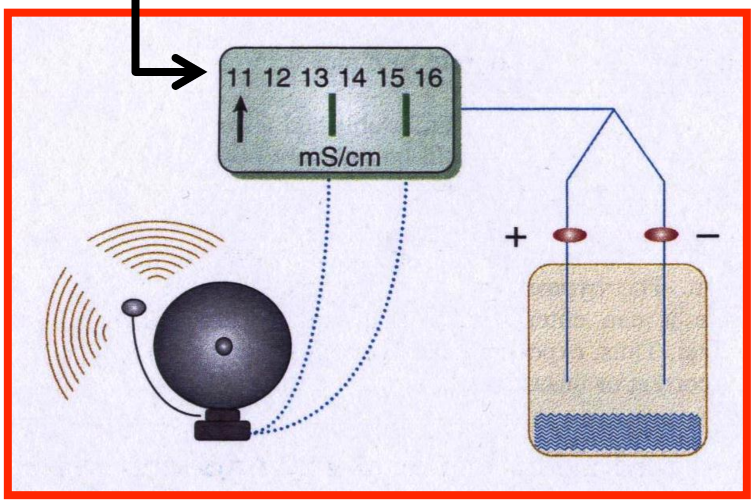
Proper mixing monitored by conductivity monitors [normal range 12-16 mS/cm]

- Determined by ionic constituents
- Greater the number of ions greater the conductivity
- Should be routinely checked by measuring dialysate Na concentration

