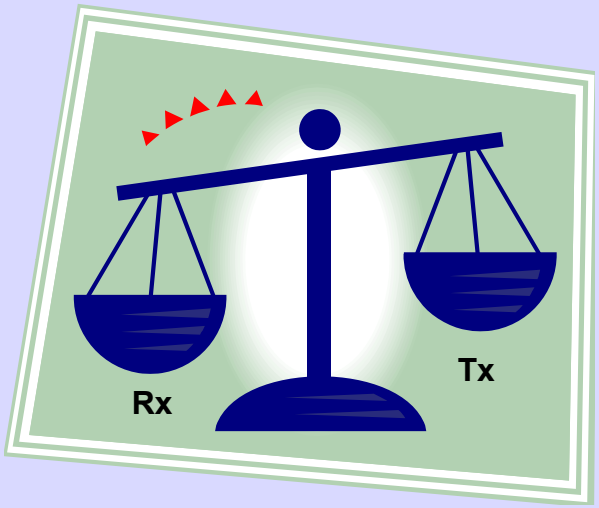


Dialysis Technology: Is the Patient Receiving the Treatment as Prescribed?

NANT New York Regional Meeting
1 - 2 December 2012
LaGuardia Airport Marriott

Joe Johnston
Sr. Vice Pres. Biomedical Services
& Technology Integration
Fresenius Medical Care

Question 1

Question – True or False

The dialysis machine, given it is approved by the FDA to be safe and efficacious, will not allow the user to place the machine in an unsafe state.

Question 1

Answer - False

a)Safety is “relative”, i.e., one prescription doesn’t fit all.

Is a 2 kg/hr UF rate safe for all patients???

b)Nearly all medical devices are intended to be used by a trained, competent, supervised individual. This is a key component of the risk analysis and the FDA approval.

The machine is only safe if you use it safely

Question 2

Question – True or False

When I enter a prescription into the machine, I know that is exactly what the patient will receive.

Answer - False

Errors, random variations, and design details about how the machine functions all affect the delivered prescription

Some Definitions for this Discussion

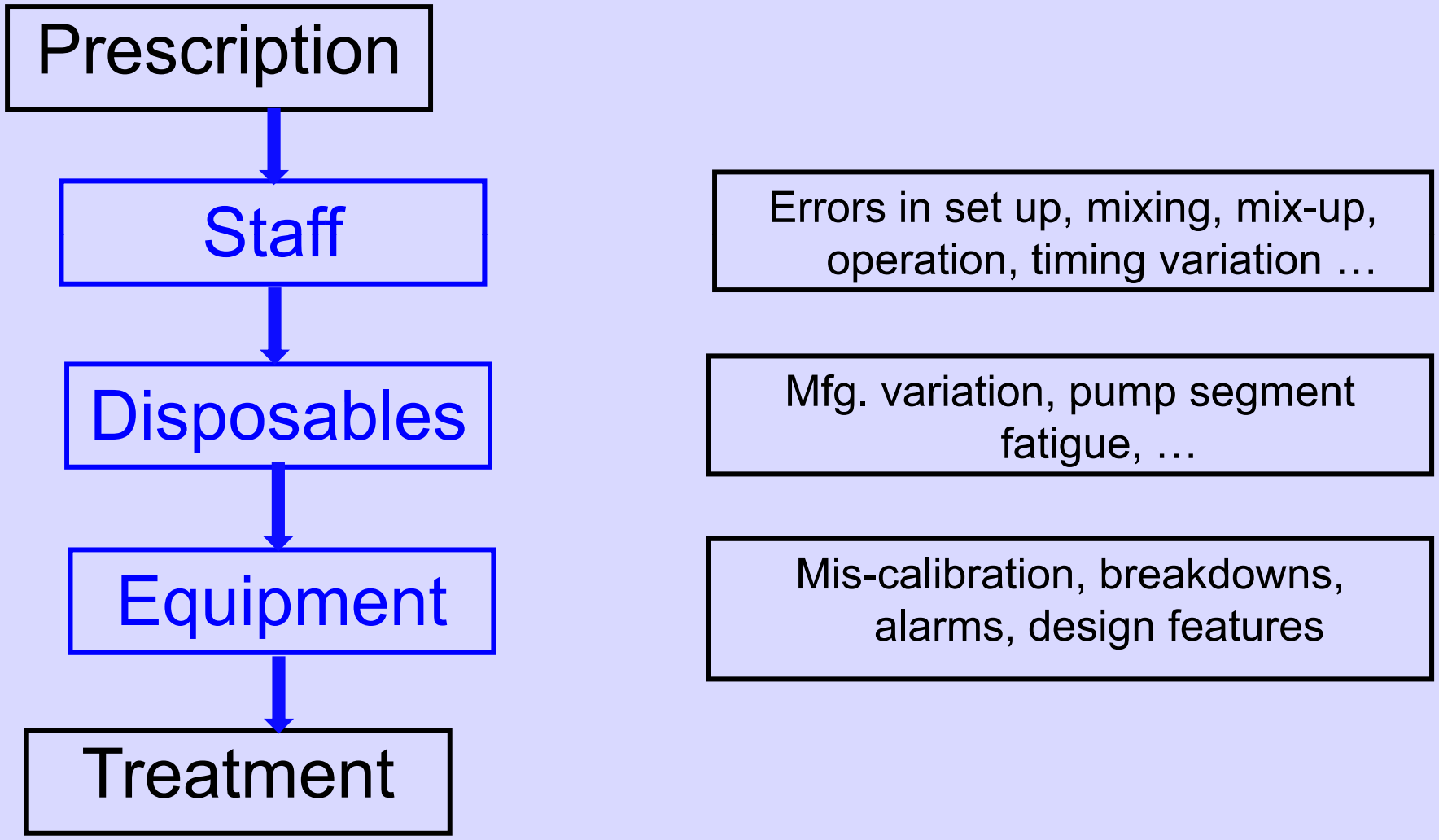
A deviation is a difference between reality and what is expected, normal, or prescribed.

- Random Variation
  - Assignable cause is not known, or is not knowable
  - Is implicit in the process

- Design Tolerance
  - Deviation that is “built-in” or planned at the time of the design
  - Should be developed using a risk based method

- Error
  - Has a known assignable cause, although perhaps not quantified
  - Can be prevented or corrected (repaired)

Dialysis Technology: The Process of Delivering a Treatment



Key Points

Objective – to show how misusing or misunderstanding the technology in a dialysis clinic can affect the prescription delivered.

