What the Dialysis Machine Doesn't Tell You

John Sweeny

29th Annual NANT Symposium

Tuesday – March 6, 2012

HUMAN OBSERVATION AND ASSESSMENT MUST COMPLEMENT ANY ELECTRONIC MONITORING SYSTEM

The Dialysis Machine as an Monitoring Assistant

- Dialyzing without a dialysis machine
  - 1940's Caregiver/Patient ratio = 4 to 1
- Dialyzing with a dialysis machine
  - 2000's Caregiver/patient ratio = 1 to 4

Automation makes the difference!

Machine Functions?
- Think Dialyzer!

BLOOD FUNCTIONS

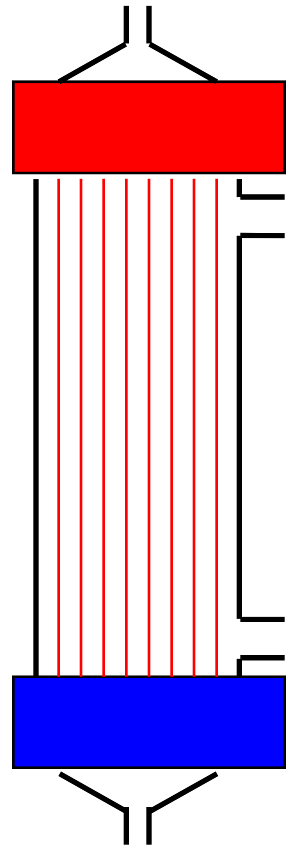
MOVE BLOOD

MONITOR FLOWRATE

MONITOR PRESSURE

MONITOR FOR AIR

MONITOR FOR LEAKS



DIALYSATE FUNCTIONS

MIX CONC. AND WATER

MONITOR MIXTURE

HEAT DIALYSATE

MONITOR TEMPERATURE

CONTROL UFR

MONITOR UFR

REMOVE AIR

CONTROL FLOW

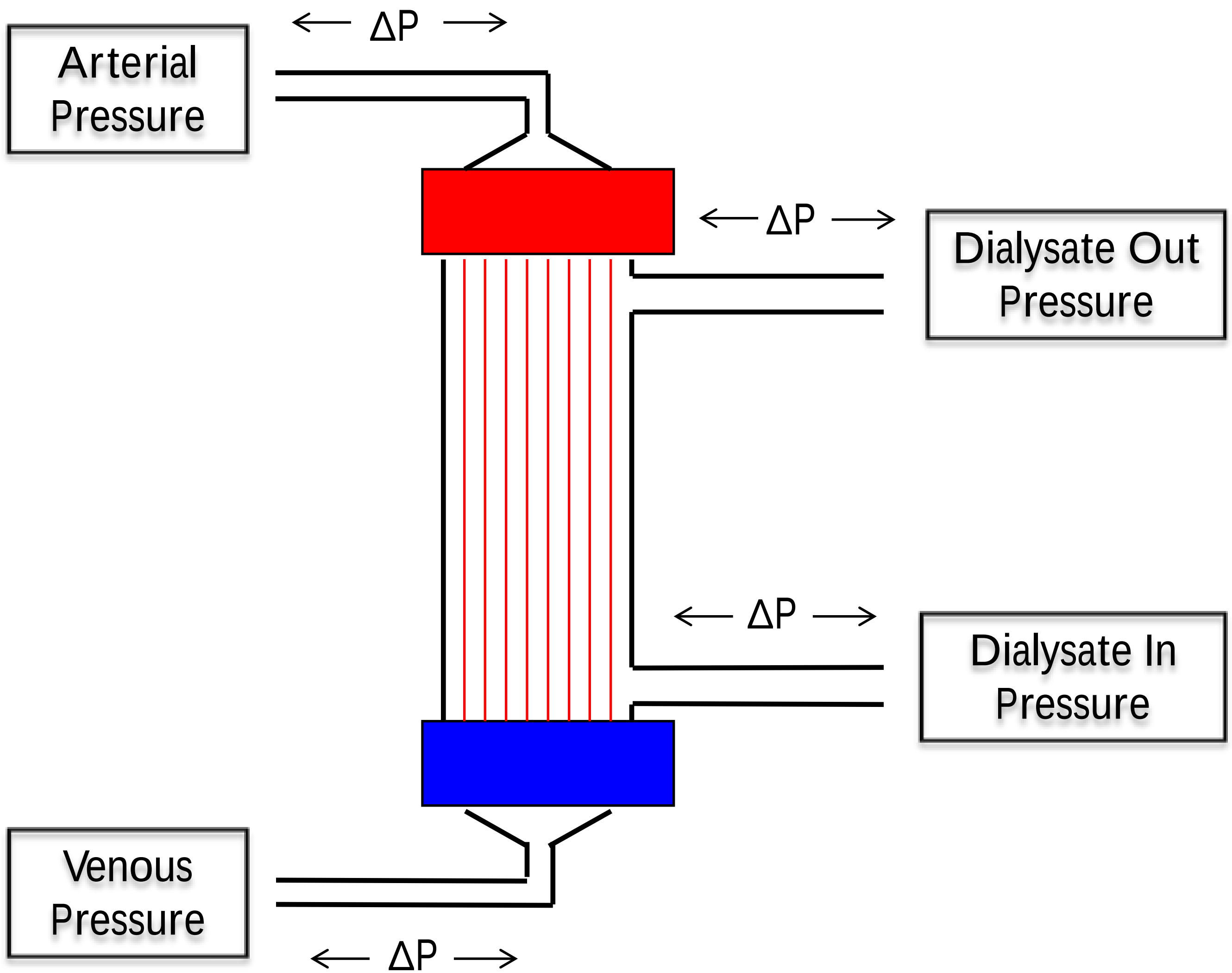
MONITOR FLOW

DISINFECT

Pressure Transducer Error

- Transducers are used to measure arterial and venous bloodline pressures as well as dialysate pressure
- The accuracy of pressure transducers are:
  - Under 100 mmHg : +/- 10 mmHg
  - Greater than 100 mmHg: +/- 10%
- Examples:
  - 80 mmHg could be 70 – 90 mmHg
  - 150 mmHg could be 135 – 165 mmHg
  - 350 mmHg could be 315 – 385 mmHg
- Calibration against a known standard pressure greatly improves transducer accuracy
- From a clinical standpoint, pressure changes after a stable treatment is established is more important than actual values.

