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
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

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

Pennsylvania Patient Safety Authority. 2010. 7(3);87-96
Fundamental Requirements of Hemodialysis Instruments

Practical Aspects

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

Hazard Prevention

- Blood loss to environment
- Hemolysis
- Air embolism
- Excessive or inadequate fluid removal
- Infection
- Acute or chronic toxicity
- Anaphylaxis
# Beeps, Buzzers and Alarms

<table>
<thead>
<tr>
<th>Blood Circuit</th>
<th>Dialysate Circuit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflow pressure</td>
<td>Conductivity</td>
</tr>
<tr>
<td>Outflow pressure</td>
<td>Temperature</td>
</tr>
<tr>
<td>Air Detector</td>
<td>Hemoglobin</td>
</tr>
</tbody>
</table>
Safety monitors
- Can not ‘prevent’ adverse events
- Can only ‘detect and mitigate’ the potential harm

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

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 \((\pi r^2 \times \text{length})\)
Possible sites for Air entry and blood loss

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

Post-pump (positive)

Pre-pump (negative)

pressure

Excessively Negative Arterial pressure

• Low BP
• Catheter /needle malposition
• Kink/Clot
• Suction/spasm of vessel wall
• Stenosis in AVF
• Long small bore needles
Unclamping of saline infusion line

Line separation

Low negative arterial Pressure

Blood pump tearing the pumping segment

Blood pump

Heparin

Injection site

Pre-pump (negative) pressure

Post-pump (positive) pressure

Venous Air trap

Air detector

Clamp

Pressure

Injection site

Unclamping of saline infusion line
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)
Low blood flow upstream

Disconnection downstream

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 venous pressure alarm

Blood pump
Venous Air trap
Pre-pump (negative) pressure
Post-pump (positive) pressure
Pressure
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
2 minutes later, patient now c/o feeling cold, and restless. SBP 80 mm Hg. IV saline (0.9%) is started and foot end is raised. Additional blankets are provided. No machine alarms. HD is continued. Patient suddenly codes and CPR is started. Nurse notices blood pool below the dialysis chair. Blankets are removed. Blood is being pumped on to the floor via the venous needle.
What happened?
Venous Needle Dislodgement

Why did the venous alarm not sound?

Safety is the freedom from unacceptable risk
International Standard Organization 2007
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

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
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 and grafts. VND: venous needle dislodgement.
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
Blood pump
Venous Air trap
Post-pump (positive) pressure
Pre-pump (negative) pressure

Air detector

• 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

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

The three stream method of preparing a bicarbonate based dialysate

Organic acid
Glacial acetic acid/sodium diacetate/citric acid

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

- 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

<table>
<thead>
<tr>
<th>Na Bicarbonate (37 mEq/L)</th>
<th>Acetic acid (4 Mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbonic Acid + Na acetate</td>
<td></td>
</tr>
<tr>
<td>Carbon dioxide + water + Na acetate (4 mEq/L)</td>
<td></td>
</tr>
</tbody>
</table>

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)
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)
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

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

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!