Examples :

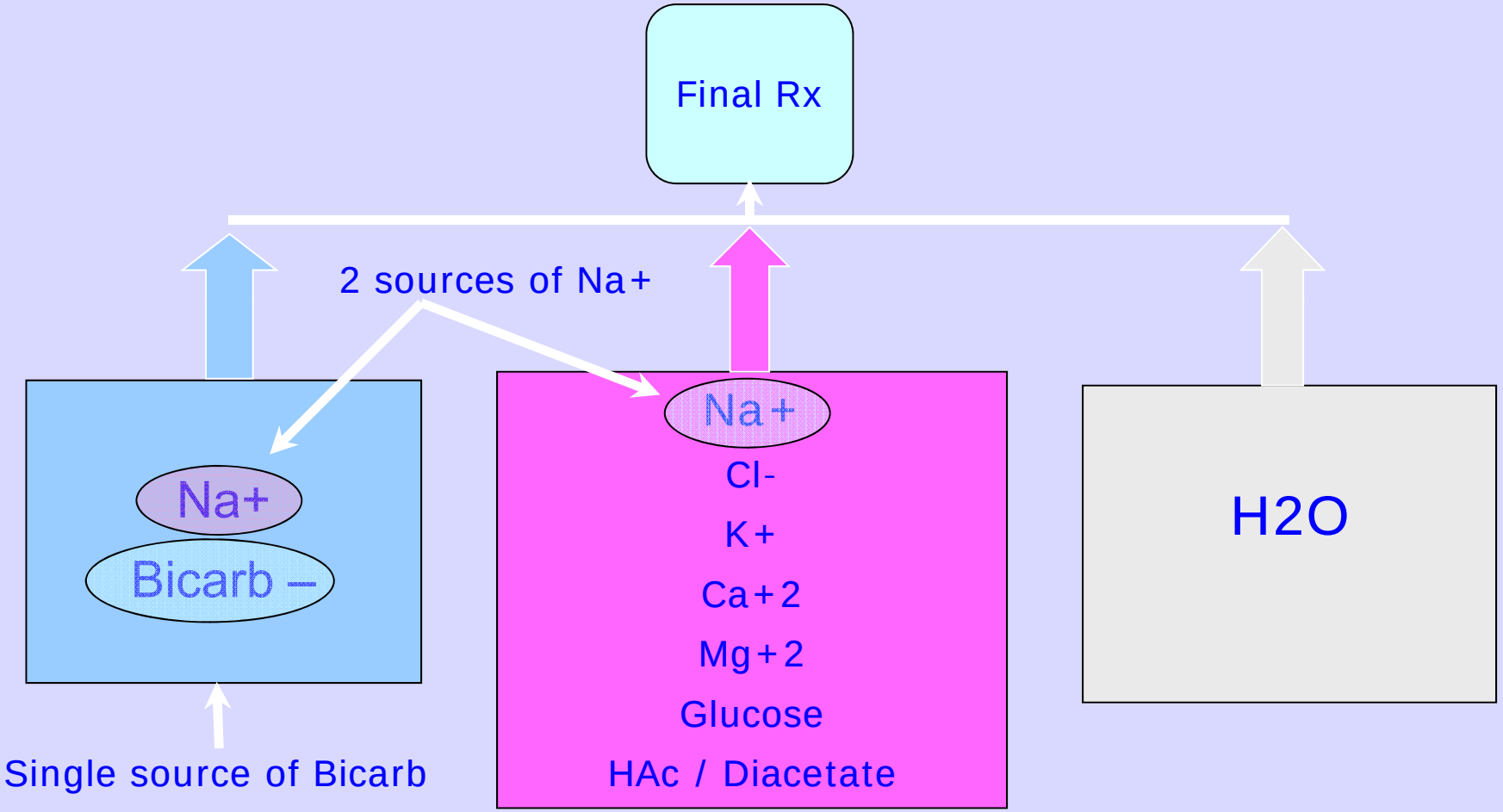
- 3 - Stream proportioning
- Blood lines
- Alarms and staff responsibilities
- Impact of conductivity different than target
- Significance of pressure alarm limits and pressure tests
- Impact of using sodium variation

3 – 2 - 1

Three Stream Proportioning Systems

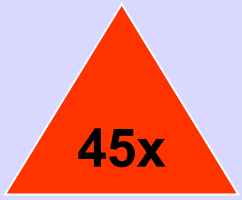
How They Really Work

Proportioning



Concentrate proportioning

- 3 stream proportioning (45X)
  - Acid concentrate + Bicarb + Water

Type	Symbol	Mixing Ratio Acid : Bicarb : Water	Post Reaction Na+ / Bicarb
Cobe		1.00 : 1.72 : 42.28	[137] / [33]

Default proportioning

If this is used, you will get the acid label concentrations in dialysate

Concentrate proportioning

3 stream proportioning

	Setting	Actual
Na^{+}	137 mEq/L	137 mEq/L
K^{+}	2 mEq/L	2 mEq/L
Ca^{+2}	2.5 mEq/L	2.5 mEq/L
Mg^{+2}	1.0 mEq/L	1.0 mEq/L
Ac^{-}	4.0 mEq/L	4.0 mEq/L
Bic^{-}	33 mEq/L	33 mEq/L

Concentrate proportioning

3 stream proportioning

	Setting/Label		Actual	
Na^{+}	140	mEq/L →	Na^{+}	140 mEq/L
K^{+}	2	mEq/L	K^{+}	2.06 mEq/L
Ca^{+2}	2.5	mEq/L	Ca^{+2}	2.57 mEq/L
Mg^{+2}	1.0	mEq/L	Mg^{+2}	1.03 mEq/L
Ac^{-}	4.0	mEq/L	Ac^{-}	4.12 mEq/L
Bic^{-}	33	mEq/L →	Bic^{-}	33 mEq/L

Concentrate proportioning

3 stream proportioning

	Setting/Label		Actual
Na^{+}	137 mEq/L	→	Na^{+} 137 mEq/L
K^{+}	2 mEq/L		K^{+} 1.96 mEq/L
Ca^{+2}	2.5 mEq/L		Ca^{+2} 2.45 mEq/L
Mg^{+2}	1.0 mEq/L		Mg^{+2} 0.98 mEq/L
Ac^{-}	4.0 mEq/L		Ac^{-} 3.92 mEq/L
Bic^{-}	35 mEq/L	→	Bic^{-} 35 mEq/L

Blood Flow Rate

The display on the machine for the blood flow rate is the exact blood flow rate of the dialysis treatment, right ?