$TMP = (P_A + P_V)/2 – (D_{in} + D_{out})/2$

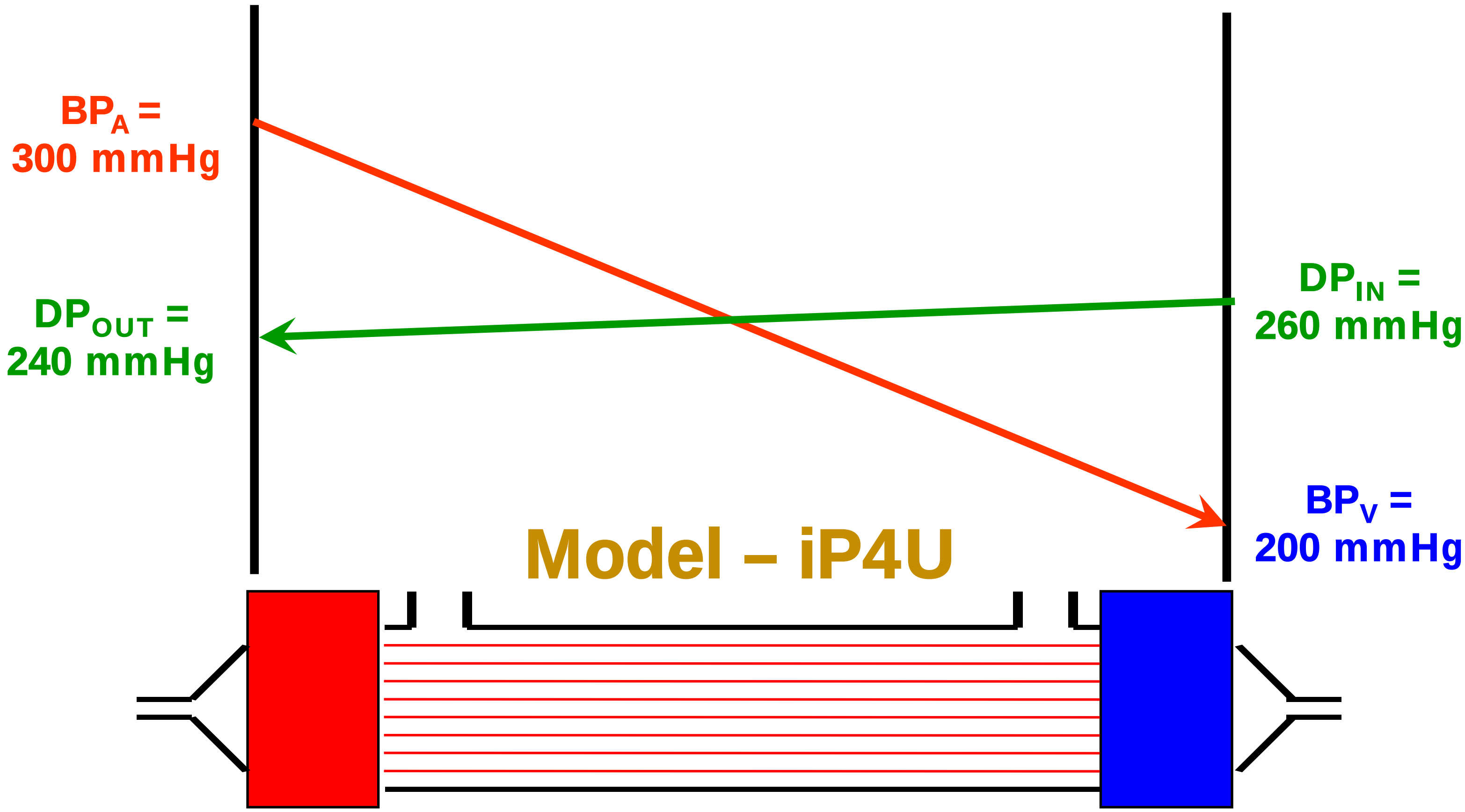


TMP Measurement Error

- The basic formula for TMP assumes that 4 pressure measurements are taken at the dialyzer
  - Blood : Arterial Pressure and Venous Pressure
  - Dialysate: Dialysate Pressure In and Out
- Allowing for transducer errors in pressure can result in TMP errors in measurement of up to 20% or more
- Present machines do not take all 4 of these measurements
- None of the pressures are measured at the dialyzer

Pressures inside a high K_{UF} Dialyzer

$$TMP = (BP_A + BP_V)/2 - (DP_{IN} + DP_{OUT})/2$$
$$= (300 + 200)/2 - (260 + 240)/2$$
$$= (500)/2 - (500)/2 = 0 \text{ mmHg}$$



What would a Dialysis Machine Read?

True TMP = 0 mmHg

