Core Survey for Dialysis: What Technicians Need to Know Part II

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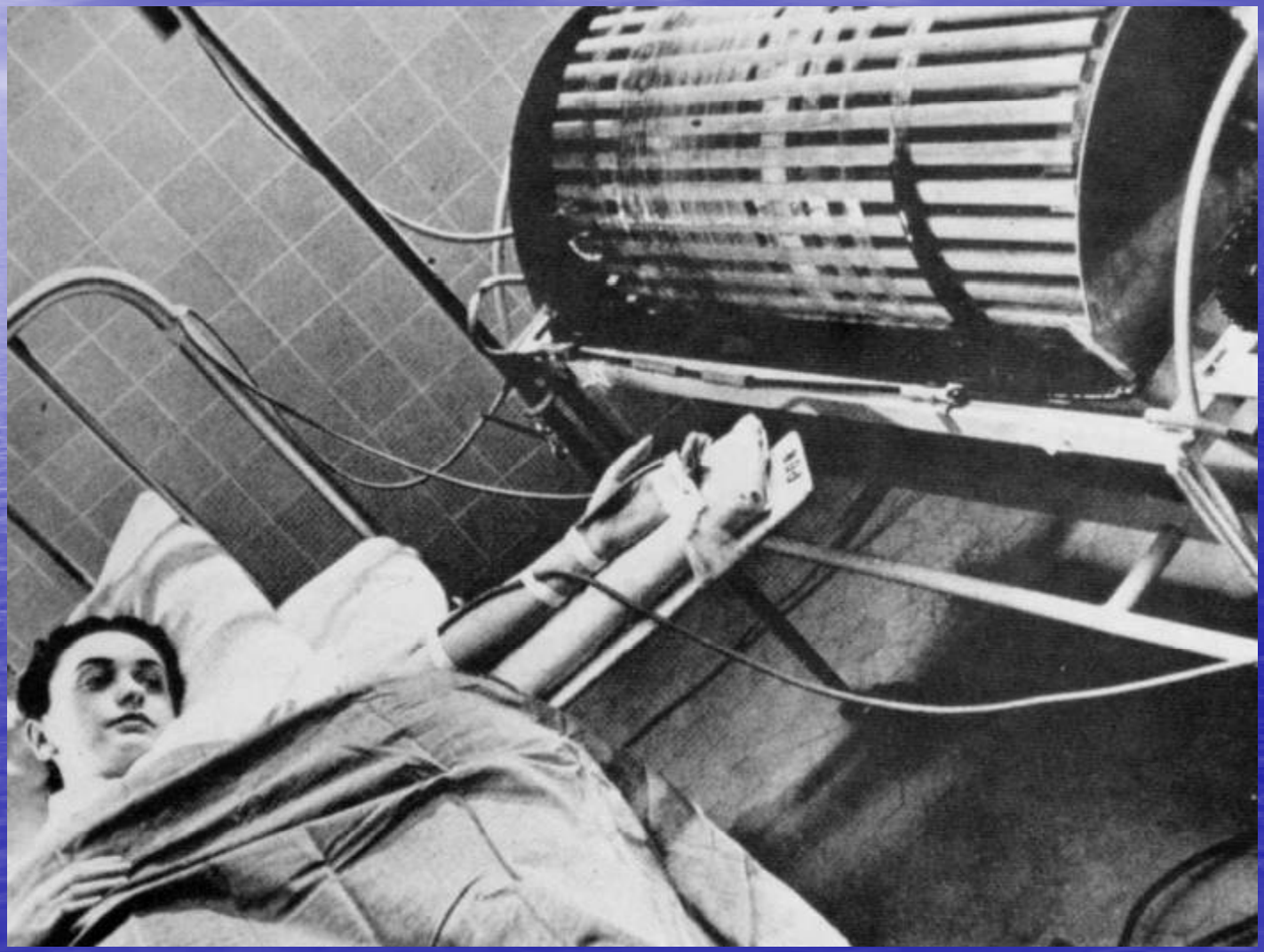
Center of Excellence BARIATRIC SURGERY