Well, ……

Blood flow

EDTNA ERCA J. 1996 Jan-Mar;22(1):3-6.

Blood flow displayed by dialysis machines: is it accurate?

Stragier A, Wenderickx D, Jadoul M.

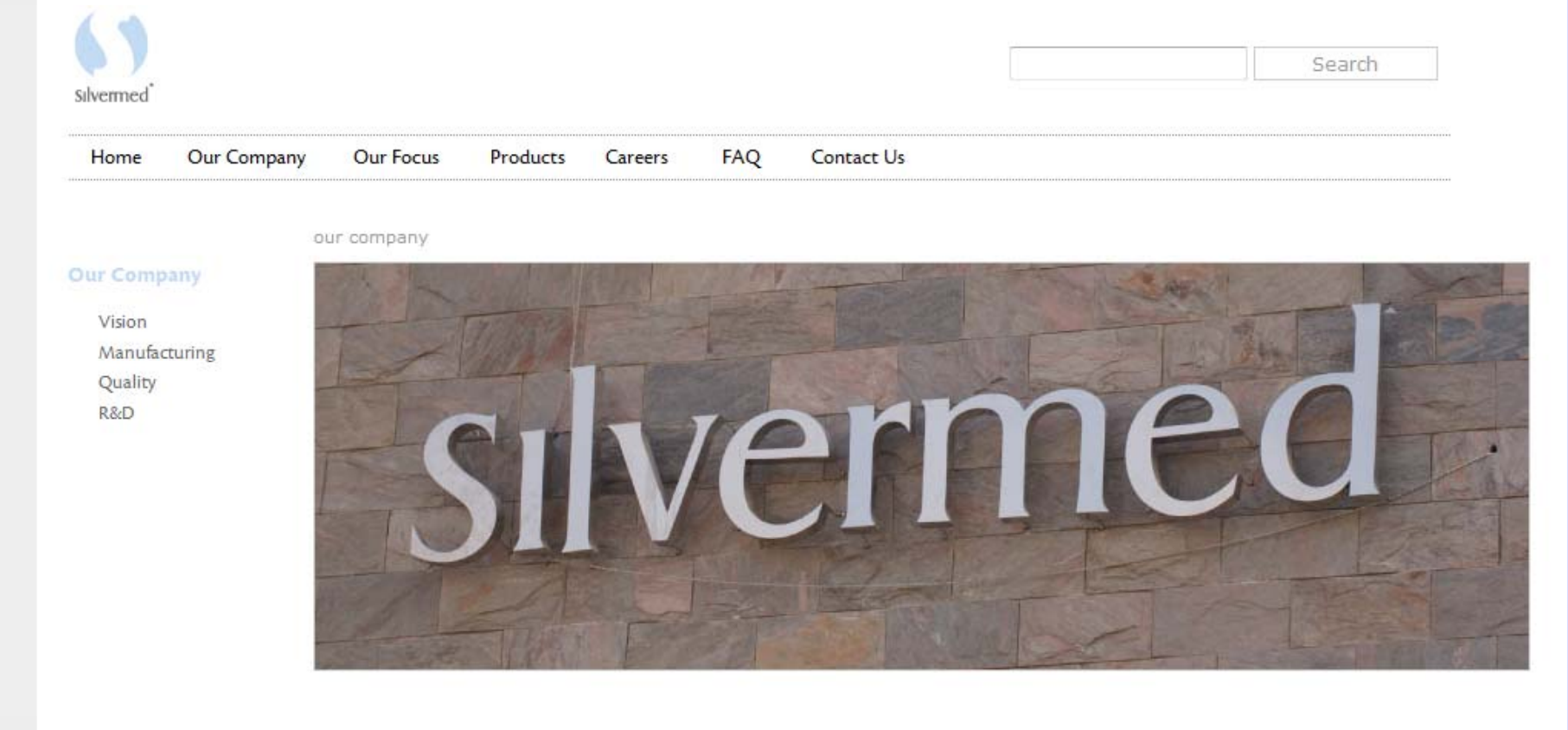
Cliniques Universitaires St-Luc Service de Néphrologie, Brussels, Belgium.

Abstract

Blood flow is a major determinant of dialysis efficiency. We reported in 1980, at the EDTNA conference in Prague (1), that the actual blood flow may be much lower than displayed by the dialysis machines. We demonstrated that the Negative Inflow Pressure (NIP), induced by the arterial needle and therefore generally referred to as arterial pressure, partly collapses the proximal blood pump segment whose inner volume is decreased. Thus the actually pumped volume per revolution is lower than the displayed blood flow.

PMID: 10723300 [PubMed - indexed for MEDLINE]

Blood flow


Silvermed
Search
Home
Our Company
Our Focus
Products
Careers
FAQ
Contact Us
our company
Our Company
Vision
Manufacturing
Quality
R&D
silvermed

Blood flow

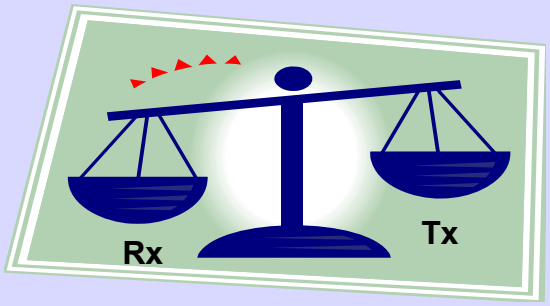
7. Tubes :

- **The optimum mix between wall thickness and sure hardness makes our tubes :**
- Withstand pressure and manipulations
- Antikink.
- Accurate and consistent flow rates over time. Excellent performance under conditions of high flow rates and pressure in the dialysis circuit.
- Highly biocompatible as been tested in the world most recognizable laboratories.
- Available in clear and frosted versions.

8. Pump segment :

- Resist fatigue which insure that the patient received the prescribed Kt/V without increasing negative pressures.
- Pump segment material insure maximum refilling after roller pump strokes even in case of high negative arterial pressure.

ALARMS !!!!!!