Company	TMP Formula	TMP Calculation	TMP Display
Baxter 1550	TMP = $(BP_A + BP_V)/2 - DPout$	(300+200)/2 – 240	+10 mmHg
Fresenius	TMP = $BP_V - DPout$	200 - 240	-40 mmHg
Baxter Tina	TMP = $BP_V - DPin$	200 - 260	-60 mmHg
Gambro	TMP= $BP_V - (DPin + DPout)/2$	200 – (260+240)/2	-50 mmHg

BP_A = 300 mmHg, BP_V = 200 mmHg, DP_{IN} = 260 mmHg, DP_{OUT} = 240 mmHg

Blood Flow Rate vs. Pressure

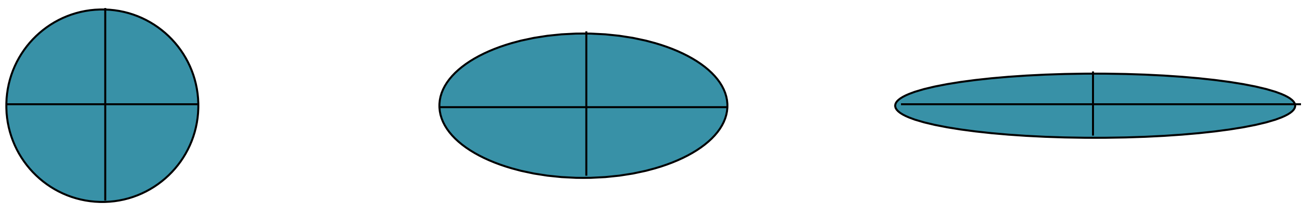
- As blood flow increases, pre-pump arterial pressures drop
- As the pre-pump pressure becomes increasingly negative, it creates a suction on the pump tubing section
- This suction causes the tubing to collapse
- As the tubing collapses, it's cross sectional area is reduced
- Reduced cross section means less blood pumped per rotation of the pump rollers