GALLUP GREAT WORKPLACE AWARD

St. Joseph Hospital ST. JOSEPH HEALTH SYSTEM

Dialysis Equipment and Reprocessing/Reuse Review in the Core Survey Process

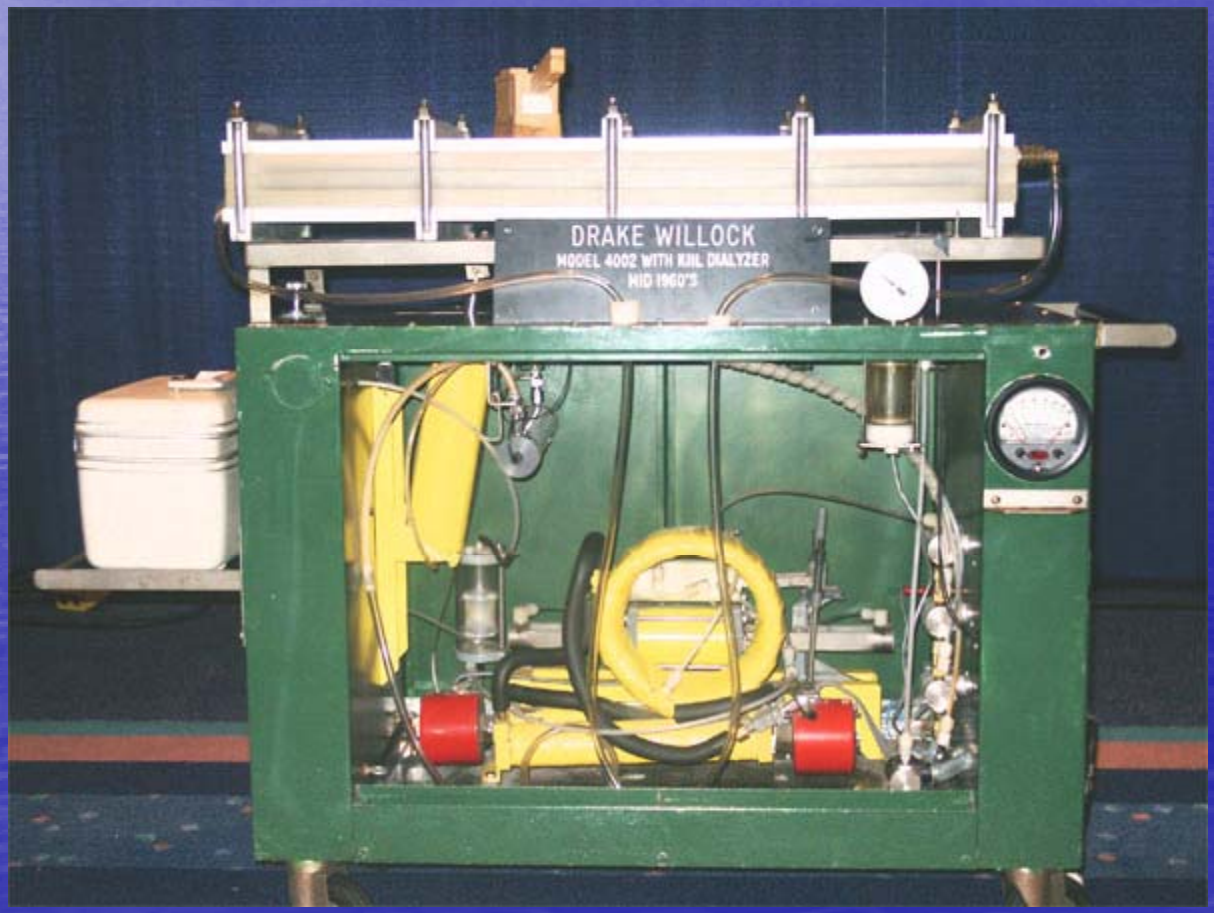
1940's – Kolff Rotating Drum



Late 1950's – Kolff-Travenol

1964 – Milton-Roy Model A

Mid-1960's – Drake-Willock Model 4002 with Kiil Dialyzer



1967 – Travenol RSP

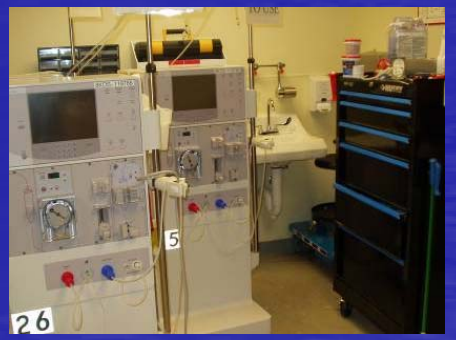
1979 – Cordis Dow Seratron

Surveyors' Role:

Ensuring dialysis-related equipment is:

- Operated &
- Maintained

In a safe manner according to the manufacturers' directions for use (DFU)(V403)



Observations of Hemodialysis Care: Equipment Operation

Observe the set up of hemodialysis machines for patient treatments: CHECKLIST #7

- Machine internal functions validated
  - Alarms tested
  - Dialysate pH and conductivity tested w/independent method
- Reprocessed dialyzers tested
- Extracorporeal circuit primed w/sufficient amount of saline
- No dummy drip chambers used!