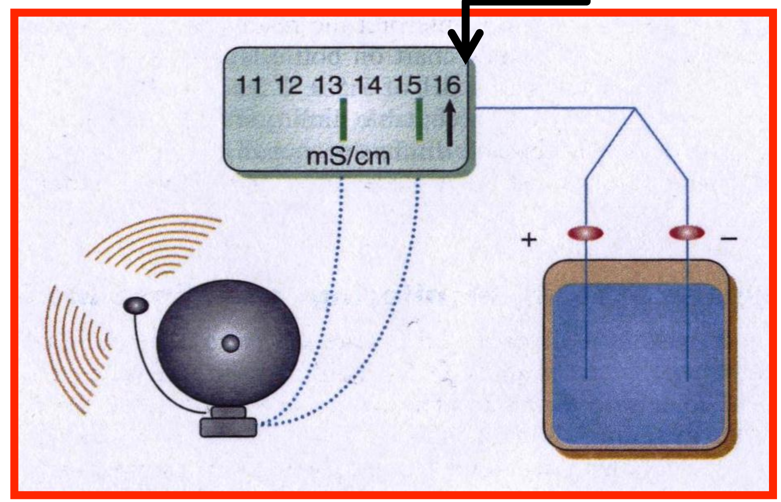


Misra M. The basics of HD equipment. Hemodialysis International 2005; 9: 30–36

Low conductivity Alarm



High conductivity Alarm

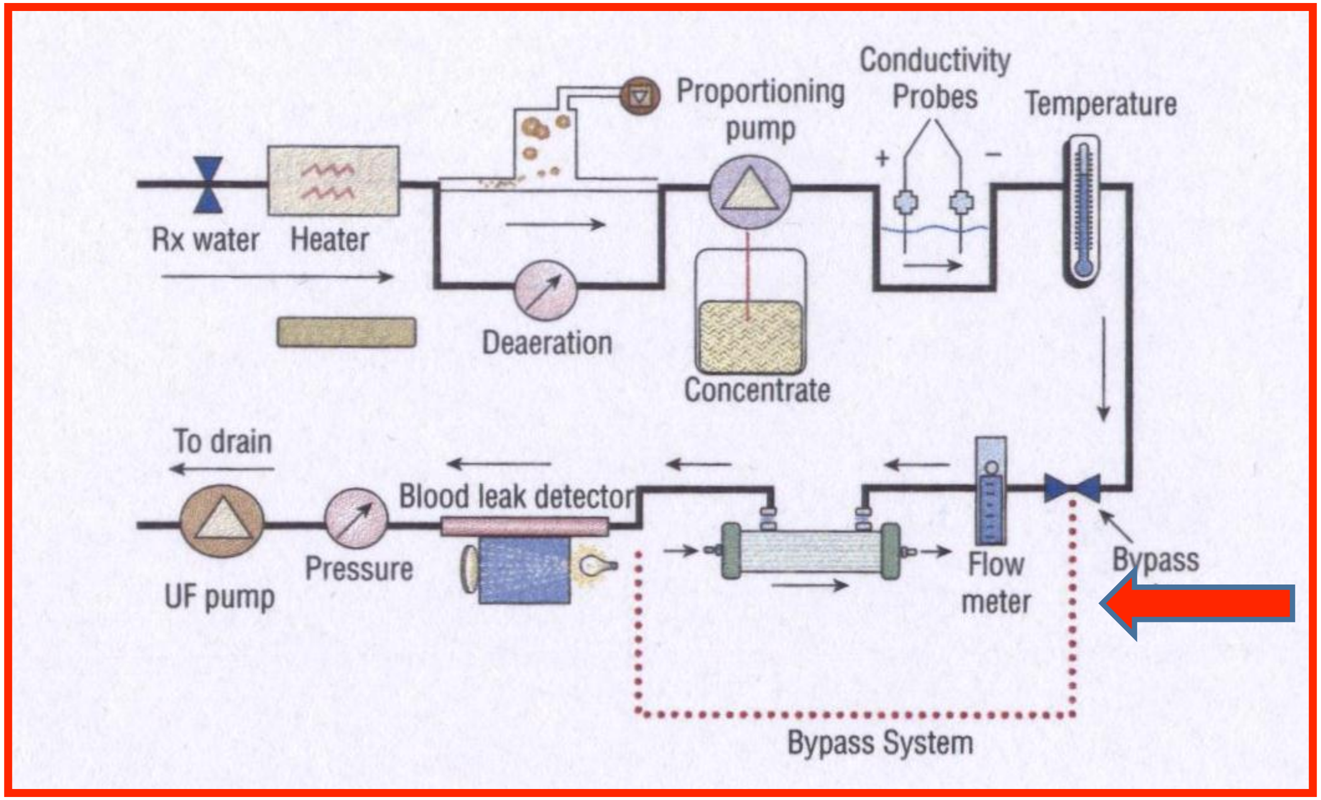


Adapted from Handbook of Dialysis Therapy. Nissenson and Fine. 4th edition, Saunders Elsevier Pubs.

Potential proportioning problems

- Causes
  - Wrong concentrate (note color coding: **Red** for acid, **Blue** for base)
  - Poor mixing
  - Clogged filters
  - Crystallization in the system
  - Human disarming of the switches
- Outcome
  - ❖ High or low plasma sodium
  - ❖ High or low plasma potassium
  - ❖ High calcium/magnesium
  - ❖ High or low plasma osmolality

Simplified Fluid Pathway



Adapted from Handbook of Dialysis Therapy. Nissenson and Fine. 4th edition, Saunders Elsevier Pubs.

Dialysate Alarms

Alarms should interrupt the supply of dialysate

- Check for 'no flow' and lack of dialysate stream at the dialyzer

Problem Solving

- Is the concentrate container empty? **[low conductivity]**
- Is the water inlet pressure normal? **[high conductivity]**
- Are there any water leaks/puddles beneath the mixing chambers? **[high conductivity]**

- Never adjust conductivity setting when the patient is on dialysis

Conclusions

- Hemodialysis machine is part of an integrated system.
- Safety alarms and monitors are not foolproof
- User errors are common
- Basic understanding of functions of blood and dialysate side circuits and equipment helps avoid complications
- Detailed technical knowledge is not necessary but fundamental knowledge must be acquired
- Patient safety is paramount!