Pressure Effects on Hemodialysis Blood Flow, Thomas Depner, M.D., Syed Rizwan, M.D., Terri A. Stasi, ASAIO Manuscript, 1991

Collapsing Tubing

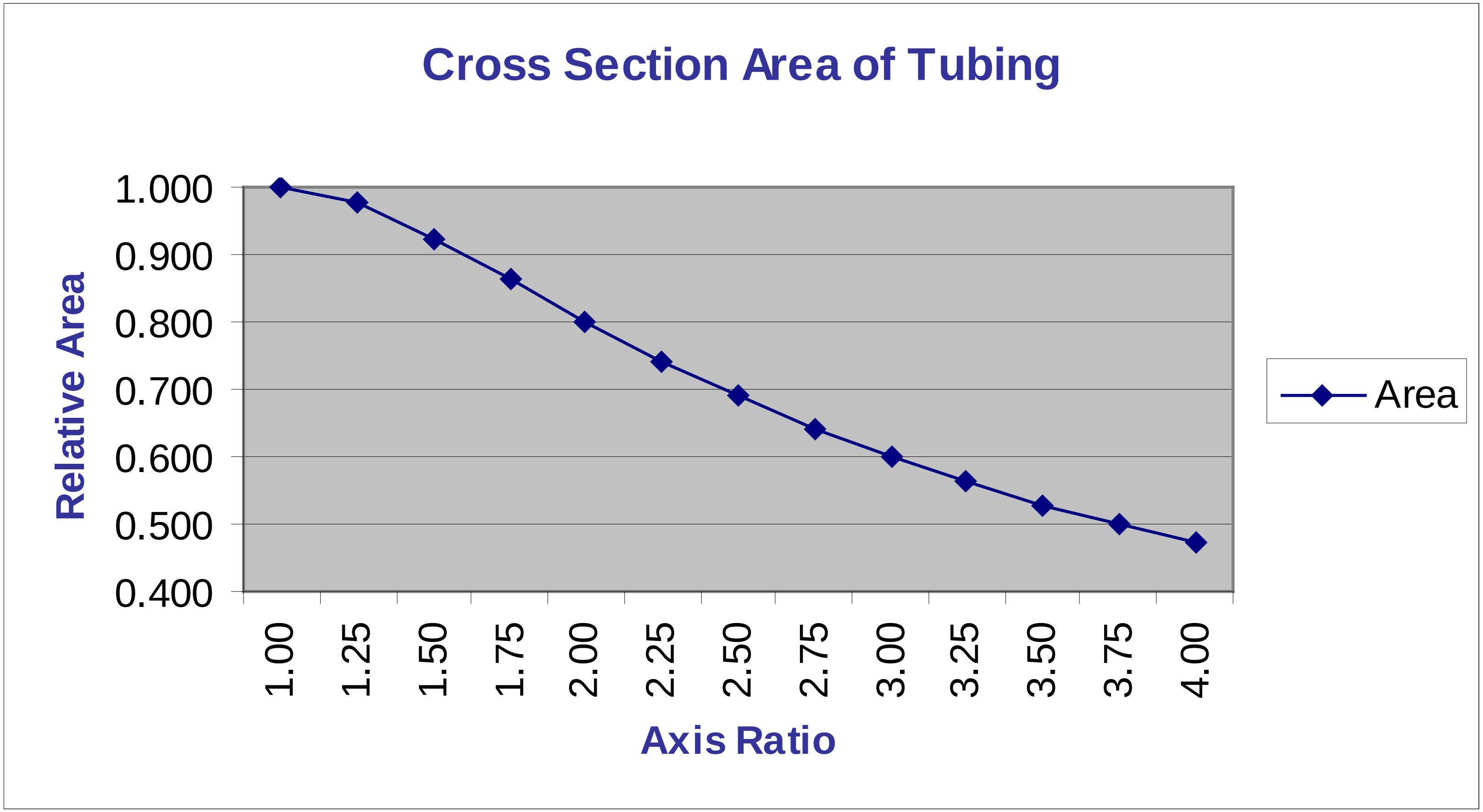
Cross sectional area = $2R/(1 + R^2)$

R = Ratio of Axis Length = Major/Minor



R = 1 **R = 2** **R = 4**

Pressure Effects on Hemodialysis Blood Flow, Thomas Depner, M.D., Syed Rizwan, M.D., Terri A. Stasi, ASAIO Manuscript, 1991



Pressure Effects on Hemodialysis Blood Flow, Thomas Depner, M.D., Syed Rizwan, M.D., Terri A. Stasi, ASAIO Manuscript, 1991

Blood Pump Speed

- Blood Pump Speed is monitored by looking at either pump voltage or rate of rotation, not actual flow.
- Blood Flow rate is reduced by:

  8.5% +/- 1.3% at a pre-pump pressure of – 200 mmHg

  33%   +/- 1.9% at a pre-pump pressure of – 400 mmHg
- Does your machine calculate clearance using blood flow rate and Dialyzer in vivo K_oA? The true clearance will be lower than the calculated value.

Clearance vs. Blood Flowrate

$$C_X = \frac{Q_B\left(e^{KoA\left(\frac{1}{Q_B}-\frac{1}{Q_D}\right)}-1\right)}{e^{KoA\left(\frac{1}{Q_B}-\frac{1}{Q_D}\right)}-\frac{Q_B}{Q_D}}$$

Where: **C_X = Clearance of solute, X** **e = 2.718**

Q_B = Blood flow rate **Q_D = Dialysate flow rate**

KoA = Dialyzer Clearance Coefficient

Tx A: Q_B = 400 mL/min Q_D = 600 mL/ min KoA = 800 then C_X = 296 mL/min

Reduce Q_B by 8.5%, then Q_B = 366 mL/min

Tx B: Q_B = 366 mL/min Q_D = 600 mL/ min KoA = 800 then C_X = 284 mL/min

The reduction is (296 – 284)/ 296 = 0.040 = 4%

4% of a 4 hour treatment is 10 minutes.

Blood Access Dislodgement

– 1967 quote about venous pressure:

"This monitor does not afford protection against disconnection or leaks in the extracorporeal circuit where atmospheric pressure prevails. A pressure at this point will change the pressure very little. A large blood loss can be sustained before the monitor pressure changes enough to produce an alarm, if it does so at all."

Grimsrud L, Cole JJ, Eschback JW, Babb AL, and Scribner BH. Safety Aspect of Hemodialysis. Trans. Amer. Soc. Artif. Int. Organs Vol XII 1967 p3.

Blood Access Dislodgement

- 1995 – Another quote on venous pressure:

  "Inadvertent dislodgement does not produce a sufficient fall in blood pressure to switch on the alarm and stop the blood pumps. This phenomena is independent of type of machine used and patient related parameters."

  Dellanna F, Stippel D, Schmitz, and Baldamus CA, Safety of Hemodialysis Machines: Surveillance of the Venous Blood Return. JASN 1995 Vol 6:486

Machine Venous Monitoring

Company	Alarm Window Width	Alarm Set	Minimum Low Alarm
Baxter System 1000/Tina	100 mmHg	Auto - 10 seconds after pump starts	+10 mmHg
BBraun Dialog+	40 – 400 mmHg Operator adjustable	Auto - 10 seconds after pump starts	+10 mmHg
Fresenius 2008K	100, 120, 160, 200 mmHg	Auto - 8 seconds after pump starts	*
Gambro Phoenix	110 mmHg	??	+10 mmHg

* At 200 mmHg alarm window, the low is set 20 mmHg below set point

All machine manuals state:

1) Venous alarm may not detect a disconnection
2) Follow access security procedures
3) Keep the access visible

Kelly TD, *Investigation Catheter Disconnection Baxter System 1000 Dialysis Delivery System Tina Model*, MedCatalyst Consulting, Sept. 16, 2010, p 12,13 of 40