Dialysis Equipment Maintenance Review in the Core Survey

- Interview the Machine Technician
  - What/how many machines maintained? Home HD?
  - What **P**reventative **M**aintenance procedures are manufacturer DFU? At what intervals or operating hrs?
- Review 12 months PM logs for 10% of HD machines (min 3)
  - According to manufacturer DFU for intervals and procedures
- Review documentation of calibration of equip used to maintain machines & test dialysate pH/conductivity

Other Core Survey Tasks for Machine Operation & Maintenance

- Water Treatment and Dialysate Review
  - Dialysate cultures from each HD machine are reviewed
- Environmental “Flash” Tour
  - Observation of machine appearance-lack of maintenance is a **trigger**
- QAPI Review
  - Oversight of technical operations
  - Audits of staff operating machines

When Would You Extend Equipment Review?

Triggers for citation or more investigation of concerns

- Trends of non-adherence to hemodialysis machine manufacturer's directions for PM
- No calibration of pH and conductivity meters or equipment calibration meters or not per manufacturer's directions
- Observations of serious lack of maintenance of ancillary equipment, e.g., scales, chairs, infusion pumps, oxygen concentrators, that has the potential to impact patient safety

Optiflux®

Advanced Fresenius Polysulfone

Optiflux®

F200NR F180NR F160NR

Hollow Fiber Dialyzers

NOT FOR REUSE

GENERAL INFORMATION

Indications: Optiflux F200NR, F180NR and F160NR dialyzers are designed for single use acute and chronic hemodialysis.

USA only: Federal law restricts this device to sale by or on order of a physician.

CAUTION: The operator should strictly adhere to the manufactures recommended procedures, warnings and cautions as listed in these instructions for use.

Contraindications: Specific contraindications for the dialyzer are unknown. Generally, the contraindications for hemodialysis are applicable. The dialyzer should only be used as directed by a physician.

Precautions: Dialyzers may leak resulting in patient blood loss or contamination with dialysate. In the event of a blood leak during dialysis, the health care provider should respond according to the facility's established protocol.

Air entering the extracorporeal circuit during dialysis can result in serious injury or death. Check the security of all extracorporeal connections prior to the initiation of dialysis and periodically throughout the treatment. The venous drip chamber should be continuously monitored with a level detector.

Warning: Due to the high water flux capability of high permeability membranes with an ultrafiltration coefficient > 8, it is necessary to use such dialyzers only in conjunction with dialysis machines that are equipped with precise ultrafiltration control, such as the Fresenius 2008 series. We recommend that dialyzers with an ultrafiltration coefficient > 6 should only be used with such UF control machines. In any case, the safety instructions for the hemodialysis machine must be followed.

The user is cautioned to regularly monitor the patient's chemistry values using quantitative measurements and analysis to ensure that the prescribed therapy is delivered. The clinical parameters monitored should at least include urea, hemoglobin and serum albumin.

Dialysate: The dialysate must meet AAMI standards for dialysis (RD5).

Side effects: In rare cases, hypersensitivity reactions to the dialyzer or other elements in the extracorporeal circuit may occur during hemodialysis. If a hypersensitivity reaction occurs, the source of the hypersensitivity should be identified and that component of the extracorporeal circuit should be excluded from future use in hemodialysis treatments for that patient. With severe reactions, dialysis must be discontinued and aggressive first line therapy for hypersensitivity reactions must be initiated. The decision to return the patient's blood in the event of a hypersensitivity reaction is the decision of the physician.

Heparinization: It is recommended to systemically heparinize the patient. Systemic heparinization is defined as administering the prescribed loading dose of heparin into the patient's vascular access and waiting 3 to 5 minutes prior to initiating the treatment. During dialysis, the dose of heparin and method of administration is the decision of the physician.

Sterile/Non-pyrogenic: The dialyzers are sterilized using the electron beam (ebeam) method of sterilization. The dialyzer blood pathway is sterile and non-pyrogenic if the blood port caps are in place and undamaged. Do not use if the dialyzer is damaged in any way. Use aseptic technique for all blood side connections. Structural integrity of the hemodialyzer is warranted for the first use only when prepared as directed.

Recommended storage: Between 5 and 30 degrees C (41 - 86 degrees F).

Dialyzer reuse: Optiflux F160NR, F180NR and F200NR dialyzers are not designed for or intended for reuse.