- Today's Culture – Tight Schedules, Busy Staff
  - What is the clinic "culture" on machine alarms?

a) We determine the cause and address problem at the moment.
b) Don't worry so much, the machine will stop or not reset on a really important alarm.
c) Quite Please !!!

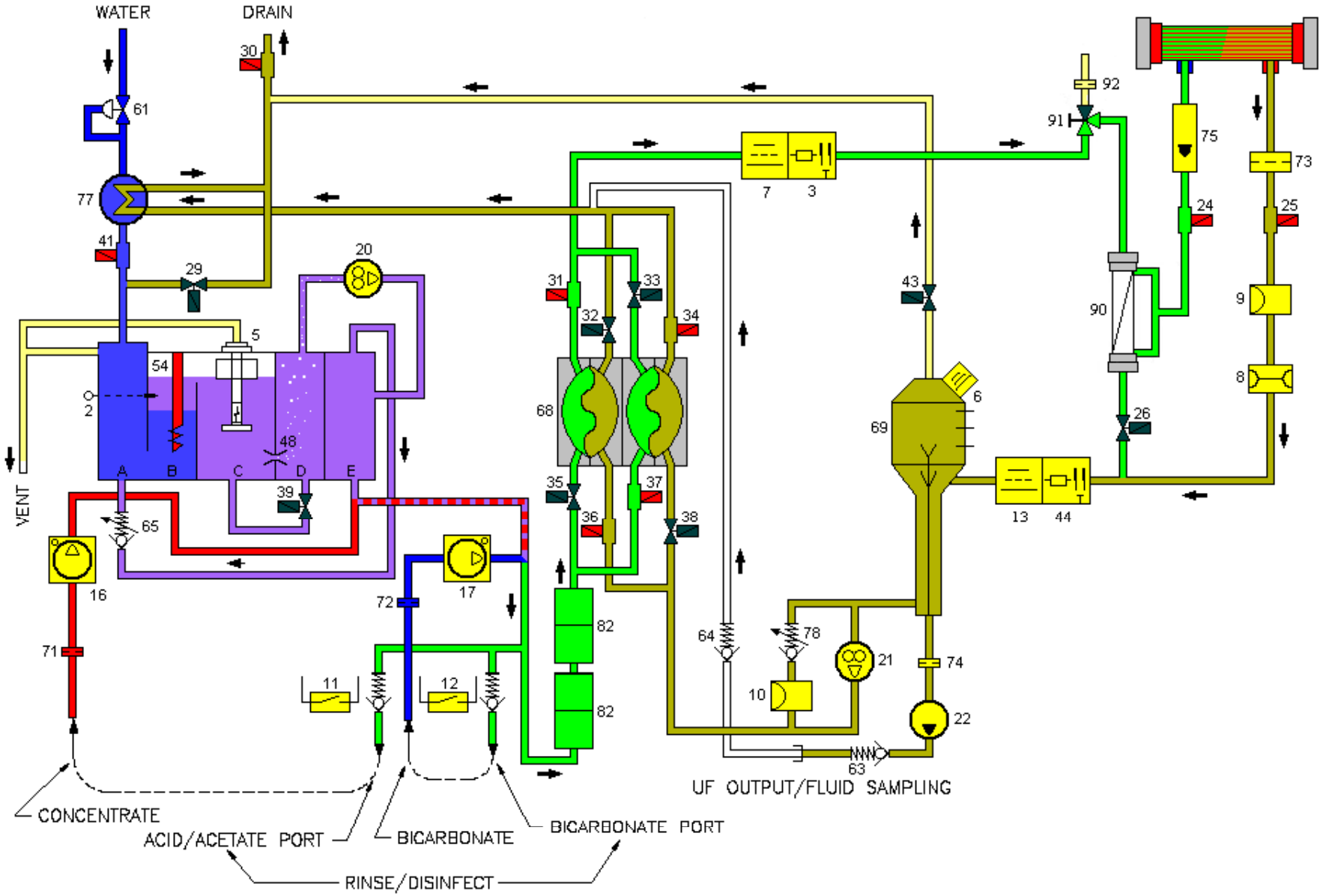
How Should Things Be?

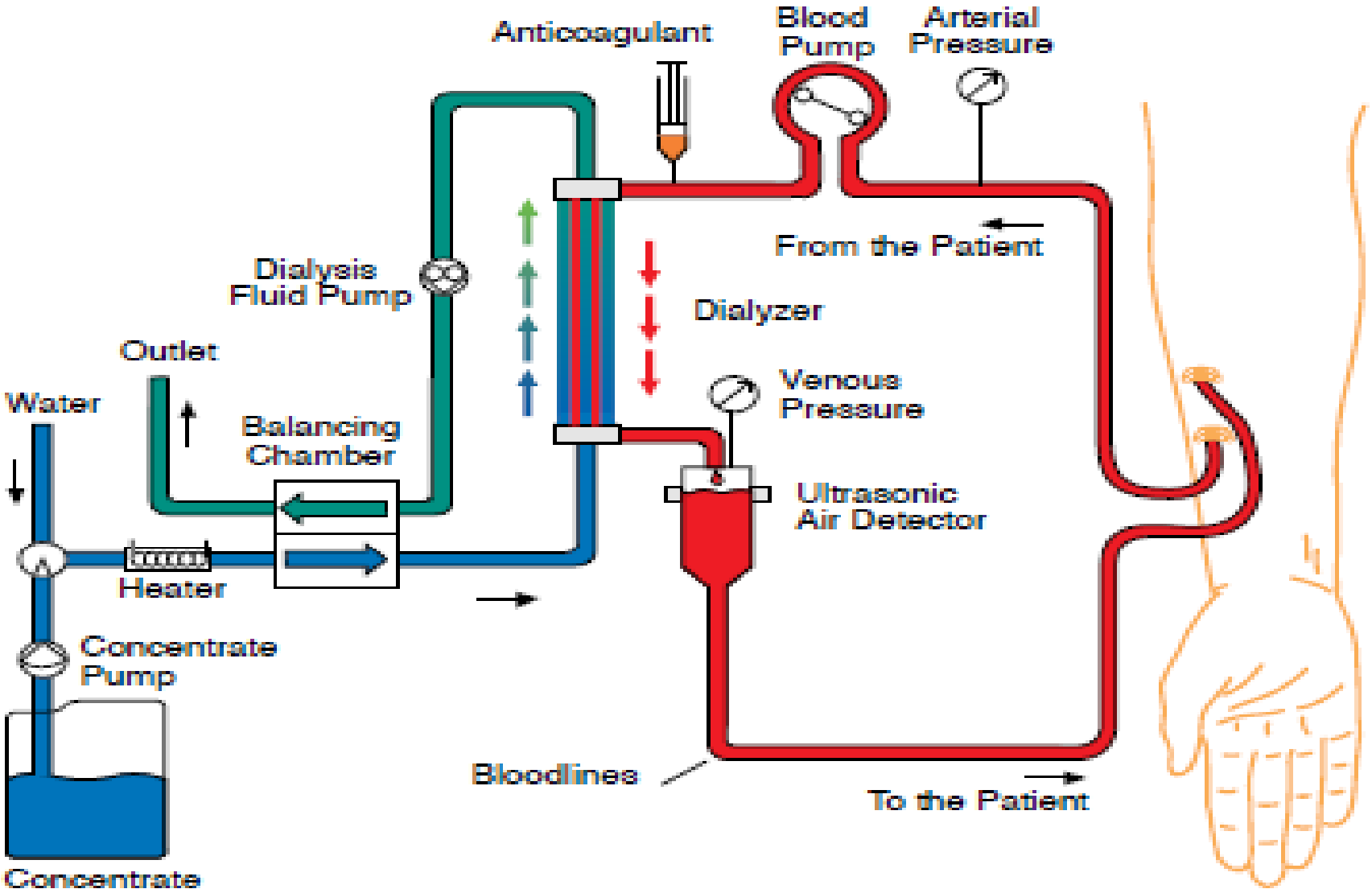
Arterial Pressure	Venous Pressure	Level Detector	Blood Leak	Blood Pump
TMP	Conductivity	Dialysate Flow	Temperature	Water Flow