Catheter Disconnect Test

Bloodline: Renax   Catheter: Medcomp Permcath

Fitting Configuration	Maximum Load (lbf) 1 lbf = 51.7 mmHg	Standard Deviation	Number of Tests
Bloodline into Permcath (not locked)	7.755 (400 mmHg)	2.542	60
Bloodline into Permcath (not locked, gauze covered)	9.863 (510 mmHg)	3.243	30
Bloodline into Permcath (not locked, taped)	7.954 (411 mmHg)	2.444	30
Bloodline into Permcath (locked, taped)	24.586 (1,271 mmHg)	6.577	4*

* Catheter came apart in all tests, the locked Luer never came apart.

Kelly TD, *Investigation Catheter Disconnection Baxter System 1000 Dialysis Delivery System Tina Model*, MedCatalyst Consulting, Sept. 16, 2010, p 22 of 40

US HD Disconnect Events

- Source of data: USA FDA Manufacturer and User Facility Device Experience (MAUDE) database

  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ctmaude/search.cfm

- Record dates: July 31, 1996 – July 31, 2010
- Disconnections during hemodialysis: 256 reports
  - Did not include home dialysis or CRRT
  - Average was 18 incidents per year
- Results of disconnection
  - 47 patient deaths
  - 183 life-threatening patient injuries
  - 26 no deaths or serious injury
- Type of disconnect
  - Catheter – 153
  - Needle – 90
  - Access Unknown - 13

Kelly TD, *Investigation Catheter Disconnection Baxter System 1000 Dialysis Delivery System Tina Model*, MedCatalyst Consulting, Sept. 16, 2010, p 29-31 of 40

Will you experience a disconnect?
(Death or Serious Injury)

- Assume 300K patients in the US dialyzing 156 times per year = 48,800,000 treatments
- 14 years times 48.8 million = 655 million treatments over database time period
- 256 incidents/655 M = 1 incident/2.56 M Treatments
- If you dialyze 8 patients per day 250 days per year = 2000 treatments per year
- Work 40 years = 80,000 treatments
- Your chance of having an incident = 80K/2.56M = 0.031 = 3.1%
- One out of every 32 CHTs will be involved in a disconnect incident involving death or serious injury

Preventing Disconnects

- Lock the rotating hub on the connection
- Tape the rotating hub directly (no gauze)
- Keep the access visible at all times
- Never turn your back when dumping prime prior to connection to the venous access
- Secure a catheter to the patient
- Frequently check the connection between the blood circuit and the patient
- During any pressure alarm, check the return line to the catheter or needle
- Only use bloodlines that are specified for the particular machine being used
- Change transducer protectors (fluid barriers) as soon as they come in contact with blood