PREPARATION FOR DIALYSIS - DRY PACK

- Place the dialyzer in the dialyzer holder in the vertical position, arterial end downward.
- Install the arterial and venous bloodlines on the hemodialysis machine.
  Note: Refer to dialysate delivery machine manufacturer's instructions for use for setting up bloodlines.
- Remove blood port caps from the dialyzer and aseptically connect the arterial and venous dialyzer ends of the bloodlines to the dialyzer. Check to be sure connections are secure.
- Aseptically spike a 1 liter bag of 0.9% sterile saline solution with a clamped dialysis priming set.
- If not already attached, attach the dialysis priming set to the saline "T" connection located just before the blood pump segment on the arterial bloodline. Check to be sure the connection is secure.
- Open the clamp on the dialysis priming set and allow saline to gravity prime the portion of the arterial bloodline from the saline "T" to the patient end.
- Clamp the main line tubing on the arterial bloodline between the patient end and the saline "T" connection.
- Start the blood pump and set a **pump speed of 150 mL/min**. Prime the rest of the arterial bloodline, dialyzer and venous bloodline with saline. While the extracorporeal circuit is filling with saline, **intermittently pinch and release the bloodline between the blood pump and the dialyzer** to help to purge air from the dialyzer. **Tap the dialyzer** to facilitate air removal from the dialyzer.
- Fill the dialyzer and blood lines with 300 mL sterile 0.9% saline solution. The drip chambers in the bloodlines should be set to and maintained at ¾ full.
- Stop the blood pump. Clamp the arterial and venous bloodlines. Aseptically connect the patient ends of the arterial and venous bloodlines together in preparation for recirculation of the extracorporeal circuit. Unclamp main line clamps on arterial and venous bloodlines.
- Perform Pressure Holding Test on Fresenius 2008 machine.
- Verify that the dialysate is within the prescribed conductivity limits with a calibrated conductivity monitor. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use a calibrated pH meter to verify that the pH of the dialysate is within the appropriate physiologic range.
- Rotate the dialyzer so the venous end is down. Attach the dialysate lines to the dialyzer. Fill the dialysate compartment with the dialyzer in the venous end down position. In order to maximize the efficiency of the dialyzer, the dialsate flow must be countercurrent to the blood flow.
- When the dialysate compartment is filled, turn the dialyzer back to the arterial end down position and place back in dialyzer holder.
- Recirculate the extracorporeal circuit at a blood flow rate of 300 to 400 mL/min and a dialysate flow 500 mL/min until all air has been purged from the dialyzer and bloodlines.
- During recirculation, to assist in removing air from the dialyzer, intermittenly pinch and release the blood tubing between the blood pump and the dialyzer. Even if the header area of the dialyzer looks free of air, it is recommended that gentle tapping of the venous end of the dialyzer with the arterial end down should be done to remove air from the dialyzer.
- Do not infuse the recirculated saline prime into the patient. Discard the recirculated saline and fill the entire extracorporeal circuit with fresh saline prior to connecting to the patient. The volume of fresh saline used to fill the extracorporeal circuit should be equal to the volume of the dialyzer and blood tubing set in use.
- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test for the absence of germicide residuals with a test intended for this application, according to the test manufacturer's instructions.

INITIATION OF DIALYSIS

- To initiate dialysis; stop the blood pump, clamp the dialysis priming set and the arterial and venous bloodlines.
- Aseptically attach the patient ends of the bloodlines to the patient's arterial and venous access. Open the arterial and venous bloodline clamps and the clamps on the patient access.
- Increase the blood pump speed slowly to the prescribed blood flow rate. Be sure to monitor the arterial and venous blood pressures carefully during this process to note any possible flow restrictions or inappropriate pressure readings.
- Once the prescribed blood flow rate has been achieved, set the prescribed ultrafiltration rate and rotate the dialyzer to the arterial end up position.

DURING THE DIALYSIS TREATMENT

- If a blood leak should occur during the treatment, the operator should follow the facility's established procedure for a dialyzer blood leak.
- Air entering the extracorporeal circuit during dialysis is a very serious event and should be avoided. A routine check of all connections prior to initiation of dialysis and periodically throughout the dialysis treatment is recommended. Constant monitoring of the venous drip chamber with a level detector is required. Should air get into the venous line during the treatment, the dialysis treatment must be discontinued without returning any of the blood mixed with air.

TERMINATION OF DIALYSIS

- When the dialysis treatment is completed, turn the blood pump off and set the UF rate to the recommended minimum. Check to see that there is enough 0.9% sterile saline solution in the bag for rinsing the blood in the extracorporeal circuit back to the patient.
- Using a hemostat, clamp the arterial bloodline between the saline "T" and the blood pump. Rinse the blood in the tubing between the saline "T" and the patient end back to the patient.
- Clamp the arterial bloodline between the patient connection and the saline "T". Remove the clamp on the bloodline between the saline "T" and the blood pump.
- Start the blood pump and set at a 150 to 200 mL/min pump speed. Intermittently pinch and release the blood tubing between the blood pump and the dialyzer to help to efficiently rinse the blood in the extracorporeal circuit back to the patient. Do not let air enter the extracorporeal circuit during rinse back.
- Once the blood has been returned to the patient, turn the blood pump off. Clamp the arterial and venous bloodlines and the patient's arterial and venous access. Aseptically disconnect the arterial and venous bloodlines from the patient's access.
- **Discard the extracorporeal circuit in an appropriate biohazard waste receptacle.** References: 29CFR, 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state and local codes.