- What do these alarms indicate?
- How should the staff react to each alarm?
- What does pushing “reset” really do?
- In a typical treatment, how often do these occur?
- Which alarms are preventable, and how should the clinic staff go about preventing them?

Patient and facility variation

Facility	# patients	# tx	% Tx with hypotension	Alarms /Tx	Alarm min/Tx	Alarm min/alarm
Facility 1	140	5097	17.7%	4.07	3.8	0.92
Facility 2	67	3005	23.0%	2.91	2.9	0.98
Facility 3	107	2852	21.6%	2.45	2.2	0.91
Facility 4	100	2296	15.3%	2.53	2.3	0.89
Facility 5	116	1855	17.1%	4.31	4.7	1.09
Facility 6	57	803	30.8%	5.83	5.5	0.94
Facility 7	83	1600	18.9%	2.68	2.5	0.95
Facility 8	67	1684	17.6%	2.62	2.4	0.91
Facility 9	193	5403	12.5%	3.57	3.2	0.91
Total/avg	930	24595	17.9%	3.37	3.2	0.94


WATER
DRAIN
VENT
A
B
C
D
E
CONCENTRATE
ACID/ACETATE PORT
BICARBONATE
BICARBONATE PORT
RINSE/DISINFECT
UF OUTPUT/FLUID SAMPLING


Anticoagulant
Blood Pump
Arterial Pressure
From the Patient
Dialysis Fluid Pump
Dialyzer
Outlet
Water
Balancing Chamber
Venous Pressure
Ultrasonic Air Detector
Heater
Concentrate Pump
Bloodlines
To the Patient
Concentrate

Machine Alarms
"MUTE PLEASE"

DID YOU KNOW?

–Pressures can migrate with each reset

– You may be marching toward limit extremes

What's the effect on the Tx?

Question 3

Question

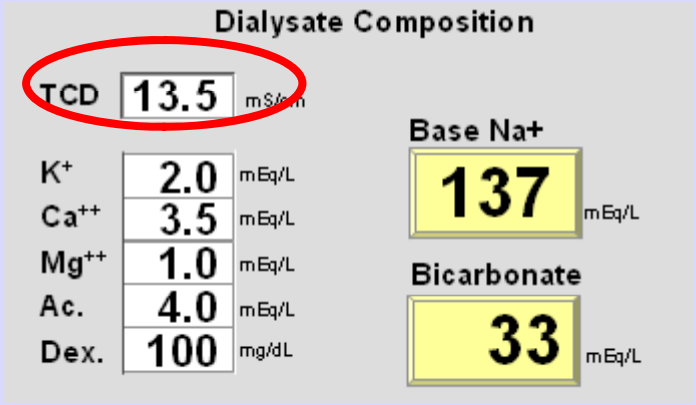
Fresenius machines allow the user to shift the conductivity limits from the default position. Shifting the limits can result in deviations from prescribed Na^+ of as much as:

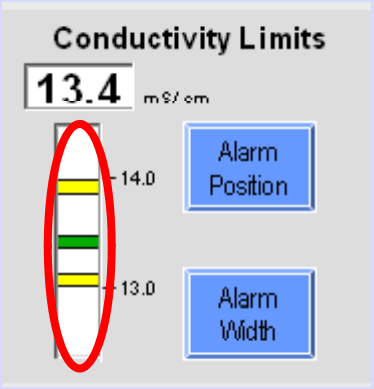
a) ~ 2 mEq/L
b) ~ 4 mEq/L
c) ~ 8 mEq/L
d) ~ 10 mEq/L