Addressing Venous Needle Dislodgement

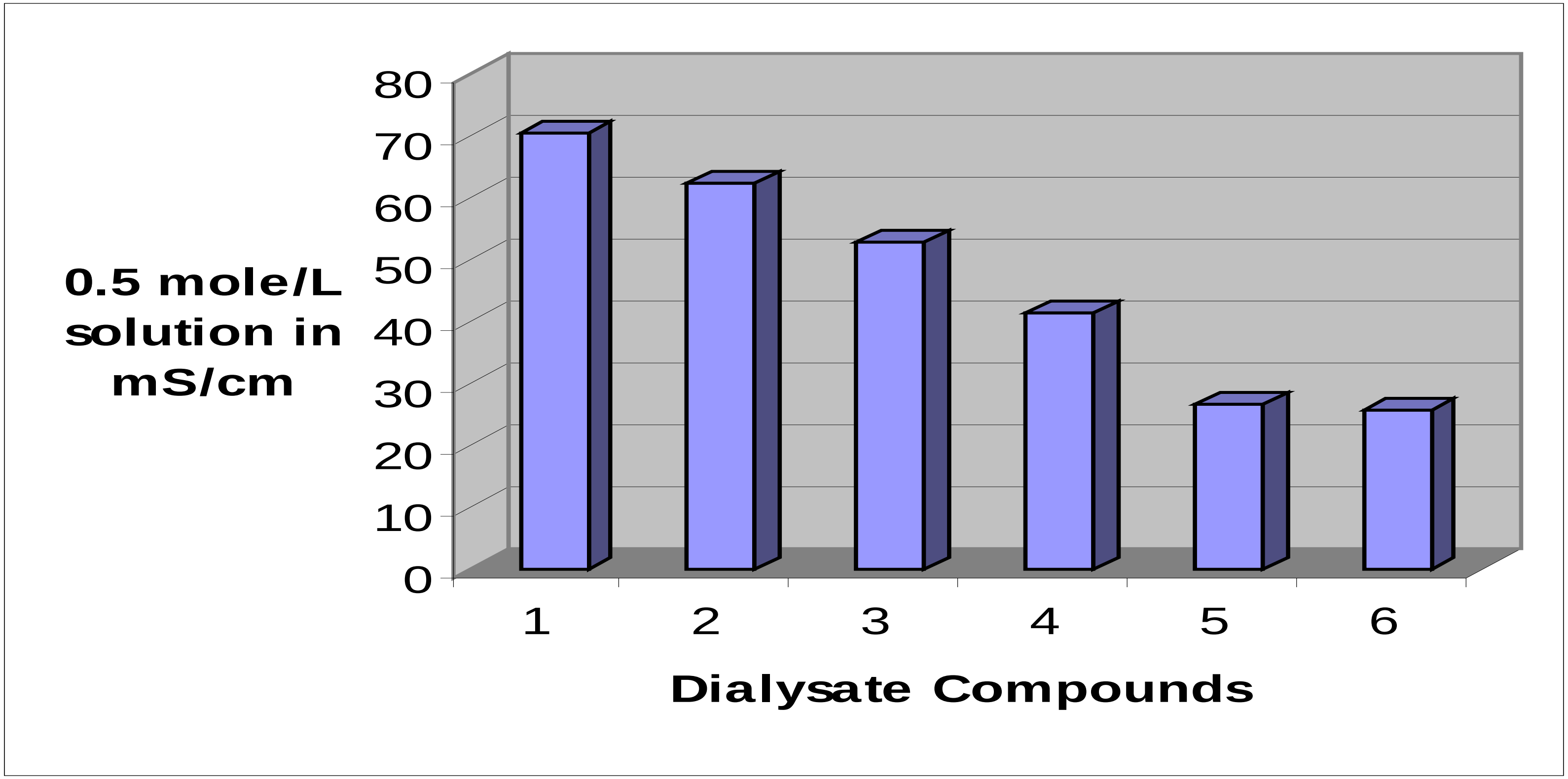
- Redsence Medical Inc.
- Received FDA clearance for it's device for home/self use for HHD in the US
- Consists of a sensor patch and an alarm unit
- Infrared light used with fiber optic cable to detect bleeding
- When blood leak occurs, blood blocks the infrared light creating an alarm

www.redsencemedical.com

Limitations of Conductivity

- Dialysis machine conductivity is a measure of the total ion concentration of the dialysate
- It cannot tell you the actual dialysate chemistry. Dialysate chemistry is the responsibility of the manufacture who tests for each component individually
- Different dialysates can have the same conductivity
  - Dialysate A: Sodium = 140 mEq/L, Potassium = 2 mEq/L
  - Dialysate B: Sodium = 142 mEq/L, Potassium = 0 mEq/L
- Each type of molecule contributes a different amount of conductivity

Dialysate Salts – Relative Conductivity



1 - Calcium Chloride
2 – Magnesium Chloride
3 – Sodium Bicarbonate

4 – Sodium Chloride
5 – Potassium Chloride
6 – Sodium Acetate

Handbook of Chemistry and Physics, 58th Edition, Editor - Robert C. West, Ph D, © 1977-78, CRC Press Inc., ISBN 0-8493-0458-X, p D-224 – D-252

Adjusting for temperature

- Each conductivity cell needs a thermistor so the conductivity can be corrected for temperature
- The actual conductivity of dialysate at body temperature is higher than what you see on the display
- All displayed conductivities are shown for dialysate at $25^{0}C$

Conductivity Temperature Compensation

Table for 14.0 mS/cm @ 25^{O} C

Temperature (degrees C)	Uncompensated Cond. (mS/cm)	% Change From 37.0^{O} C
34.0	16.44	-5.19
35.0	16.73	-3.52
36.0	17.04	-1.73
37.0	17.34	0.00
38.0	17.65	1.79
39.0	17.97	3.63
40.0	18.30	5.54

Dialysis Technology – A Manual for Dialysis Technicians, 3rd Edition, Jim Curtis & Philip Varughese, © 2003, National Association of Technicians/Technologists, p 200.