Technical data: These data represent typical *in vitro* performance. Actual *in vivo* performance may differ.

	F160NR	F180NR	F200NR	
Ultrafiltration coefficient (*in vitro* bovine blood 32%)	50	60	62	mL/hr/mmHg
Clearance Qb 300/Qd 500, Qf=0				
Urea*	266	274	277	mL/min
Creatinine	238	251	253	mL/min
Phosphate	230	238	250	mL/min
Vitamin B_{12}	152	168	173	mL/min
Lysozyme**	70	74	84	mL/min
Priming volume blood	83	98	112	mL
Flow resistance blood (Qb = 200 mL/min)	50	51	55	mmHg
Maximum TMP	600	600	600	mmHg
Maximum blood flow	600	600	600	mL/min
Maximum dialysate flow	1000	1000	1000	mL/min
Surface area	1.5	1.8	2.0	m^2

*Sodium used as a marker for urea.
**Lysozyme, MW 14,300 Da, used as surrogate for MM
Note: Clearance tests performed using aqueous solutions of sodium, creatinine, phosphate, Vitamin B_{12} and Lysozyme

Membrane material:	Advanced Fresenius Polysulfone®
Fiber inner diameter (nominal):	200 microns
Membrane wall thickness:	40 microns
Housing:	Polycarbonate
Potting compound:	Polyurethane
O-ring:	Silicone
Blood connections:	DIN 13090 Part 3
Dialysis fluid connections:	DIN 58352 Part 2
Sterilization Method	Electron Beam

IFU Example

- Start the blood pump and set a **pump speed of 150….**
- Recirculate the extracorporeal circuit at a blood flow rate of 300 to 400 mL/min and a dialysate flow 500 mL/min until all air has been purged from the dialyzer and bloodlines.
- Do not infuse the recirculated saline prime into the patient. Discard the recirculated saline and fill the entire extracorporeal circuit with fresh saline prior to connecting to the patient.

Extending Equipment Review

May include*:*

- Review of the PM logs for an additional 10% of HD machines
- Review of additional months of calibration meter logs
- Review of maintenance documentation of patient care equipment that is in observable disrepair

Summary

- Facilities are required to operate and maintain dialysis machines and equipment per manufacturers' directions
- The Core Survey focuses on review of the operation and maintenance of the hemodialysis machines
- The review is conducted across several Core Survey Tasks

Reviewing Dialyzer Reprocessing / Reuse in the Core Survey

- Involves several survey tasks
  - **Presurvey prep:** for allocation of time and survey team assignments
  - **Entrance Conference:** questions about reuse program
  - **Patient Interviews:** Fully informed (V312)

What Are the Standards for Dialyzer Reuse?

- Association for the Advancement of Medical Instrumentation (AAMI) sets dialyzer reuse standards
- RD47: 2002/2003 "Reuse of Hemodialyzers" is adopted by Reference into the ESRD Conditions for Coverage
- Reuse Condition for Coverage is ordered in 3 sections for survey "flow"
  - "Processes:" V301-325
  - "Practices:" V326-353
  - "Oversight:" V354-383

The Dialyzer Reprocessing / Reuse Process

- Dialysis treatment discontinuation
- **Transportation & handling**
- **Dialyzer pre-cleaning**
- Dialyzer testing
- Dialyzer sterilization/disinfection
- **Labeling**, documentation & inspection
- Storage
- **Testing, setup & rinsing for clinical use**

The ESRD Core Survey Focuses on the Critical Elements of Reuse that most impact patient safety and facility validation of equipment function

Reprocessing/Reuse Review in the ESRD Core Survey

- **Observe:**
  - Reprocessing area during Environmental "Flash" Tour
  - Transportation of used/dirty dialyzers to reprocessing room/area after patients' treatments
  - **Manual** pre-rinse procedures for 1-2 dialyzers
  - Set up/rinsing of reprocessed dialyzers for patients' treatments- ***Checklist #7***
- **Interview:** Reuse technician focused on critical elements
- **Review:** Facility oversight of Reuse program

Reuse Review Worksheet

The Critical Elements of Dialyzer Reprocessing/Reuse Process

Dialyzer Transportation & Handling (V331)