Machine settings: 137 mEq/L Na^+ / 35 mEq/L Bicarbonate – TCD = 13.56 mS

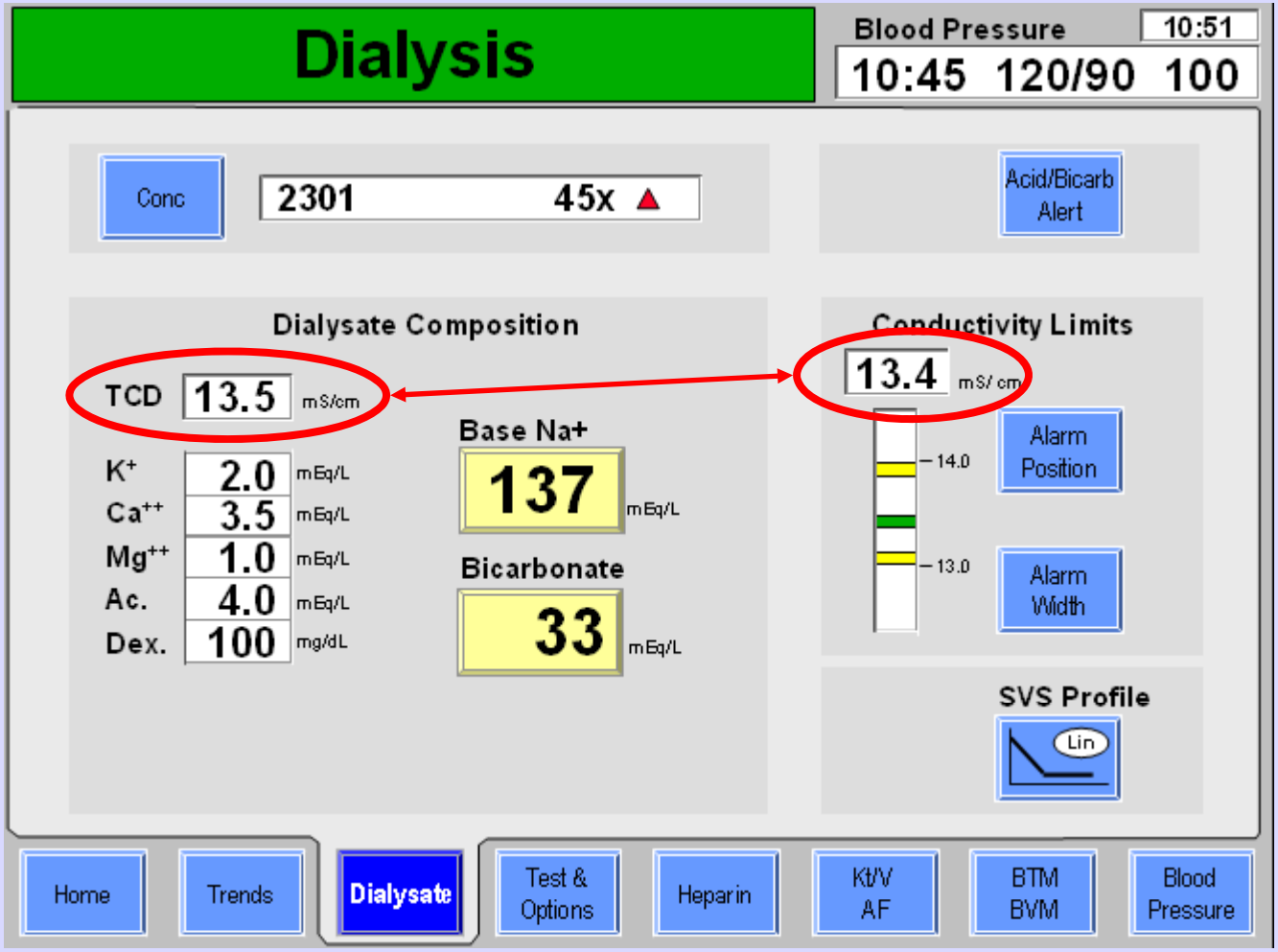
Machine Alarms
Conductivity

- Conductivity
  - Limits are +/- 0.5mS/cm around theoretical or target conductivity (TCD)
    - TCD is the target conductivity for the prescribed concentrate, Base Na+ and Bicarbonate value