Temperature Compensation Error

Conductivity @ 37^{0}C = 17.90 mS/cm

Company	Compensation	Display	% Difference
Baxter	2.20 % / ^{0}C	13.79 mS/cm	-1.00
B.Braun	2.10 % / ^{0}C	13.94 mS/cm	0.00
Fresenius	2.10 % / ^{0}C	13.94 mS/cm	0.00
Gambro	2.07 % / ^{0}C	14.00 mS/cm	+0.43
Nikkiso	2.05 % / ^{0}C	14.03 mS/cm	+0.65

A 1.00 % change in conductivity for a 140 mEq/L Sodium bath is a change of 1.40 mEq/L in the Sodium level

Conductivity Cautions

- The calibration of conductivity is only as good as the reference used
- For machines using conductivity feedback to proportion concentrates, the machine needs to know the expected conductivities for acid and bicarbonate
  - Changing from a 140 mEq/L Sodium bath to a 145 mEq/L bath will not yield a higher Sodium unless the higher conductivity for the new bath is inputted to the machine
- Machines can't tell the difference between 45x acid concentrate and 35X acetate concentrate
- Amuchina D and 36.83X acid have the same conductivity due to the Sodium Chloride added to the Amuchina D disinfectant
- Citric acid solutions have been accidently substituted for bicarb concentrate without causing alarm (not all home patients can read)
- Old or over mixed bicarb concentrate cannot be detected my the machine

Machines vs. Environment

- Machines cannot detect:
  - Chemicals in the incoming water
  - Microbiological contamination in the incoming water
  - Low levels of residual chemicals from dialyzer reprocessing
  - Low levels of residual chemicals used to disinfect the machine's fluid pathway
- Technicians must preform the testing necessary to ensure that chemical and bacteria levels meet the clinical requirements for safe dialysis
- Patient reactions to contaminated water is still the number one cause of patient related injuries

Microbubble Trouble

- Machines can only detect air bubbles larger than 850 µm using ultra sound.
- Air bubbles below a diameter of 441µm will past through a venous drip chamber (Flow = 500 mL/min)
- The microbubbles lodge in the capillary system causing obstruction of blood flow, immediate inflammatory response, complement activation, clotting, and platelet aggregation
- Most of the resulting tissue damage occurs in the lungs

Barak M, Katz Y; *Microbubbles: Pathophysiology and Clinical Implications* , Chest 2005,Vol 128, p 2918-2932

Microbubble Creation and Life

- Microbubble sources include
  - Priming of the blood line and dialyzer
  - Turbulent blood flow at the venous access
  - Formation by the blood pump
- Bubbles dissolving time is based on their size
  - 1 µm radius = 1 second
  - 10 µm radius = 1 to 6 seconds
  - 100 µm radius = 100 to 600 seconds
  - 1000 µm radius = 11 to 70 days

Barak M, Katz Y; *Microbubbles: Pathophysiology and Clinical Implications* , Chest 2005,Vol 128, p 2918-2932

Microbubble - Future

- Better technologies need to be developed to detect the presence of microbubbles
- Methods need to be created that prevent the return of microbubbles to the patient
- More studies are needed to determine the long term effect of microbubbles on the chronic hemodialysis patient
  - Fluoro-carbon compounds which can increase bubble dissolving time
  - Surfactants which change bubble adhesion to capillaries

Barak M, Katz Y; *Microbubbles: Pathophysiology and Clinical Implications* , Chest 2005, Vol 128, p 2918-2932

Compensating for the machine

- Understand the processes that enable hemodialysis therapy
- Proper care of the machine results in proper care of the patient
- Equipment monitors aren’t a replacement for caregiver/patient relationships.
- It’s not the numbers that are most important, what counts is what is done with them to ensure patient safety and successful treatment .