- **Transported in clean & safe manner**
  - Not leaking on each other
  - Not "manhandled"
  - Dialyzer bags (optional)
    - Contains material that leaks
- **Must be reprocessed or refrigerated within 2 hours of treatment to prevent microbial growth**
  - Dialyzer refrigeration
    - No temperature specified
    - Not allowed to freeze
    - Is especially important for centralized (off-site) reprocessing

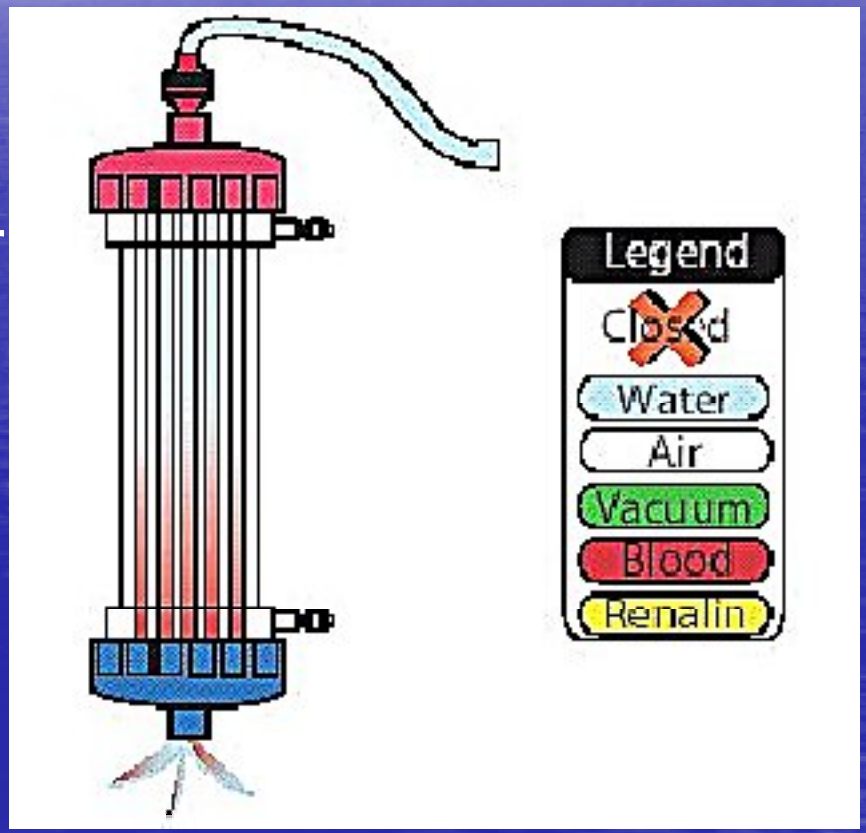
Dialyzer Pre-Cleaning

- Pre-clean area (pre-rinse sink) procedures
  - **Header cleaning**
  - Fiber (blood compartment) flush
  - Reverse ultrafiltration
  - Do not exceed maximum TMP of the dialyzer:
    - 600 mmHg ≈ 12 psi
  - Ensure that effluent from dialyzer is controlled

All optional procedures

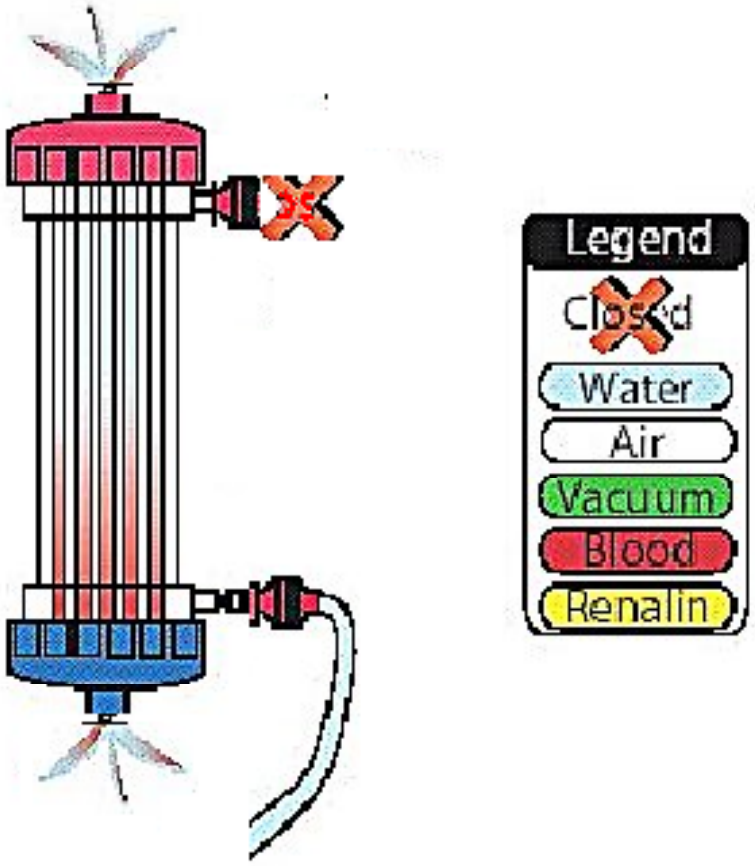
Dialyzer Cleaning: Manual Blood Compartment Flush -*Arterial to Venous*