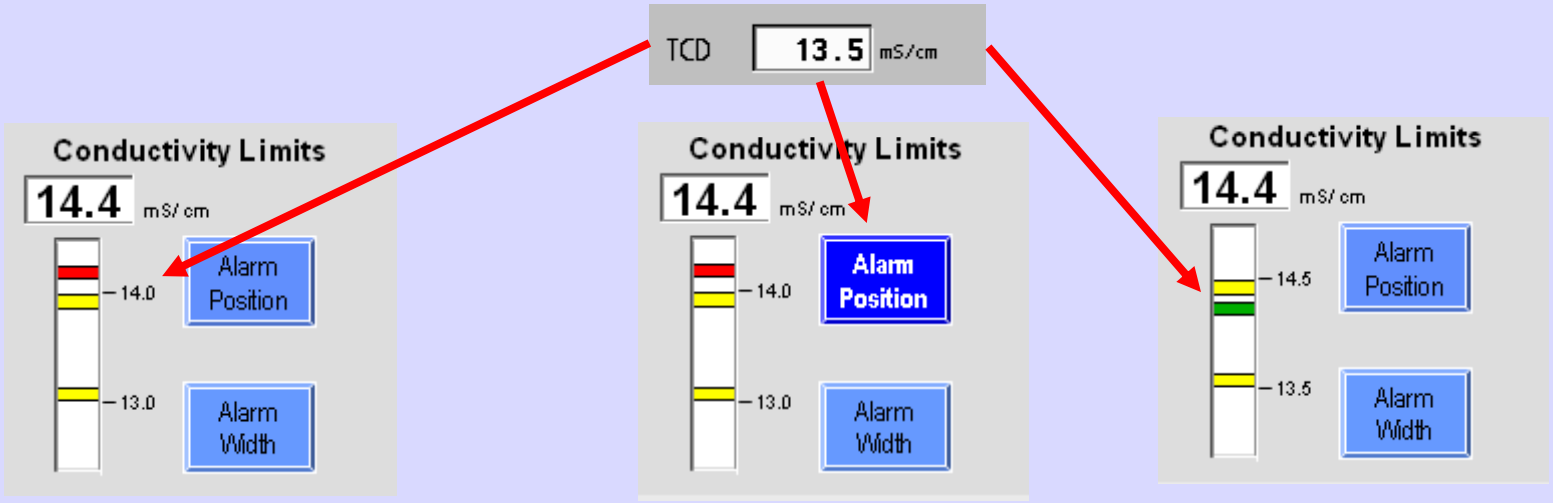


Dialysate Screen - TCD



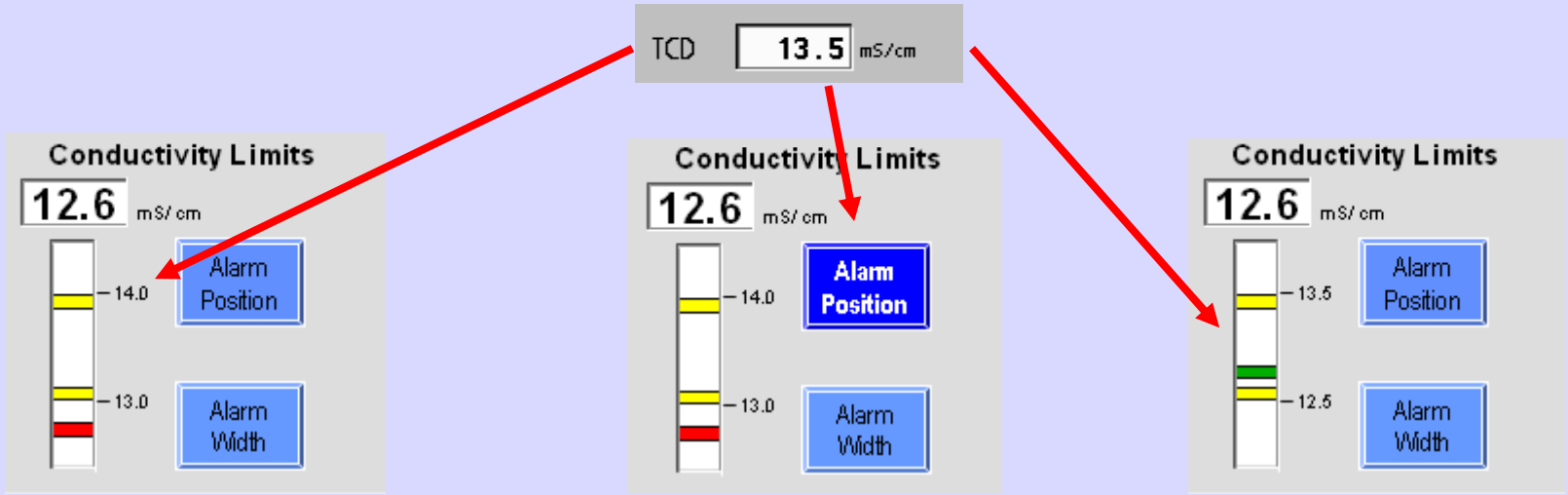
Conductivity Limits

- Limits can be adjusted either up or down an additional 0.5mS/cm
  - Maximum alarm setting is + 1.0mS/cm of TCD with the lower limit at TCD



Conductivity Limits

- Minimum alarm setting is – 1.0mS/cm of TCD with the upper limit at TCD
- 0.9mS/cm variation from TCD



Question 3

Answer

Shifting conductivity limits from the default position can produce variations in NaCl from prescription of:

a) ~ 2 mEq/L

b) ~ 4 mEq/L

c) ~ 8 mEq/L

d) **~ 10 mEq/L**

It's about 1 mEq/L Na^+ for each 0.1 mS

Machine settings: 137 mEq/L Na / 35 mEq/L Bicarbonate – TCD = 13.56 mS

Question 3a

Question

True or False

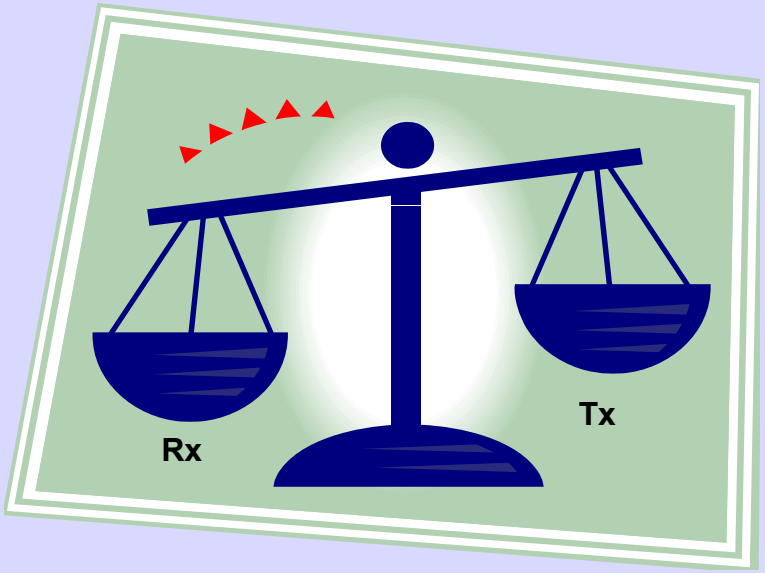
Deviations in the prescribed sodium are only an issue for Fresenius machines. Other manufacturers don't allow shifting of the conductivity alarm limits.

Answer

False

The default alarm limits are wider (+/- 5% vs. 0.5 mS). Variations from Rx can still be significant.

Dialysis Technology: Is the Patient Receiving the Treatment Prescribed?



TMP

Machine Alarms
TMP

- Transmembrane Pressure (TMP)
  - The force that causes ultrafiltration to occur across the dialyzer membrane
  - TMP limits center around actual TMP at the start of TX or when reset is pushed
  - Approx. +/- 40 mmHg (+/- 60 for low flux).

Did you know ….
When you started the Tx, or pushed reset for a TMP alarm, you are telling the machine “the TMP is exactly where I want it, leave it there”

Question 4

Question

When using a high flux dialyzer (e.g., Optiflux 180) the TMP alarm activates when UF removal changes by:

a) ≤0.5 kg/hr
b) ~ 1.0 kg/hr
c) ~ 1.5 kg/hr
d) ≥2.0 kg/hr

Machine Alarms
TMP

- Ultrafiltration Coefficient (Kuf) is a specification of each dialyzer

	16NRe	18NRe	20NRe	160NR / 160NRe	180NR / 180NRe	200NR / 200NRe	250NRe
Therapy	SU	SU	SU	SU	SU	SU	SU
Surface Area (M^2)	1.5	1.8	2.0	1.5	1.8	2.0	2.5
Prime Volume (ml)	84	103	114	84/83	105/98	113/112	135
Kuf* (in vitro bovine 32%)	10	12	14	45/50	55/60	56/62	107
Sterilant	E beam	E beam	E beam	EtO/E beam	EtO/E beam	EtO/E beam	E beam
KOA Urea (ml/min/m^2)	1010	1045	1214	1064	1239	1317	1662
Lysozyme** (ml/min)				47/70	60/74	78/84	118
Product Code	0500306E	0500308E	0500312E	0500316N/ 0500316E	0500318N/ 0500318E	0500320N/ 0500320E	0500325E

Machine Alarms
TMP

Example:

- 18 NRe (low flux, Kuf = 12 mL/hr/mmHg)
- 180 NRe (high flux, Kuf = 60 mL/hr/mmHg)

Same TMP will pull 5 times more water per hour through the high flux dialyzer, compared to the low flux equivalent.

Machine Alarms
TMP

For a TMP alarm setting of - 40 mmHg:

18 NRe alarms at 0.480 L per hour

180 NRe alarms at 2.4 L per hour

Question 4

Answer

When using a highflux dialyzer such as the Optiflux 180, TMP alarms when UF removal changes by:

a) ≤0.5 kg/hr

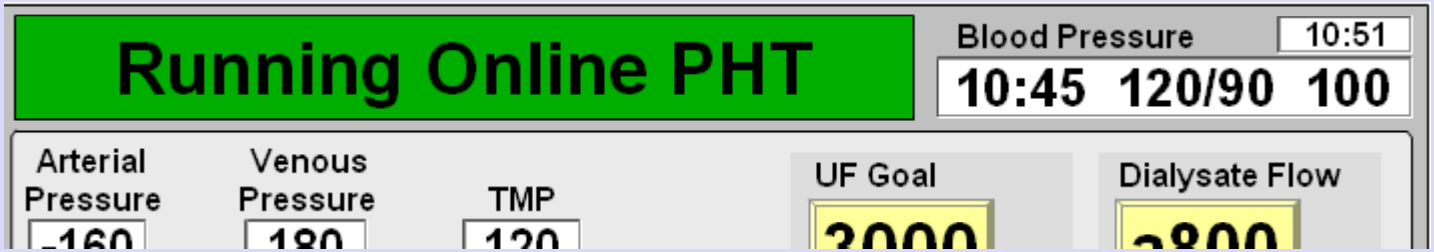
b) ~1.0 kg/hr

c) ~ 1.5 kg/hr

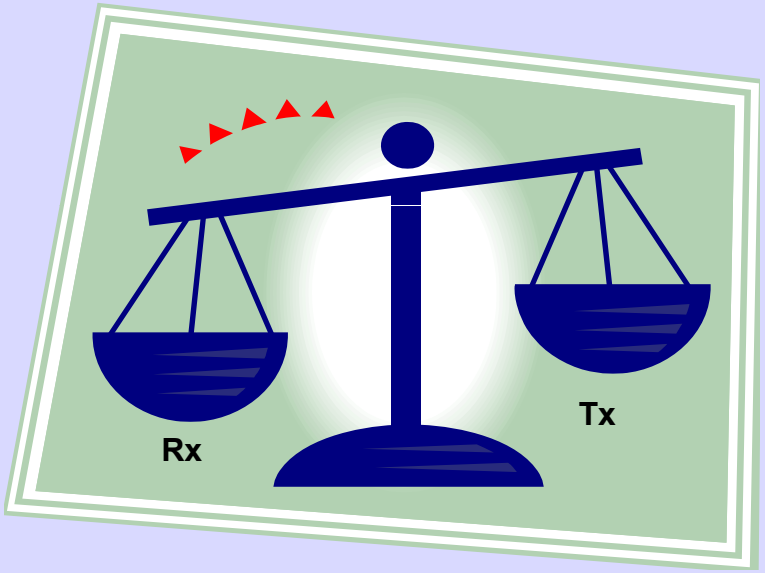
d) ≥2.0 kg/hr

Machine Alarms

- Online Pressure Holding Test
  - Assure this feature is turned ON!!!!
    - Runs every 12 minutes during a treatment
    - Catches hydraulic leaks of 300 ml/hr



Dialysis Technology: Is the Patient Receiving the Treatment Prescribed?



NaCl

Question 5

Question

Improper use of Sodium Variation can result in patient sodium loading of:

a) 2.8 gm NaCl for every 5 mEq/L over pt. base
b) 4.5 gm NaCl for every 5 mEq/L over pt. base
c) 8.7 gm NaCl for every 5 mEq/L over pt. base

Default Setting

	Acid	Bicarb	Dialysate
SODIUM 100	100.00	37.00	137.00
POTASSIUM 2.0	2.00		2.00
CALCIUM 2.5	2.50		2.50
MAGNESIUM 0.75	0.75		0.75
CHLORIDE 105.25	105.25		105.25
SODIUM ACETATE 0.0	0.00		0.00
ACETIC ACID (ACETATE) 4.0	4.00		4.00
BICARB		37.00	33.00
TOTAL BUFFER			37.00
DEXTROSE, gm/L 200	2.00		2.00
THEORETICAL CONDUCTIVITY			13.50
THEORETICAL pH			7.22

Can be changed by the operator/machine

Raise Sodium to 150 mEq/L

	Acid	Bicarb	Dialysate
SODIUM 100	112.50	37.50	150.00
POTASSIUM 2.0	2.25		2.25
CALCIUM 2.5	2.81		2.81
MAGNESIUM 0.75	0.84		0.84
CHLORIDE 105.25	118.41		118.41
SODIUM ACETATE 0.0	0.00		0.00
ACETIC ACID (ACETATE) 4.0	4.50		4.50
BICARB		37.50	33.00
TOTAL BUFFER			37.50
DEXTROSE, gm/L 200	2.25		2.25
THEORETICAL CONDUCTIVITY			14.78
THEORETICAL pH			7.17

Can be changed by the operator/machine

Question 5

Answer

Improper use of Sodium Variation can result in patient sodium loading of:

a) 2.8 gm NaCl for every 5 mEq/L over pt. base

b) 4.5 gm NaCl for every 5 mEq/L over pt. base

c) 8.7 gm NaCl for every 5 mEq/L over pt. base (recommended dietary intake is approx. 2.0 gm/day)

Key Points for Review

Objective – to show how misusing or misunderstanding the technology in a dialysis clinic can affect the prescription delivered.

Specifically:

- Kinds of variation in dialysis
- 3 - Stream proportioning
- Blood lines
- Alarms and staff responsibilities
- Impact of conductivity different than target
- Significance of pressure alarm limits and pressure tests
- Impact of using sodium variation

Key Points for Review

- Know your stuff
  - How the devices work
  - What alarms mean
  - What happens when the noise is ignored or just silenced
- It does matter ! Tx's are affected!
- Patients come first ! The rest will be just fine.

Questions

Thank You