- Step objective:
  - To flush the blood compartment with AAMI-quality water to remove residual blood
- Step duration:
  - This flush is typically done until the discharge is fairly clear



Dialyzer Cleaning: Manual Reverse Ultrafiltration

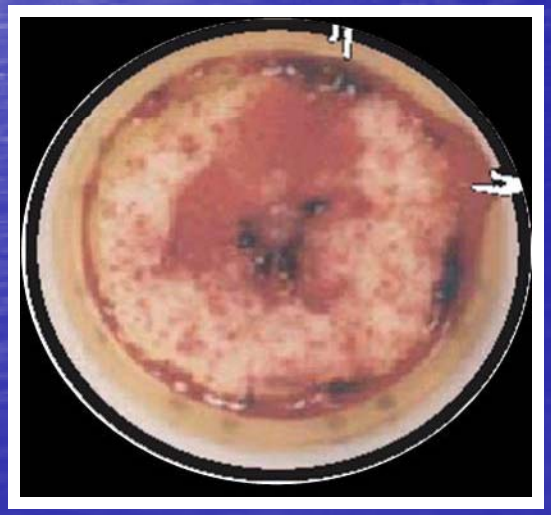
- Step objective:
  - To remove as much residual blood as possible by reverse ultrafiltration of **AAMI-quality water** through the dialyzer membrane
- Step duration:
  - Typically 5 to 10 min.
- **Caution:**
  - **Not to exceed the dialyzer's labeled max transmembrane pressure**



Dialyzer Cleaning:

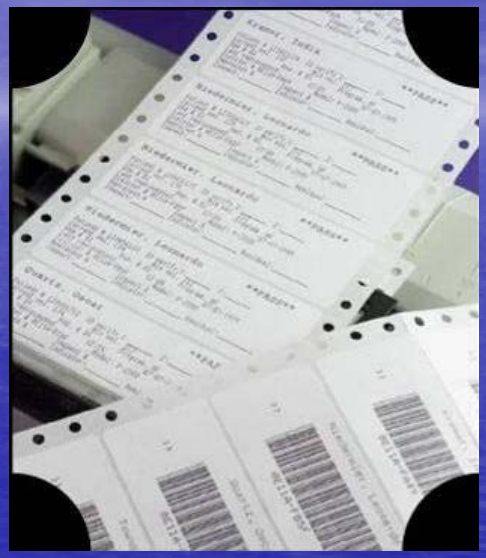
Header Removal & Cleaning (V334)

- Use only AAMI water to remove debris
- Disinfect cap, header & O-ring
- Reassemble wet with germicide
- Do nothing that may damage potting compound or fibers



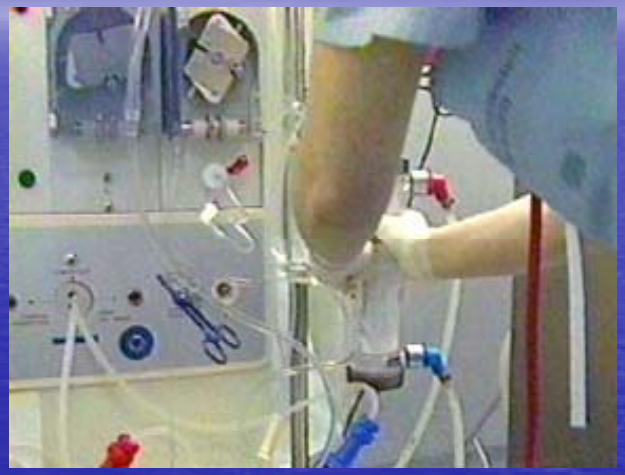
Labeling & Documentation

- Required information:
  - Patient name
  - Number of previous uses
  - Date of last reprocessing
  - **Similar name warning** (V330)
  - Initials of person performing reprocessing
- **Must be labeled for patient BEFORE first use** (V328)



Setup for Clinical Use/Reuse

- Preparing dialyzers
  - Dialyzer inspection
    - Labeling
    - "Filled" w/germicide
    - Sufficient "dwell time"
    - Aesthetics
  - **Testing for germicide presence** (V350)



Set up For Use: Rinse-Out & Testing

- ***Germicide rinse-out / priming with sufficient saline*** *(V352)*
- ***Testing for absence of residual germicide*** *(V353)*
- ***2 people ID patient and dialyzer match*** *(V348)*

Environmental "Flash" Tour

- **Patient treatment area: Observe**
  - Strong germicide odors? (V318)
  - 25% sample of patients on dialysis:
    - Dialyzers appearance
    - Labeling as required: prior to 1st use, sufficient info
- **Reuse room: Observe**
  - Condition of equipment (V318,403)
  - Stored reprocessed dialyzers for aesthetics (V343), protected from unauthorized access (V421)
  - Dirty dialyzers at room temp<2hrs (V331)
  - Dialyzer refrigerator temp monitored (V331)

Observations of Hemodialysis Patient Care

- **Watch carefully** for the pre-dialysis safety/germicide checks & priming
  - Germicide tests: Note reagents used: high level for germicide presence (V350); low level for germicide absence/residual (V353)
  - Priming with sufficient amount of saline per manufacturer's DFU (V352)
  - Patient/dialyzer ID done by 2 people when patient is at station (V348)

Use Checklist #7

Dialyzer Reprocessing/Reuse Review

- **Observe**
  - **Transportation** of dialyzers to reuse room sanitary; at room temp <2 hours; refrigerator temp monitored (V331)
  - **Pre-cleaning** procedures for 1-2 dialyzers AAMI quality H_2O (V333); pressures monitored (V332); follow steps for header cleaning (V334)
- **Interview** reuse tech focus on critical areas:
  - **Germicide** DFU handling, dilution, storage (V319,320, 345)
  - **Labeling:** before 1st use (V328); similar names warning (V330)

Dialyzer Reprocessing/Reuse Review (cont.)

Review:

- **Reuse QA audits**- 12 months
  - Dialyzer labeling-quarterly (V366)
  - Preparation for clinical use (V368)-***observing*** *staff setting up for treatments-quarterly*
  - Reprocessing procedures (V367)-***observing*** *reuse techs reprocessing-semiannually*
- **Reprocessing equipment PM-** 12 months
  - Daily calibration of automated systems (V316,317)
  - Follow manufacturer DFU for PM procedures
- **Reuse adverse events** ("complaint" log)-12 mos
  - Actions taken to prevent recurrence (V355-357, 635)

Still More Core Survey Tasks for Reuse…

- **Medical Record Reviews**
  - **Review** dialysis treatment records for documentation of germicide tests & Pt/dialyzer ID
- **QAPI**
  - Audits should be summarized in the QAPI minutes
  - Look for action/performance improvement plans if problems were identified by the QAPI committee (V635)

Review of Centralized Reprocessing

- **Observe** set up & take down of reprocessed dialyzers at the facility
- **Observe** reprocessing procedures, review reuse logs **at the centralized site**
- Any deficient practices at centralized reprocessing sites affect all user ESRD facilities; Condition-level findings must be cited for all user facilities
- Each ESRD user facility must have P&Ps for tasks performed at that facility (e.g., set up for use, rinse back post treatment)
- No separate tags: discussed in the IGs of pertinent tags (i.e., V331 for transportation & handling)

Why and How Would You Extend Reuse Review? *Triggers*

- Improperly done dialyzer pre-cleaning, header cleaning
- Water for pre-cleaning dialyzers not purified to AAMI
- No functional water pressure gauge for pre-cleaning
- Germicide not stored, mixed or handled per DFU
- Knowledge deficit of reuse tech in key patient safety areas per interview guide
- Dialyzers not transported in a sanitary manner
- Dirty/used dialyzers left at room temperature for >2 hours before reprocessing

Some are citable on identification, may conduct more interviews, observations

Why and How Would You Extend Reuse Review? *Triggers* (cont.)

- QA audits listed not done or incomplete
- Noticeable strong germicide odors and/or patient or staff complaints regarding germicide odors
- Serious adverse events possibly related to dialyzer reprocessing/reuse, **e.g., dialyzing patient on another patient's dialyzer,** without documentation of appropriate actions taken to prevent future similar events

Include detailed review of Reuse oversight in QAPI Review, interview technical administrative personnel, observe entire reprocessing procedure, review ambient air germicide vapor tests, review all Reuse QA audits

Risks & Hazards

"Like **all aspects** of dialysis, dialyzer reprocessing has associated risks and hazards if not performed properly."

Wayne Carlson

Total Cell Volume (TCV)

- Manufacture data
  - Different techniques to achieve TCV
- 20% loss TCV ≈ 10% loss of urea clearance
- "Whenever possible, the user measure the original volume of each hemodialyzer before the first pateint use and record that value as the reference TCV for all subsequent reprocessing."
  - May use average preprocessing volume (10 dialyzers or 20% of the monthly usage of dialyzers, whichever is less)